

User Guide

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TABLE OF CONTENTS

ΙΝΤΙ	RODUCTION	12
1	1 Welcome	12
1	2 Flexible CRA v4	12
1	3 What Does It Mean To Be High Risk?	13
	Risk thresholds	13
	Breast cancer	13
	BRCA1/2 mutations	14
	Colon cancer	14
	Finding your high or moderate risk patients	14
2.	GETTING STARTED	15
2	1 Your Institution Specific URL	15
	Configuring CRA v4 for your institution	15
	Secure log in	15
2	2 Recommended Web Browsers	16
	Disable pop-up blockers	16
	Display settings for monitors	16
2	3 Saving Data	16
2	4 Timeout Due To Inactivity	17
	Resetting your timeout	17
2	5 One Active Web Session Per User	17
2	6 Two Different Users Working On The Same Record	17
3.	NAVIGATION, RISK QUEUES AND FILTERING APPOINTMENTS	18
F	gure 3. Provider Dashboard for CRA v4	19
3	1 Worklist	19
	Filter your worklist	21
	Search your worklist by name or MRN	21
	Figure 3-1. Searching Your Worklist for Patients with 'ella'	22
	Opening an older appointment	22
	Completed appointments	22 3



	Rela	ited articles	.23
	3.2	Navigation Bars	. 23
	Left	navigation: Worklist, risk queues, batch printing and genetic tests	.23
	Тор	navigation: Logout and utilities	. 24
	3.3	Utilities Overview	. 24
4.	QUI	CK ACTIONS FOR EVERY APPOINTMENT	. 26
	4.1	Women's Imaging Quick Actions	. 27
	4.2	Risk Clinic Quick Actions	. 28
	4.3	Import/Export Pedigrees	. 28
5.	AUE	DIT REPORTS	. 29
	5.1	Audit Report Headings	. 29
6.	CLIN	IIC REPORTS	. 29
	6.1	Exporting as CSV	31
	6.2	Standard vs Custom Reports	. 31
	6.2 Po	pulation Screening	. 31
	"Hig	h Risk Breast/Ovarian Screening Report"	. 32
	"Bre	east Ovarian Screening Simplified"	. 32
	"Hig	h Lifetime Breast Cancer Risk"	. 32
	"Ris	k Patient"	. 33
	6.3 Hi	gh risk clinic	. 33
	"Ge	netics Tests Completed"	. 34
	"Ge	netics Patient Mutation"	. 35
	"Ge	netics Patient"	. 35
	"Ge	netics Patient by Clinic"	.36
	"Ge	netics Provider Referral"	. 37
	6.4	Clinic Operations	. 38
	"Pa	tient Volume"	. 38
	Pati	ent tracking and management	. 38
	Refe	erral patterns	. 39
	65	Output for Eurther Analysis	20
	0.0		
			4



	"Pa	tient Risk Results"	39
7.	RES	ET PASSWORD	41
8.	MA	NAGE PROVIDERS	41
8	.1	Provider List	42
8	.2	Search for a Provider	42
8	.3	Quick Actions: Edit or Delete	43
8	.4	Provider Types	43
9.	MA	NAGE CLINICS	45
9	.1	Add/Edit Clinics	45
9	.2	Assessment Type	46
9	.3	Time Zone	46
10.	U	ISER ROLES AND PERMISSIONS	47
1	0.1	Two Roles	47
Т	able	10-1 CRA Health Application Roles	47
1	0.2	Ability To Edit Clinical Data	47
11.	N	IANAGE USERS	48
1	1.1	Creating New User Account/s	49
1	1.2	Deleting A User	50
1	1.3	Edit Or Disabling A User	50
1	1.4	Reset Password	50
	Sett	ing temporary passwords for others (Administrator only)	51
12.	A	PPOINTMENTS ON THE WORKLIST	53
1	2.1	Manually Add Appointments	53
F	igure	12-1 New appointment form	54
1	2.2	Import Appointments	55
1	2.3	Creating Test Patient Appointments	56
1	2.4	Edit Appointments	57
	Cha	nging patient's date of birth or gender	57
1	2.5	Copy Appointment	57
	Pati	ent data follows each new appointment	58
1	2.6	Delete Appointment	58
	Exce	eptions- appointment with clinical information	58
13.	н	IEALTH QUESTIONNAIRES FOR CANCER RISK ASSESSMENT	60
			5

🖲 CRA Health

	Screening	60
Ask	king about unaffected family members at the time of screening	61
Table	13-1 Comparing Select CRA Questionnaire for Screening Settings	61
13.2	High Risk Clinic	61
Table	13-2 Comparing CRA's Questionnaires for High-Risk Clinics	62
Pat	ient Portal Form has a 'Submit' button	62
14. E	EDIT SURVEY	63
14.1	Family History	64
Ade	d a new relative:	65
Ade	d or edit up to three diseases	65
14.2	Cancer Risk Factors	66
Bre	east risk	66
Fig	ure 14-2 Breast Cancer Risk Factors	68
E	Breast density	69
Col	orectal risk	69
14.3	Necessary vs sufficient data	69
14.3 14.4	Necessary vs sufficient data Imaging Study	69 70
14.3 14.4 14.5	Necessary vs sufficient data Imaging Study Documents List	69 70 71
14.3 14.4 14.5 14.6	Necessary vs sufficient data Imaging Study Documents List Follow Ups	69 70 71 71
14.3 14.4 14.5 14.6 14.7	Necessary vs sufficient data Imaging Study Documents List Follow Ups Returning To The Work List	
14.3 14.4 14.5 14.6 14.7 15. F	Necessary vs sufficient data Imaging Study Documents List Follow Ups Returning To The Work List RUN AUTOMATION DOCUMENTS	
14.3 14.4 14.5 14.6 14.7 15. F 15.1	Necessary vs sufficient data Imaging Study Documents List Follow Ups Returning To The Work List RUN AUTOMATION DOCUMENTS Automation document filename	
14.3 14.4 14.5 14.6 14.7 15. F 15.1 / 16. (Necessary vs sufficient data Imaging Study Documents List Follow Ups Returning To The Work List RUN AUTOMATION DOCUMENTS Automation document filename CREATE DOCUMENTS	
14.3 14.4 14.5 14.6 14.7 15. F 15.1 A 16. (16.1	Necessary vs sufficient data Imaging Study Documents List Follow Ups Returning To The Work List RUN AUTOMATION DOCUMENTS Automation document filename CREATE DOCUMENTS Standard Templates	
14.3 14.4 14.5 14.6 14.7 15. F 15.1 A 16. (16.1	Necessary vs sufficient data Imaging Study Documents List Follow Ups Returning To The Work List RUN AUTOMATION DOCUMENTS Automation document filename CREATE DOCUMENTS Standard Templates	
14.3 14.4 14.5 14.6 14.7 15. F 15.1 A 16. C 16.1 "Su 16.2	Necessary vs sufficient data Imaging Study Documents List Follow Ups Returning To The Work List RUN AUTOMATION DOCUMENTS Automation document filename CREATE DOCUMENTS Standard Templates Urvey Summary," a clinical note	
14.3 14.4 14.5 14.6 14.7 15. F 15.1 A 16. C 16.1 "Su 16.2 Kee	Necessary vs sufficient data Imaging Study Documents List Follow Ups Returning To The Work List RUN AUTOMATION DOCUMENTS Automation document filename CREATE DOCUMENTS Standard Templates Irvey Summary," a clinical note Customizing Templates	
14.3 14.4 14.5 14.6 14.7 15. F 15.1 A 16. C 16.1 "Su 16.2 Kee 16.3	Necessary vs sufficient data Imaging Study Documents List Follow Ups Returning To The Work List RUN AUTOMATION DOCUMENTS Automation document filename CREATE DOCUMENTS Standard Templates urvey Summary," a clinical note Customizing Templates eping letters to just one page Download A PDF On Demand	
14.3 14.4 14.5 14.6 14.7 15. F 15.1 A 16. C 16.1 "Su 16.2 Kee 16.3 17. F	Necessary vs sufficient data Imaging Study Documents List Follow Ups Returning To The Work List RUN AUTOMATION DOCUMENTS Automation document filename CREATE DOCUMENTS Standard Templates Invey Summary," a clinical note Customizing Templates eping letters to just one page Download A PDF On Demand RISK SCORES ON DEMAND	
14.3 14.4 14.5 14.6 14.7 15. F 15.1 A 16. C 16.1 "Su 16.2 Kee 16.3 17. F 18. F	Necessary vs sufficient data Imaging Study Documents List Follow Ups Returning To The Work List RUN AUTOMATION DOCUMENTS Automation document filename CREATE DOCUMENTS. Standard Templates Invey Summary," a clinical note Customizing Templates pownload A PDF On Demand RISK SCORES ON DEMAND PATIENT CLIPBOARD	

6

CRA Health

18	3.2	Protecting Patient Information	81
18	3.3	Review the Patient's Breast and BRCA1/2 risk status	82
18	3.4	Putting a Patient Back On The Worklist	82
18	3.5	Patient Declines Risk Assessment	82
19.	F	POPULATION SCREENING WORKFLOWS AND INTERFACES	83
19	9.1	Overview of Interfaces	83
	Inb	ound	83
	Ou	tbound	84
19	9.2	Clinical Decision Support Messages	84
	Bre	ast/Ovarian	84
	Lyn	ch Syndrome	85
	Che	est wall radiation	85
	Ave	erage risk	85
19	9.3	Patient Reports Atypia, LCIS and/or Genetic Testing	85
	No	risk scores on survey summary	86
	Ver	ify self-reported pathologies	86
20.	F	PATIENT MANAGEMENT USING RISK QUEUES	89
20).1	Managing High-Risk Patients	89
	Pat	ients who are high lifetime breast cancer or high BRCA1/2 mutation risk	90
Fi M	gure uta	e 20-1 Patients with an Elevated Lifetime Risk of Breast Cancer or an Elevated Risk of BRCA tion	90
	Qu	ick Actions for high-risk patients	90
	Filt	ering by Follow-up actions or events	90
	Do	cument follow-up encounters or patient's disposition	91
20).2	Managing Moderate Lifetime Risk Patients	92
21.	E	BATCH PRINTING	92
21	l.1	Common Documents	92
21	L.2	Put On Hold	93
21	L.3	Sort, Filter, Then Generate	93
Fi	gure	e 21-3 Selecting All Documents Applies to the Current Page	94
22.	(GENETIC TESTS QUEUE	95

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7

🖲 CRA Health

22.1	Filtering Genetic Tests Queue	95
23.	RISK CLINIC MODULE	96
23.1	Navigating Within Risk Clinic	97
23.2	Updating Patient Demographics	97
23.3	Pedigree Drawing	97
То	op tool bar overview	98
	No need to frame your pedigree	98
	Printing your pedigree	98
	Organizing your pedigree	99
	Pedigree features	
v4	Automatically frames your pedigree for printing	101
Qı	uick actions: adding/deleting relatives, multiples, grouping, consanguinity	102
	Adding children to create siblings or half-siblings	102
	Adoption status	103
На	alf siblings	103
"La	asso" family members	104
	to create twins	
	to define a consanguineous relationship	
	to group siblings	105
Tip	ps for organizing pedigrees	105
	Hiding in-laws	105
	Watch videos	106
Pe	edigree settings	106
23.4	Pedigree examples	107
"F	loating" cousin, niece/nephew	107
Fig	gure 23-4 Floating or unattached cousin	108
Fa	mily tested for same gene but found different variants	
23.5	Family History Details	

8



Add information about the proband or a family member	
Demographic details	110
Current Age	110
Age of death	
Ethnicity, race, nationality/ancestry	
Gender	112
Diseases, procedures	
Figure 23-5.1 Drop down choices when user types 'bre'	
Figure 23-5.2 Using a comma to break up a disease comment for pedigree display.	
Breast cancer	115
Breast cancer (triple negative)	115
Colon cancer	
Colon polyps	
Figure 23-5.3 Pedigree and survey summary view of two family members with poly	yp count 117
Endometrial cancer	117
Hyperplasia	117
Prostate cancer	
Unknown cancer	
Uterine cancer	
23.6 Genetic Testing	
Figure 23-6 Defining status of genetic test	
Adding a gene into existing panel	
'Other' panel	
Keeping up with the gene panels	
23.7 Cancer Risk Factors	126
23.8 Mutation Risk	
"Risk and Recommendations" details	
Meeting NCCN HBOC v1.2020 guidelines	



Figu	ure 23-8 Patient who meets multiple NCCN criteria (in bold) for HBOC testing	129
23.9	Cancer Risk	
23.10	Recommendations	
23.11	Documents	
Nev	Ν	132
Figu	ure 23-11 Pedigree diagram needs to be saved before a survey summary is genera	ited 133
Edit	ting	
23.12	Imaging Tests	
23.13	Follow-Ups	
24. P	ATIENT PORTAL	
24.1	Patient Emails or Mobile Number	
24.2	Invitation	137
Ma	nual invite	
Aut	omatic invite	138
24.3	Patient Accepts	
We	lcome page	
Figu	ure 24-3 'Welcome' page for mobile friendly surveys	141
24.4	Completed Surveys	
24.5	Timeline	
Lin	expiration	142
Re-	invite	142
Aut	omatic reminders	
Арр	pointment begins	143
24.6	Opt Out of Patient Portal	
24.7	Sharing the Pedigree During a Telehealth Session	144
24.8	Workflows	
Figu	ure 24-8 Automated invitation and reminder workflow	146
Pric	or to the appointment	146
In c	linic on patient's mobile device	
25. C	RA LAB CONNECT	
		10
		10



26. 0	QUESTIONS?	147
26.1	Risk Models	147
l ge	et several different risk scores from different tools	147
l ge	et 'N/A' (not available) for a model	147
Hel	p review cases	148
26.2	Survey Summary Does Not Show Risk Scores	149
26.3	Published Studies Using CRA	149
26.4	Online Help	149
26.5	Contact CRA Health	150
Sup	pport line	150
Υοι	a Customer Success Manager	150



1.1 Welcome

Welcome to CRA Health's v4 User Guide for the Provider and Patient Portal. CRA Health v4 provides patient and clinician toolsets for collecting and analyzing family history information for the identification and management of patients at high risk for hereditary diseases (Figure 1). Our focus today is on breast cancer risk and colorectal cancer risk assessment. However, CRA Health is actively reviewing risk models for other cancers and conditions and will include additional risk assessment solutions in our product offering in the future. This guide describes the complete suite of product features currently available. For more information about our product suite, you can go online at https://www.crahealth.com/product-suite-comparison/.

Figure 1. CRA Health v4 comprehensively identifies women at high risk of developing breast cancer for screening & prevention to improve patient care & outcomes.



Throughout this guide, keyword links are embedded into the body of the text and allows the reader to quickly jump to relevant sections of the guide.

1.2 Flexible CRA v4

Every CRA client begins with a standard deployment to achieve efficient workflows in breast imaging and/or high-risk clinic. However, your configuration of CRA v4 can be altered to meet specific screening program or workflow needs.

This guide will point out areas within the system where a different configuration is possible:

- 1. General
 - a. <u>Force the system to log you out</u> of your first CRA v4 session in the event you log into a new session on another computer

12



- 2. Screening centers
 - a. Include GAIL model in the definition of high lifetime risk for breast/ovarian cancer
 - b. Use National Comprehensive Cancer Network (NCCN) hereditary breast/ovarian cancer testing guidelines in the definition of high breast/ovarian mutation risk
 - c. Use NCCN Lynch Syndrome testing guidelines in the definition of high colon cancer mutation risk
 - d. <u>Automatically accept patient reported atypia and LCIS</u> for risk calculation without the need for staff to confirm with the patient
 - e. Define which letters go onto batch print list
- 3. Risk clinic centers
 - a. Set all your pedigrees to <u>'hide-in-laws'</u>

1.3 What Does It Mean To Be High Risk?

One in eight women will develop breast cancer in her lifetime, however, women at high risk for breast cancer are significantly under-identified. Each year, millions of women in the United States do not receive a simple risk assessment that could change their lives. Early identification of high-risk patients using risk assessment tools allows physicians to engage their patients in a discussion of hereditary, hormonal and pathological factors that may contribute to their increased risk. Some factors cannot be influenced such as family history (the primary factor in determining breast cancer risk.) Factors such as BMI may be improved through patient behavior modification. Once identified as high-risk, a patient can collaborate with her physician to create a personalized breast cancer screening plan and follow-up schedule. Appropriate options will vary based on the particular risk factors involved and the shared decision making between the patient and physician. Because the accepted breast cancer risk models each incorporate different risk factors, an individual patient will have varying results across the models based on her specific answers to the risk assessment questions.



For more information, contact <u>support@crahealth.com</u> and ask for our white paper, 'What Does It Mean To Be High Risk?' which includes a case study and listing of common risk factors used by current models that are available in CRA v4.

Risk thresholds

Breast cancer

CRA Health v4, by default, considers the following as high risk for breast/ovarian cancer: a lifetime score by any of the accepted models that is >=20%. Accepted models included in CRA Health v4 are BRCAPro, Claus, Tyrer-Cuzick.

The Gail model is provided in the CRA Health Risk Engine; however, results are not used in the definition of high risk. Gail can be used to assess 5-year risk and patient eligibility for chemoprevention. Nonetheless, if your institution would like the GAIL model scores to be included in your high-risk criteria (e.g., based on the insurance guidelines in your area), please contact our CRA project manager.

The system considers a lifetime score between 15-19.99% by any of the accepted as moderate risk.



BRCA1/2 mutations

CRA has licensed National Comprehensive Cancer Network (NCCN) guidelines for hereditary breast, ovarian and pancreatic cancer (HBOC) genetic testing. A CRA user can see if the patient meets NCCN HBOC cancer testing guidelines in different areas of the tool:

- clinical decision support message at the top of the CRA survey summary
- in the <u>Risk Clinic module, mutation risk page</u>
- on the Provider dashboard, <u>Risk Calculations Quick Action button</u>, after a risk score has been run

These guidelines can be used to as criteria for <u>high risk queues</u> in place of or in addition to
 BRCA1/2 mutation scores.

CRA Health v4, by default, considers the following as high risk for a BRCA1/2 mutation:

- 1. If BRCA1/2 mutation score by any of the accepted models is >=10%,
- 2. if patient has a personal history of ovarian cancer or
- 3. if patient has a personal history of breast cancer diagnosed <=45 years of age.

Accepted BRCA mutation models included in CRA Health v4 are BRCAPro, Myriad, Tyrer-Cuzick.

Colon cancer

CRA Health v4 considers the following as high mutation risk for colon cancer (Lynch Syndrome):

 Mutation score by any of the accepted models >=5%. Accepted models included in CRA Health v4 are MMRPro and PREMM¹

CRA Health v4 provides a lifetime colon cancer risk score based on CCRAT model inputs; however, no published professional society guidelines currently exist that define what the threshold for 'high' risk is or what the clinical pathway would be for patients meeting the 'high' risk threshold.

Finding your high or moderate risk patients

CRA v4 puts your high and moderate risk patients in <u>queues available on the left-hand navigation bar</u>.

Return to Table of Contents

¹ CRA is in discussions with Dana Farber Cancer Institute to update the PREMM license.

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2. <u>GETTING STARTED</u>

All CRA v4 users should be familiar with this section, how to <u>navigate through the Provider Portal</u>, which <u>quick actions</u> are right for your workflow and understand <u>queues</u> if you plan on managing high or moderate risk patients. These aforementioned areas of the user guide will reinforce training you received before CRA v4 go-live.

2.1 Your Institution Specific URL

A CRA <u>super user</u> or application administrator within your institution will initially receive:

- a unique Web address that is specific to your institution;
- a username and temporary password, in separate emails (if you are using <u>CRA's standard log in</u> protocol)

The name of your institution will already have been created and will appear in the upper right corner of the landing page (see Figure 3).

The administrator will be responsible for <u>adding additional users</u> from your institution, plus <u>assigning</u> <u>roles</u> and clinics that will be visible to each CRA user.

Configuring CRA v4 for your institution

As part of go-live, your institution is configured based on the needs of your screening program or highrisk clinic. As your needs change, please contact your CRA project manager to revise your configuration.

Some configuration examples include

- 1. <u>Models</u> implemented and their respective <u>risk thresholds</u> that define patients that appear in CRA <u>queues</u>
 - a. Including Gail model results in your definition of high risk
 - b. Whether you want to turn on competing mortality² setting for Tyrer-Cuzick calculations
- 2. Use of logos in the Provider Portal and in letters
- 3. Labels as they appear in the pedigree
- 4. Allow a staff member to only have one active session with CRA v4, which may aid audit. For example, CRA v4 can be configured so a user cannot sign in from two different computers at the same time.

Secure log in

Users can securely log into CRA Health v4 applications in one of three ways.

- 1. Standard log in: CRA stores usernames and passwords.
- 2. Lightweight Directory Access Protocol (LDAP): users can sign into both the Clinician Application and/or Patient Clipboard with their institutional credentials.

² Competing mortality factors in whether a patient, based on her age, may die of other causes instead of breast cancer. Of not, the death rates used in Tyrer-Cuzick calculations are based on populations (United Kingdom, Sweden, or Slovenia) that may not reflect the clinician's patient.

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 Security Assertion Markup Language (SAML): from either the Clinician Application and/or <u>Patient Clipboard</u>, users will click an icon to reach a second log in screen. Then users sign in with their institutional credentials.

As part of go-live, your institution's IT department will determine which method you will use to log in.

2.2 Recommended Web Browsers

CRA Health recommends users launch v4 using the Google Chrome or Microsoft Edge Chromium browser but v4 is also compatible with the following browsers: Internet Explorer 11 (with Java script enabled) or higher and Mozilla Firefox. Safari can be used for the <u>Patient Clipboard</u> module but is not a recommended browser for the Provider Application at this time.

Disable pop-up blockers

Please confirm you have disabled your browser's pop-up blockers when generating Clinic Reports.

Display settings for monitors

Your operating system will usually default to the recommended settings that are appropriate for your monitor. CRA recommends the following display settings:

- scaling at 100%
- display resolution of 1920x1080

The screenshot below shows what may happen with a display setting that is not recommended by your monitor. Under the Mutation Risk page within the Risk Clinic module, the top navigation banner wraps around and hides the 'Run Risk Models' and 'Print' buttons that appear above 'Risk & Recommendations'. Go to the section on <u>Mutation Risk</u> in this user's guide to see screenshots of how this page should look.



2.3 Saving Data

Clinical information can be entered by the patient through <u>CRA surveys</u> or by the provider through the Clinician Application. Throughout the Clinician Application, a Save or Cancel button will appear on forms or views. If you use the back arrow of your browser, the data will NOT be saved.

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One exception is the <u>Edit Survey</u> and <u>Pedigree</u> pages. Once data is added or modified on these pages, the data point is automatically saved.

2.4 Timeout Due To Inactivity

Due to patient privacy concerns, please consider whether the workstation where you will access v4 is in a high traffic area or in a more controlled area.

After ~30 minutes of inactivity, the Provider Dashboard will automatically time out and ask you to return to the login screen.

Please confirm that the Web address of the log in page includes your unique institutional code.

The <u>Patient Clipboard</u> will time out after ~15 minutes of inactivity. The application will return to the log-in page.

Session ha	s expired.
Go back t	o Login.

	CRA Health
Health Questionnaire	
Please login to see the list of appointments	for today.
Username: hsimpson	
Password:	

Next

Resetting your timeout

As of this release, only the 15-minut timeout window for <u>Patient Clipboard</u> can be customized. The 30minute timeout window for the Provider Portal cannot be extended. If you have questions, please contact your CRA Health Project Manager.

2.5 One Active Web Session Per User

For optimal functionality, a <u>CRA Health v4 user</u> should only initiate one session of the Provider Portal. For example, if you are working on a CRA Health v4 record in your office and but need to see a patient immediately in another workspace, please sign out of your office workstation before signing into another workstation elsewhere. The same user cannot have two active sessions of CRA Health v4 running at the same time.

Notes:

- Two different users can sign into CRA Health v4 and work on different parts of the system.
- Two different users can even be working on the same patient record. However, if two different users are updating a patient's risk factor at the same time, the person who last touched the specific data field will overwrite the other user's entry.

You can choose to configure your system so that your initial CRA v4 session is closed out the moment you log onto a second web session from a different computer.

2.6 Two Different Users Working On The Same Record

Two different users can sign into CRA Health v4 and work on different parts of the system.

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Two different users, including the patient, can even be working on the same appointment record. However, if two different users are updating a patient's risk factor at the same time, the person who last touched the specific data field will overwrite the other user's entry.

If you open an appointment record that is in progress by another colleague or the patient, you will receive a warning message. The message will indicate when the person last accessed the record. You can proceed to edit data if you wish. However, for best results, wait until your colleague or patient is finished before opening the appointment record.



Return to Table of Contents

3. NAVIGATION, RISK QUEUES AND FILTERING APPOINTMENTS

The landing page for the Provider Application includes a worklist with <u>quick action buttons</u> for each appointment, quick links to a <u>queue</u> of high or moderate risk patients, a list of documents ready for batch printing, genetic tests and <u>utilities</u> for users. <u>See Figure 3</u> or review this video to help you



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18



Figure 3. Provider Dashboard for CRA v4

Health					Ut	ilities—		Homei cra qa	Simpson	Logout
Schedule										
High or	<u>moderate ri</u>	sk queu	<u>es</u> tatus					Search by n	ame or MRN	
0 10/26/2020	Azeroth and 1 m	ore • New a	and 2 more •					Name / N	RN	
C Refresh #Add /	ppointment 🔹 Upload Appoi	ntments Bate	ch print qu	eue				28 Ap	ots ex x	1 2 +
Date and Time 🚽	Patient Name 🕈	MRN ¢	DOB	Appointment Provider + Visit Number +	Accession Number +	Clinic Name ¢	Status	Has Pre	Quick Action	
10/21/2020 08:00 AM	TestBreastRisk, Margarete	99910212001	09/23/1970			Azeroth	New	No		1300
Genetic te	ests queue	99920201007	01/01/1972	Hughes, Kevin S		Azeroth	Completed	No	ZZC	1 * 🖬 🕯
08/26/2020 08:00 AM	TestBreastRisk, Cassandra	99908262001	09/23/1970			Azeroth	Completed	No		1 * 🖬 🕯
07/31/2020 08:00 AM	TestSuperShortBreast, Kat	99907312001	09/23/1970			Azeroth	Completed	No		1 * 🖬 🕯
07/02/2020 08:00 AM	TestSuperShortBreast, Brig.	99907032001	09/23/1970	Apgar, Virginia		Azeroth	New	No		1 * 🖬 🕯
05/07/2020 08:00 AM	TestBreastRisk, Alexandra	99905072001	09/23/1970			Azeroth	In Progress	No		1 * 🖬 🕯
04/30/2020 08:00 AM	TestBreastRisk, Claudia	99904302001	09/23/1970			Azeroth	Completed	No		1 * 🖬 🕯
04/16/2020 08:00 AM	TestBreastRisk, Brittany	99904162001	09/23/1970			Azeroth	Completed	No		1 * 🖬 🕯
02/15/2020 08:00 AM	TestPatientPortalForm, Kelly	99902152001	09/23/1970			Azeroth	Completed	No		1 * 🖬 🕯
10/31/2019 08:03 AM	TestPatientPortalForm, Clara	99905161804	09/23/1970			Azeroth	Completed	No		1 * 🖬 🕯
05/19/2018 08:00 AM	Test, Ruth	99905181801	09/23/1970			Azeroth	Completed	No		1 * 🖬 🕯
05/18/2018 08:01 AM	TestPatientPortalForm, Carla	99905181802	09/23/1970			Azeroth	In Progress	No	- Z 🗹 🛛	1 * 🖬 🕯
05/18/2018 08:01 AM	TestSuperShortBreast, Kelly	99905181804	09/23/1970			Azeroth	In Progress	No		
05/18/2018 08:00 AM	TestSuperShortBreast, Rose	99905181803	09/23/1970			Azeroth	In Progress	No	<u>* 7 6</u>	1 3 🖬 🕯
	TestPatientPortalCorm Jar	00005161910	09/23/1970			Azeroth	In Progress	No	- 200	1 * 0

3.1 Worklist

When you sign into CRA v4, you are immediately brought to a dashboard that includes **today's** worklist. The list is not filtered by Appointment Status but is filtered by all clinics you are authorized to access based on your user profile. (Contact your institution's <u>CRA administrator</u> if you need access to more or fewer number of clinics.)

Date and Time 🗸	Patient Name	MRN ¢	DOB	Appointment Provider + Visit Number +	Accession Number •	Clinic Name 🕈	Status	Has Pre	Quick Actions
08/21/2020 08:00 AM	TestMinus, Christine	99908072003	09/23/1970			Stars Hollow Clinic	In Progress	No	
08/14/2020 08:00 AM	TestBreastRisk, Hayley	99908142002	09/23/1970			Stars Hollow Clinic	In Progress	No	
08/07/2020 05:00 AM	TestPhxBrCa, Amanda CE3	99908072001	09/23/1970	Roche, Constance A		South Park Grace Hospital	Completed	No	
08/07/2020 08:00 AM	Test, Dan CE3460	99908072002	09/23/1970			South Park Grace Hospital	Completed	No	
08/05/2020 08:00 AM	TestLifetime, Abigail WithF	99908142001	09/23/1970			Stars Hollow Clinic	Completed	Yes	

If you are authorized to access patients at more than one clinic in your institution, the list of clinics will be displayed in alphabetical order.



You can <u>filter</u> this list of appointments further or sort the list on any of the following columns:



- Date/Time: for appointment
- Patient Name: always displayed as last name, first name, middle name
- MRN: medical record number
- Appt Provider: the clinician who is having the clinical encounter with the patient.
- Visit Number: this value is usually associated with an appointment feed but can be edited using Edit Appointment
- Accession Number: this value is usually associated with an appointment feed
- Clinic Name
- Referring Provider

The "Status" and "Has Previous Assessment" columns cannot be sorted but can be filtered.

The "S" column refers to risk status and the meaning is represented by icons. A patient record can either be:



• "New"- no one has opened or started work on this record since the appointment was created. An appointment can be created manually or by an appointment feed from your scheduling system.



• "In progress"- staff has started work through Edit Survey or Risk Clinic or a patient has started a CRA survey.



"Completed" - staff has started work on the appointment and returned to the dashboard. Or an appointment is considered "Completed" if a patient has started and finished a CRA survey. An appointment may be set to "Completed" even if a risk score has not been run against the patient record. Learn more here.

The "P" column tells you if patient has a previous completed risk assessment in CRA v4.

- Open circle indicates "No," the patient has not previously completed risk assessment.
- Closed circle indicates "Yes," the patient has previously completed risk assessment.



Filter your worklist

Filters are provided at the top of your worklist.

Sche	uule					_				
Appoir	ntment Date	Clinic		Appoint	ment Provider Assessment Status				Search by nam	ne or MRN
	8/5/2021 -	South Park Grace Hosp	ital and 1 more	- All -	New and 2 more	-			Name / MRN	Q Q
C Re	fresh 📅 Add Appointr	ment 🤰 Upload Appointments								105 Appts ex c 1 2 3 4 5 + ++
S P	Date and Time 🗸	Patient Name 🌢	MRN ¢	DOB	Appointment Provider ©	Visit Number ¢	Accession Number 🕈	Clinic Name 🕈	Referring Provider ¢	Quick Actions
୦୦	07/30/2021 08:00 AM	TestSubmit, Raven	99907232101	09/23/1970				South Park Grace Hospital		X X C 🗎 🛪 🖬 🗰 🚥
୦୦	07/23/2021 08:01 AM	TestYammer, Lindsay	99907232102	09/23/1972				South Park Grace Hospital		🛔 🗷 🖻 济 🖬 🗰 🚥
~ 0	07/19/2021 08:00 AM	TestCenturaCM1, Sierra NCCNv	99907192101	09/23/1980				South Park Grace Hospital		💄 🗷 🖻 济 🖬 🗰 🚥
~ 0	07/10/2021 08:00 AM	TestGroupEdit, Clare Comment	99907102101	09/23/1970				Stars Hollow Clinic		🛔 🗹 🖻 ネ 🖬 🗰 🚥
୦୦	06/25/2021 08:00 AM	TestNCCNv2.2021, Tony	99906252101	09/23/1970				South Park Grace Hospital		
~ 0	06/22/2021 08:01 AM	TestNCCNv2.2021, Victoria	99906232102	09/23/1970				Stars Hollow Clinic		
୦୦	06/22/2021 08:00 AM	TestNCCNv2.2021, Claudia	99906232101	09/23/1970				Stars Hollow Clinic		
*0	06/11/2021 08:00 AM	TestRelease, Chelsea	99906112101	09/23/1970				South Park Grace Hospital		💄 🗶 🕑 🗎 🛪 🖬 🗰 🚥
*0	06/10/2021 08:00 AM	TestBreastRisk, Evelyn	99906102101	09/23/1970				South Park Grace Hospital		
~•	05/28/2021 08:00 AM	TestOrderingProvider, Brigitte	99905282101	09/23/1970				South Park Grace Hospital	Homer, Jeanne	
~ 0	05/28/2021 08:00 AM	TestPatientPortalForm, Daisy C	99905142101	09/23/1975	Li, Bruno Kostanza			Stars Hollow Clinic	Rivera, Walter	🛛 🗶 🖉 🖻 🛪 📾 🗰 🚥
~ 0	05/27/2021 08:00 AM	TestFormBloodline, Brandy	99905142102	09/23/1970				Stars Hollow Clinic		🛛 🗶 🖉 🗎 🛪 🖬 🗰 🚥
~ 0	05/24/2021 08:00 AM	TestCareNE, Renate	99905242101	09/23/1970				South Park Grace Hospital		
~ 0	05/24/2021 08:00 AM	TestSSBPtBRCA12, Regina	99905242102	09/23/1970				South Park Grace Hospital		
~ 0	05/24/2021 08:00 AM	TestSuperShortBreast, Selby	99905242103	09/23/1970				South Park Grace Hospital		🚢 🗷 🖻 🛪 🖬 🗰 🚥
*0	05/14/2021 08:01 AM	TestBreastRisk, Carla	99905142104	09/23/1970				South Park Grace Hospital		🚢 🗶 🗭 🖹 🔅 📾 🗰 🚥
~•	05/14/2021 08:00 AM	TestTwoPanels, Autumn	99905142103	09/23/1970				South Park Grace Hospital		
~•	05/14/2021 08:00 AM	TestGeneTestedYES, Rene Scre	99901271901	09/23/1970				South Park Grace Hospital		🛔 🗹 🖻 济 🖬 🗰 🚥
~ 0	05/03/2021 08:00 AM	TestOrderingProvider, Brigitte	99905282101	09/23/1970	Li, Bruno Kostanza			South Park Grace Hospital	Homer, Jeanne	🛔 🗷 🖻 济 🖬 🗰 🚥
~ 0	04/30/2021 08:00 AM	TestTRFReceived, Jasmine	99904302101	09/23/1970				Stars Hollow Clinic		💄 🗷 🖻 🛪 🖬 🗰 🚥
					CDA H	with a popping the second				

You can filter your worklist by

- 1. a specific appointment date by
 - using the calendar icon,
 - choosing a quick action date of "Today", "Yesterday" or "Tomorrow,"



- typing in a specific date. Currently, there is no way to filter your worklist by a range of dates;
- 2. a specific clinic or by any of the clinics by using the Clinic drop down;
- 3. appointment provider
- 4. appointment status

Search your worklist by name or MRN

The Quick Search in the upper right corner allows you to find a specific person or a group of individuals that meet your criteria. Partial names or MRNs are allowed in the search box in conjunction with specific filtering criteria.

Search by name or MRN	
ella	Q

21



Figure 3-1 below shows how you can find a group of patients that include 'ella' in their name within the clinic 'BWH Imaging', on any given day (since date filter is unchecked). The search term 'ella' may be part of the patient's first name, middle name or last name.

Figure 3-1. Searching Your Worklist for Patients with 'ella'

Schedule

Appointment Date	Clinic BWH Imaging	Assessment Stat	us re ¥						Search by r	ame or MRN	Q
C Refresh 🛱 Add A	ppointment 💄 Upload App	ointments								3 A	ppts
Date and Time +	Patient Name	MRN 🗢	DOB	Appointment Provider	Visit Number 🕈	Accession Number •	Clinic Name •	Status	Has Pre	Quick Actions	
06/13/2017 08:00 AM	TestBreastRi <mark>sk,</mark> Isabella	99906071701	09/23/1970				BWH Imaging	Completed	No	****	ė •••
06/25/2017 07:45 AM	ChestWallTEST, Stella	20170626	06/19/1955				BWH Imaging	Completed	No	* 2 2 8 * 8	··· 🗎
07/03/2017 10:15 AM	ModeRiskTEST, Ella	201707031	07/01/1970				BWH Imaging	Completed	No		··· 🗄

You can refine the search by entering the patient's Last Name (or any characters that are part of the Last Name) followed by the First Name (or any characters of the First Name). If multiple parts of the patient's name are used in searching, you will need to enter in order of Last Name, First Name, Middle Name separated by a space.

The worklist search feature behaves differently than the search feature associated with queues.

Opening an older appointment

CRA v4 allows you to track clinical encounters for each patient. You can open an older appointment to review the previous state of the patient's family history, risk factors or review prior risk scores. A warning message will appear to confirm you wish to open a prior appointment even though a newer appointment has been completed.

Older Appointment	
You have selected an older appointment for th	is patient.
Selcted Appointment Date:	6/15/2017 8:00:00 AM
Most Recent Completed Appointment Date:	2/5/2019 8:00:00 AM
Do you want to continue to edit this older reco	ord or use the most recent?
Continue With Old Appointment	Use Most Recent Appointment

Completed appointments

<u>The "Status" column</u> found on the dashboard indicates if an appointment is "New", "In Progress" or "Complete."

Currently, a 'Completed' appointment means one of two actions has occurred:



- 1. A staff member opened and exited out of the appointment by returning to the dashboard, queue, or utility. CRA v4 assumes that when an appointment is opened, a user will either edit data, enter new data or a risk calculation was run.
- 2. A patient starts and completes a CRA survey by reaching the 'Thank you' screen

A "Complete" appointment does not always mean a risk calculation was run on this appointment if your system does not have an <u>automation process</u> set up. You can view if risk scores were calculated by clicking on the Quick Action button <u>Risk Score Calculation</u>.

An appointment will NOT be marked complete if user opens appointment but lets the record <u>time out</u> or directly logs out of CRA v4 while working on the appointment.

Related articles

Learn how to create appointments here.

3.2 Navigation Bars

As you navigate through the v4 Provider Portal, pages within each section will be framed by the top and left navigation bars.

Left navigation: Worklist, risk queues, batch printing and genetic tests

Left navigation bar includes:



1. Worklist schedule icon, which can be expanded to reveal a count of patients in each queue. Click on this icon to return to the Provider dashboard from anywhere within the Clinician Application;



2. Combined Lifetime Breast Cancer or Risk of BRCA Mutation high risk queue icon, which brings you to an interactive list of patients whose <u>lifetime breast cancer score is >=20%</u> or is at high risk for a BRCA1/2 mutation based on your screening center's criteria. Staff can also see who is high risk for the day using a tablet with <u>Patient Clipboard</u>;



3. Lifetime Breast Cancer <u>high risk</u> queue icon, which brings you to an interactive list of patients whose <u>lifetime breast cancer score is >=20%</u>. You can read more about managing patients on any of these queues in the <u>queue section of this user's guide</u>;



4. Lifetime Breast Cancer <u>moderate risk</u> queue icon, which brings you to an interactive list of patients whose lifetime breast cancer score is 15-19.99%. You can read more about managing patients on any of these queues in the <u>queue section</u>;





5. **BRCA1/2 mutation** high risk queue icon, which brings you to a list of patients that meet your screening center's <u>criteria</u>. You can read more about managing patients on any of these queues in the <u>queue section</u>;

-	
-	

6. <u>Batch Printing</u> icon, which brings you to a list of documents that are ready for batch printing based on your site's <u>automation</u> configuration;

<u> </u>	
8—	

7. Genetic Tests icon, which brings you to a list of patients whose genetic test status is pending because laboratory findings still need to be documented in the system.

Hover over the icons to remind yourself what each of these icons represent.

You can always return to the worklist schedule, view a risk queue, the batch print list or genetic test list from any screen within the Clinician Application.

Top navigation: Logout and utilities

The top navigation bar includes the <u>Utilities</u> icon, log out button and indicates the user's name, plus his/her institution. A user can always access Utilities from anywhere within the system.



3.3 Utilities Overview



Clicking on the Utilities icon will reveal several CRA utilities to help manage your workflow and data. Below is a brief overview of each utility. Users have access to specific utilities based on their <u>user roles and permissions</u>.

- 1. <u>Audit Reports</u>: <u>Superusers</u> can run a report to determine how staff members or automated functions have accessed or modified patient records;
- 2. <u>Clinic Reports</u>: Any user can generate summary reports or patient lists;
- 3. Manage Clinics: <u>Superusers</u> can create or change the name of their institution's clinics;
- Manage Providers: <u>Superusers</u> can edit the list of providers that are stored in the CRA Health database;
- 5. <u>Manage Users</u>: <u>Superusers</u> can add new users to the system, edit, delete, and assign <u>user roles</u> or temporary passwords for other users;
- 6. **Manage Test Patients**: Any user can easily create test patients with the minimum required information for any clinic;

24

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- Reset Password: Any user can quickly generate a new password. However, if your institution has an <u>LDAP interface</u> or uses SAML to authenticate, you would reset passwords outside of the CRA Provider Portal through your IT department;
- 8. **Web Tablet**: Any user can go directly to the in-clinic <u>Patient Clipboard</u> URL. This is the URL you provide to your IT department for tablet devices.

Return to Table of Contents

QUICK ACTIONS FOR EVERY APPOINTMENT 4.



You can view data or create documents on demand for a patient appointment or edit details about an appointment through the Quick Action buttons.

Note: For institutions that have purchased the CRA v4 Patient Portal feature, an additional icon will appear to the left of the Risk Clinic icon (DNA strand).



1. Risk Clinic: Enter the <u>Risk Clinic module</u> to use the pedigree drawing tool, add additional test results, view risk graphs or document recommendations;



2.

Edit Survey: Quickly edit a patient's survey response through this view;



Run Automation: Click this button to re-run risk scores, interface with your 4. EHR/PACS/RIS system, and generate documents at a local printer based on your institution's automation configuration;

5. Risk Calculation: Click on this calculator icon to run, re-run models or quickly review risk scores for completed appointments. When an appointment is first created and users have not added or edited clinical data, the icon will appear grey and the function is Ħ disabled until the appointment has started. Read more about this in the section, "Risk Scores on Demand";

6. Edit Appointment: Make changes to the appointment such as editing the referring physician or basic demographic information about the patient;



7.

Ħ

More Actions: Additional features for specific appointments, such as deleting an appointment, are available through this icon.

- "Patient Summary" gives you a read-only view of CRA's clinical note;
- "Pedigree" allows you to view a static image of the patient's family health history;
- Patient Summary
- Pedigree
- Import /Export ▶
- 🛗 Delete Appointment
- Copy Appointment Mark Incomplete
- 🖋 Update MRN



- "Import/Export" allows you to import a CRA Health data file (.xml or HL7) with personal health information from another pedigree drawing tool. Or you can export to a CRA Health system at another institution where a privacy and data sharing agreement is in place;
- "<u>Delete Appointment</u>" will remove a specific appointment from the worklist. If your patient has more than one appointment and you wish to expunge all patient data, you will need to delete all appointments;
- "Copy Appointment" allows you to manually create another appointment at a future date. All data from the current appointment will be pulled forward to that future appointment;
- "Mark Incomplete" allows you to mark a same day appointment so that it re-appears on the tablet worklist. The <u>appointments status</u> will change to 'In Progress";
- "Update MRN" allows any user to change a patient's medical record number as it exists in the CRA Health database.

The screenshot below indicates, for instance, how you would update a hospital-based MRN that was stored in CRA to a master MRN that the entire health system currently uses.



4.1 Women's Imaging Quick Actions

The <u>workflow for women's imaging</u> typically involves both the <u>Patient Clipboard</u> and Provider Portal. In the Provider Portal, commonly used Quick Action buttons include Edit Survey, Re-run <u>Automation</u>, New Document or View Scores.

- Mammography technicians may use <u>Edit Survey</u> to update clinical data after the patient has turned in the tablet;
- Nurse navigators may want to
 - generate a Survey Summary on demand for a patient whose risk assessment was recently completed. This document can be scanned into an electronic health record;
 - o <u>quickly review risk scores</u> on a completed appointment;



4.2 Risk Clinic Quick Actions

The workflow for high risk clinic typically involves Quick Actions such as <u>Pedigree</u>, <u>New Document</u>, View Scores or <u>Copy Appointment</u>.

4.3 Import/Export Pedigrees



You can import pedigrees from other pedigree drawing tools that follow the HL7 standard.

Or with the appropriate data sharing agreements in place, CRA v4 clients from different institutions can manually export a patient record from one institution and later upload the record into a separate institution's instance of CRA v4.

Importing steps

- 1. Create an appointment in anticipation of importing a pedigree.
- 2. Go to 'More actions'
- 3. Hover over 'Import/Export' selection
- 4. Select 'Load from XML' or 'Load from HL7'
- 5. Data will now populate into the appointment record
- 6. No changes will be made to
 - Medical record number. If you need to update the MRN <u>follow additional steps found in</u> <u>this user guide</u>.
 - Appointment date and time

Exporting steps

- 1. Identify the patient appointment record of interest
- 2. Go to 'More actions'
- 3. Hover over 'Import/Export' selection
- 4. Select 'Save as XML' or 'Save as HL7'
- 5. You have the choice to keep the record de-identified or identified.

Contact your CRA project manager to learn more about how to exchange data across different institutions that use CRA v4.

Return to Table of Contents

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5. <u>AUDIT REPORTS</u>

This is a <u>utility</u> only available to <u>CRA administrators</u>.

You can create an audit report based on a medical record number. The report will describe every action that was taken including when clinical data was entered or changed. You may wish to request help to interpret results by contacting <u>CRA support</u> at any time.

- 1. Click on Utilities.
- 2. Choose 'Audit Reports'.
- 3. Enter the medical record number (MRN) of interest. This entry must be an exact match.
- 4. Click 'Run Report'.
- 5. Wait for about 30 seconds based on the number of appointments associated with your MRN.

5.1 Audit Report Headings



The following is a definition list for audit report headings:

- MRN: medical record number
- ApptID: an internal CRA v4 identifier that distinguishes a patient's unique clinical encounter. A patient may have multiple appointments in CRA over time.
- UserID: identifies the staff member or describes which part of the v4 system was responsible for a particular action. A blank UserID entry typically, but not always, indicates CRA v4 system was responsible for the edit.
- Modified: date, minute and seconds the action was taken. Note the timestamp is based on UTC.
- Action: describes whether data was inserted (created) or updated
- Table: describes a specific area of the database where the data is stored
- Field: describes the field within the affected data table
- PK: an identifier to help CRA engineers understand data changes within the system
- Old value: if a data point was changed or updated, old value describes what the original data point was
- New value: if a data point was changed or updated, new value describes what the new data point became

Return to Table of Contents

6. <u>CLINIC REPORTS</u>

This is a <u>utility</u> available to any <u>CRA user</u>.

CRA v4 can summarize your institution's data by clinic, by a specific period of time (up to one year) or by both parameters.



- 1. Click on Utilities
- 2. Click on the dropdown choice for

Clinic Reports

- 3. A new page will load with search parameters.
- 4. Choose the parameters of interest:
 - a. report this is required



b. clinic - this is a required parameter. The default choice is 'All Clinics'

Clinic Reports	
Report * Genetic Tests Completed Report	
Zlinic * All Clinics •	
Report BWH Imaging	-
01/21/2010	
04/21/2018	
limit to appointments with assessment type:	
Include test patients	
Report will appear in a new window/tab so please disable popup blockers. Also please note the report m several minutes to generate.	iay take

c. timeframe. Currently users can only run a report for a years' worth of data. If your time period is greater than 12 months, you will get the following message:

30



You have selected a date range (start date: 2017-10-03), end date: 2020-02-28) longer than 12 months. Please choose a date range less than 12 months.

- d. assessment type
- e. inclusion of test patients-this is unchecked by default
- 5. Click 'Run Report.'
- 6. Wait for about 30-45 seconds based on the time frame or number of clinics in your search parameter.
- 7. A new tab within your browser will launch with results. Make sure your <u>browser</u> is not blocking pop-ups.
- 8. You can print or save the report as a PDF using your browser's print option.

Depending on the report you choose, the results will include summary information or identifiable patient information. Some reports include both on the same page.

6.1 Exporting as CSV

Follow the steps above to enter your search parameters. Rather than clicking on "Run Report", click instead on 'Export to CSV.'

Each table in your report will be a separate CSV file.

6.2 Standard vs Custom Reports

CRA Health v4 provides a standard set of clinic reports for both Women's Imaging and Risk Clinic workflows. Standard Clinic Reports is a <u>Utility</u> that any CRA v4 user role can access.



You can request custom reports based on the structured data within your CRA v4 system. Contact your Project Manager to learn more.

6.2 Population Screening

Currently CRA offers several reports to support your screening program.

- 1. "High Risk Breast/Ovarian Screening Report": a summary of high-risk patients by breast/ovarian and colon cancer models;
- 2. "Breast Ovarian Screening Simplified": a summary of screen-positive patients including clinical characteristics;
- 3. "<u>High Lifetime Breast Cancer Risk Report</u>": a list of patients who meet your institution's threshold for high lifetime risk;
- 4. "High Risk Patient Report": a list of patients who meet your institution's threshold for high lifetime or mutation risk;
- 5. "Intermediate Risk Report": a list of patients who meet the threshold for <u>moderate lifetime</u> breast/ovarian cancer risk;
- 6. "Patient Consent Report": a list of patients who declined risk assessment and a summary of reasons why they declined. This report is only relevant for institutions who choose to consent patients to do cancer risk assessment;
- 7. "Patient Risk Results Report": a list of patient risk assessment variables for further analysis;
- 8. "Risk Scores By Age": a table of lifetime risk scores by age group.



"High Risk Breast/Ovarian Screening Report"

This report provides multiple summaries:

- completed appointments, completes surveys and Patient Portal compliance by clinic
- high-risk patients by breast/ovarian and colon cancer models

"Breast Ovarian Screening Simplified"

This report is developed for screening centers and provides a summary of screen-positive patients including

- how many have a personal history of breast cancer
- how many have bilateral breast cancer
- how many have a personal history of ovarian cancer

The report (screenshot below) shows screen-positive patients if a screening program uses Tyrer-Cuzick 8 for lifetime risk and BRCAPro for breast/ovarian mutation risk.

E	Breast Ovarian Screening Simplified Report		CRA He	alth
tun	Date: 3/19/2021			
se	r: bklin			
p	ort Date: From 1/1/2020 to 12/31/2020			
In	e All Clinics			
n	t appointments to assessment type: None			
at	In the second metal second second second second second metals (continue)	Kauch Park Grane Hornitali	(Stars Hollow Cloid)	Total
	Total Number Of Risk Assessments Completed	19	15	34
2	Total Number Of Risk Assessments Completed UNIQUE	18	14	32
3	Total Number Of Patients Who Self Reported Breast Cancer	1	1	2
4	Total Number of Patients Who Reported Bilateral Breast Cancer	0	0	0
5	Total Number Of Patients Who Reported THEY Have Ovarian Cancer	1	0	1
δ	Total Number Of Patients Identified With TC8 Score 20% Or Greater	4	5	9
7	Total Number Of Patients Identified With BRCAPro Score 10% Or Greater	6	1	7
•	Unique Patients and Total For All Clinics is the sum of unique patients within a clinic, it is possible th All Clinics count, would count this patient twice.	he same patient had separate clinical encounter	s in two different clinics. As such	. Total for
•	Total Appointments reflects the number of appointments that were created by an appointment fee	ed or on demand by stall.		
•	 Completed Risk Assessment means for a given appointment, the patient reached the end of survey typically means a risk score was calculated by staff or if CRA automation is deployed. Completed Risk 	y (if applicable) or user opened then exited the a sk Assessments may be lower than Total Appoint	ppointment. A completed risk as tments.	sessment
	Consistent Out and any his last that Completed Did. Assessments If staff consistent the prosition			

"High Lifetime Breast Cancer Risk"

This report lists patients who meet your institution's <u>threshold for high lifetime risk;</u>

Currently, this report only looks at appointments whose <u>assessment type</u> is 'cancer screening.' Your institution can maximize the utility of this report by creating follow up 'cancer genetics' appointments in v4 to indicate that a high lifetime risk patient is being managed in high risk clinic.



The sample report below shows that during the report period, a total of two patients were identified as high lifetime risk. However, one patient who has a personal history of atypical hyperplasia was seen in high risk clinic (counted as a genetics patient).

High <mark>L</mark> Risk R	ifetime Breas eport				CR	A Health	
Run Date: 8/14/20	20						
User: bklin							
Report Date: From	5/14/2020 to 8/14/2020						
Clinic: All Clinics							
Limit appointment	s to assessment type: None						
Include Test Patier	its: Yes						
Total							
	Genetics Pt			Un	ique Patients		
No							1
Yes							1
Total							2
Patient Details							
MRN	Name	DOB	First High Risk Appt	Last High Risk Appt	Risk	Genetics Pt	PHx
99908142001	TestLifetime, Abigail WithFollowUp	09/23/1970	07-07-2020	07-07-2020	44.81642	Yes	Atypical Hyperplasia

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06-12-2020

24.928901 No

09/23/1970 06-12-2020

"Risk Patient"

The following fields are included in the Patient Risk Results report:

- Name
- MRN
- DOB
- Assessment Date

99906122001 TestKendrick, Anna

- Assessment Type
- Lifetime Risk
- Lifetime Risk Score
- Mutation Risk
- Mutation Risk Score
- Referring Physician
- Clinic

6.3 High risk clinic

Currently CRA offers several reports to support your Risk Clinic program.

- 1. "Genetics Tests Completed Report";
- 2. "Genetics Patient By Clinic Report";

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- 3. "Genetics Patient Mutation Report";
- 4. "Genetics Patient Report";
- 5. "Genetics Provider Referral Report";

"Genetics Tests Completed"

This report includes two summary and patient level information.

The first summary table describes how many patients are in the clinic population, followed by the number that had a completed BRCA, Lynch, hereditary cancer gene panel or Other gene panel test.

- Completed means the <u>status of the gene panel</u> is documented as "Completed" or "Completed, Patient Informed"
- The column 'Other Gene Tests Completed' represents the gene panel called 'Other'. In some instances, the CRA user may not know the exact panel name if a patient says 'I know my sister had genetic testing and was BRCA1 negative.' See section on how to enter <u>genetic test results</u> for more details.
- A gene panel date must be within the query period to be counted in this report

The second summary table is similar to the first table, but the counts are broken down by appointment provider.

The final table is a listing of each patient that make up the patient population identified using the query parameters.

Genetics Tests Completed Report



Run Date: 4/15/2021 User: hsimpson Report Date: From 3/28/2021 to 3/30/2021 Clinic: All Clinics Limit appointments to assessment type: None Include Test Patients: Yes

Risk Clinic Totals

Patients	BRCA Related	Lynch Related	Hereditary Cancer	Other Gene
	Tests Completed	Tests Completed	Gene Panels Completed	Tests Completed
1	0	0	1	0

Provider Totals

Provider	Patients	BRCA Related Tests Completed	Lynch Related Tests Completed	Hereditary Cancer Gene Panels Completed	Other Gene Tests Completed
	1	0	0	1	0

Individual Patients

Appointment Date	MRN	BRCA Related Tests Completed	Lynch Related Tests Completed	Hereditary Cancer Gene Panels Completed	Other Gene Tests Completed
03/29/2021	99903292102	0	0	1	0



"Genetics Patient Mutation"

This report provides two summary tables and patient level information.

The first summary table describes how many patients in the clinic population were identified with BRCA, Lynch, other hereditary mutation or VUS. It also identifies the number of patients referred into the clinic with a previously identified mutation.

The second summary table is similar to the first table, but the counts are broken down by appointment provider.

The final table is a listing of each patient that comprise of the patient population based on the query parameters.





Run Date: 8/18/2020 User: hsimpson Report Date: From 5/18/2020 to 8/18/2020 Clinic: All Clinics Limit appointments to assessment type: None Include Test Patients: Yes

Risk Clinic Totals

Patients	Identified with a BRCA Mutation	Identified with a Lynch Mutation	Identified with an Other Hereditary Mutation	Identified with a VUS	Referred into the program with an identified mutation
3	1	0	1	0	0

Provider Totals

Provider	Patients	Identified with a BRCA Mutation	Identified with a Lynch Mutation	Identified with an Other Hereditary Mutation	Identified with a VUS	Referred into the program with an identified mutation
	2	0	0	1	0	0
Sutter, John Augustus	1	1	0	0	0	0

Individual Patients

Appointment Date	MRN	BRCA Mutation	Lynch Mutation	Other Hereditary Mutation	VUS	Referred into the program with an identified mutation
06/19/2020	99906192001	Yes	No	No	No	No
07/31/2020	99907312001	No	No	No	No	No
08/17/2020	99908152001	No	No	Yes	No	No

"Genetics Patient"

This report provides summary and patient level information. This is intended to understand referral patterns into your clinic. E.g. was the patient appointment the result of internal referral or external referral. In addition, this report describes if this patient was related to another patient in your clinic.



The first table gives an overall count of unique patients seen during the query period.

The second table gives a count of unique patients seen broken out by provider.

The last table gives a listing of every patient that met the query criteria.

Column	Notes
Appointment Date	Patients most recent completed appointment date
MRN	Medical record number
Personal history of cancer	Yes/No
Referrals	Internal or External referral. Enter information in the <u>Edit Appointment form</u> to classify whether the appointment came from in-house/network provider.
Related to another patient	1= yes, 2=No. Enter information in the Edit Appointment form to declare if patient is related to another in the clinic.
Provider Name	Appointment provider

"Genetics Patient by Clinic"

This report providers metrics also found in "High Risk Breast/Ovarian Screening," but includes detailed metrics not available in the screening report: the number of unique patients, the number of appointments in the event a patient was seen multiple times during the query period, number of patients with a personal history of cancer and whether a prior completed appointment.

The first table gives an overall count of unique patients seen during the query period.

The second table gives a count of unique patients seen broken out by provider.

The third table gives a count of unique patients an whether the patient has completed a prior appointment.

The last table gives a listing of every patient that met the query criteria.

Column	Notes
Appointment Date	Patients most recent completed appointment date
MRN	Medical record number
Personal history of cancer	Yes/No


Referrals	Internal or External referral
Previous appointments	1= yes, 2=No
Clinic	Clinic name

"Genetics Provider Referral"

This report provides identifiable patient information. This is intended to understand what happened to the patient after the appointment: did the clinical encounter result in internal or external referral? Users are expected to enter this through the Risk Clinic Follow Up feature.

The output generates metrics about each patient appointment.

Column	Notes
Provider	Appointment provider
Appointment Date	Patients appointment date
MRN	Medical record number
Internal referral to Gyn Onc	Use the follow up feature to indicate if appointment resulted in this type of internal referral
Internal referral to Surg Onc	Use the follow up feature to indicate if appointment resulted in this type of internal referral
External referral generated	Use the follow up feature to indicate if appointment resulted in an external referral



Genetics Provider Referral Report



Run Date: 8/19/2020	
User: bklin	
Report Date: From 5/19/2020 to 8/19/2020	
Clinic: All Clinics	
Limit appointments to assessment type: None	
Include Test Patients: Yes	

Risk Clinic Totals

Provider	Appointments	Internal referrals to Gyn Onc	Internal referrals to Surg Onc	External referrals generated
Kevin S Hughes, M.D.	1	0	1	0
Meredith Grey, M.D.	1	0	0	1

Individual Patients

Provider	Appointment Date	MRN	Internal referral to Gyn Onc	Internal referral to Surg Onc	External referral generated
Meredith Grey, M.D.	07/10/2020	99907102001	No	No	Yes
Kevin S Hughes, M.D.	08/05/2020	99908142001	No	Yes	No

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6.4 Clinic Operations

"Patient Volume"

The following fields are included in the "Patient Volume" report:

- Appointment Physician
- Patient Name
- Medical Record Number
- Clinic
- Primary Care Physician
- Current Age
- Insurance
- Referring Physician
- Visit Date

Patient tracking and management

"Patients with Documented Follow-ups" lists follow-up actions for high-risk patients such as whether patient has scheduled enhanced screening, is considering or declined recommendations.

38



Referral patterns

"Patient Referring Providers" can help you understand referral patterns by breaking down the number of patients by referring provider

6.5 Output for Further Analysis

All CRA Clinic Reports can be downloaded as a CSV file for further analysis or be linked with other files.

"Patient Risk Results"

This report is mostly widely used for research given the number of fields that can be exported.

The following fields are just some of the fields included in the Patient Risk Results report:

- MRN: medical record number
- Patient Name
- Date of Birth
- Age
- Gender
- Ethnicity
- Personal history of breast cancer
- Personal history of ovarian cancer
- Test Patient
- Risk Clinic Patient
- High Risk BRCA: highest score from any of the breast/ovarian mutation risk models
- High Risk Lynch: highest score from any of the Lynch syndrome mutation risk models
- High Risk Breast Cancer: highest score from any of the breast/ovarian lifetime risk models
- Moderate Risk Breast
- Risk score (all models)
- NCCN HBOC

Case Study

I would like a report for every patient in our database in an excel spread sheet that has the following: patient's name, MRN, DOB, Age, Race, All scores and models, if patient has ever been diagnosed with breast cancer, if patient has ever been diagnosed with ovarian cancer, if patient is Ashkenazi Jewish.

Return to Table of Contents





7. <u>RESET PASSWORD</u>

This section applies to institutions that use the <u>standard CRA method of signing in</u>. If your institution has adopted authentication via <u>LDAP</u> or SAML, then this section does not apply to you.

Any user in CRA 4.0 can reset or update their own password.

- 1. Click on Utilities
- 2. Click on "Reset Password"
- 3. Complete the form by entering your current password, then entering your new password and confirming it by entering it again
 - a. Note the strong password requirements when creating a new password:
 - must be at least 8 characters long
 - must contain at least 1 uppercase letter, 1 lowercase letter, 1 digit and 1 of these special characters ~ ! @ # \$ % ^ * () _ + = .

Reset Password			
Change Password			
Password must be at least 8 ch	aracters long and contain at least 1 uppercas	etter, 1 lowercase letter, 1 digit and 1 of these special characters \sim ! @ # \$ % * () _ + = .	
Current Password*	New Password*	Retype New Password*	
			A Read and a

- 4. Click on 'Update'
- 5. Click on the Calendar icon to return to the Provider Portal dashboard

If you have forgotten your password, please contact your institution's CRA administrator to reset your password. You do not need to contact CRA Support. Once you receive the temporary password, you can sign into CRA v4 but will be immediately brought to the 'Reset Password' page so you can create a new permanent password.

As always, remember the best practices:

- Don't share accounts
- Don't share passwords
- Choose strong passwords

8. MANAGE PROVIDERS

This is a <u>utility</u> only available to <u>CRA superusers</u>.

You can store and manage a list of providers within CRA v4. Providers can be linked to an appointment and assume the role of:

- 1. appointment provider
- 2. referring provider

A referring provider can be further categorized as an internal referring physician or external referring physician.

Click on "Manage Providers" from the Utilities icon.





8.1 Provider List

The screenshot below shows a list of providers that can be sorted by name, provider identification numbers. Additional columns provide quick information about the provider. Quick action buttons allow you to edit or delete a provider of interest.

Provider Type Appointment Provid	ler and 4 more					Search by provider name or id
C Refresh 🕹 Ac	Id New Provider	Middle Name	National Provider ID +	Local Provider ID +	Provider Type	21 Providers + 1 2 > Quick Actions
Antar	Mohamed				Outside Referring Provider	8 Î
Atkins	Michael				Outside Referring Provider	
Badlissi	Anthony				Outside Referring Provider	2 B
Baltus	Marissa				Outside Referring Provider	
Barretto	John				Outside Referring Provider	
Bisson	Ryan				Outside Referring Provider	
Brown	Lisa				Outside Referring Provider	
Sapp	Elizabeth	P			Outside Referring Provider	
Fawbush	Melinda	w			Outside Referring Provider	
Hughes	Kevin	S		030188	Appointment Provider	
Hughes	Willaim				Outside Referring Provider	
ones	Henry	Test			Outside Referring Provider	
Grvin	Cathryn				Outside Referring Provider	
McCarthy	Philip				Outside Referring Provider	
Vonroe	Jennifer	C			Outside Referring Provider	2 Î

The provider list is by default sorted by Last Name in descending order. However, you can sort by the following columns:

- 1. Provider Last Name
- 2. Provider First Name
- 3. National Provider ID
- 4. Local Provider ID: Typically, this id is associated with scheduling systems that do not use the National Provider ID

You can	filter the	list by Pro	vider Type, A	Active Statu	s or search by	the provider	s name or ID	
		/			, 			
Manage Provider	\$							
Provider Type	. Ac	tive Status					Search by provider name or id	
Appointment Provid	er and 4 more 👻 🕖	Active 👻					Name / Id	Q
C Refresh 🛔 Add	New Provider						5519 Providers «	1 2 3 4 5 > >>
Last Name +	First Name 🗢	Middle Name	National Provider ID 🗢	Local Provider ID 🗢	Provider Type	Active Status	Ouick Actions	

8.2 Search for a Provider

The Manage Providers search box differs from the Provider Portal dashboard search box in



significant ways. The search feature is designed to give a more specific search result.

Imagine two providers, "Joe Smith" with local provider id 12345 and "Virginia Smith" with global provider id of 54321. If you search on:

- "Smith", the results display both providers.
- "Virginia", the results display "Virginia Smith."
- "Joe Smith", the results display "Joe Smith."
- "Smith Joe," the results display "Joe Smith."

However, if you search on "Joe Jones", the results display no findings. If your search on "Joe Smit", the results display no findings.

If you search on

- "Smith 12345", the results display "Joe Smith."
- "Smith 54321", the results display "Virginia Smith."

However, If you search on "Smith 1234", the results display no findings.

8.3 Quick Actions: Edit or Delete



For any provider listed, click on the edit icon to edit details.

The screenshot on the right show the fields that can be documented for a provider. If your institution has an appontment feed, data about your referring providers can be viewed or edited in this form.



For any provider listed, click on the delete icon to remove a provider from the list.

Title	•	Degree	M.D.		*		
First Name*	Vriginia						
Middle Name							
Last Name*	Apgar						
Role/Responsibility			•	Site			
National Provider ID				Loc Provider	iD		
institution	NewYork-Prest	oyterian Colu	umbia U	niversity Medi	ical Center		
Address 1*	630 West 168t	h Street					
Address 2							
City/State/Zip*	New York			NY	۲	10032	
Country*	United States		٠				
Phone				Fax			
Email							

8.4 Provider Types

CRA v4 allows you to define three provider types so unique workflows can be adopted:

- appointment provider
- outside referring provider
- in-office referring provider



Choosing "Appointment Provider" will make the provider available as an appointment clinician.

Return to Table of Contents

9. MANAGE CLINICS

This is a <u>utility</u> only available to <u>CRA superusers</u>.

Institution names along with corresponding license information are managed by CRA Health. Super users can add additional or edit existing clinics within their institution. If you need to edit the name of the institution as it appears on your banner, contact support@CRAHealth.com.

9.1 Add/Edit Clinics

To add a new clinic:

1. Select Utilities icon from the top navigation bar



- 2. Select 'Manage Clinics' from the menu
- 3. On the new page, you will have ability to sort your clinics, edit, delete or add new clinics and set the time zones for each of your clinics

CRA	Health				Homer Simpson Logout G 🕐
i≣₀ ∦	Manage Clinics				Search Clinic Q
£ 20	Clinic Name +	ata. Clinic Code 🗢	Assessment Type 🕈	Time Zone 🕈	Quick Actions
X	Azeroth	AZ	Cancer Screening	Eastern Standard Time	 iii
-	Multidisciplinary Breast Care Clinic		Cancer Genetics	Eastern Standard Time	 iii
	South Park Grace Hospital		Cancer Screening	Eastern Standard Time	 iii
	Stars Hollow Genetics Clinic		Cancer Genetics	Eastern Standard Time	⊘ [†]

- 4. Select Add Clinic and a new form will appear with the following fields:
 - a. Clinic name: Your clinic name will appear in standard templates and reports that exist in the system;
 - b. Clinic code: No action needed. The data is used to configure your appointment feed;
 - c. Assessment type: Select whether the clinic is a screening or high-risk clinic;
 - d. Survey type: If your clinic is using a tablet or kiosk to deliver a patient survey, define the default survey;
 - e. Time zone: Set the local time for your clinic of interest
- 5. Click the Save button when data entry is complete

 \oslash

To Edit a clinic

- 1. click on the edit icon
- 2. The same form will appear for you to edit.

Clinic Name	Clinic	: Code
Women's Imaging QA Test		
Assessment Type	Time	Zone
Cancer Screening	• (UT	C-05:00) Eastern Time (US & Car
Survey Type		
Super Short Breast	•	



9.2 Assessment Type

CRA Health Provider Portal uses assessment type in summary reports. "Cancer screening" is the default assessment type, typically associated with a breast imaging clinic but a user can specify whether the clinic is focused on addressing breast, colon or other health outcomes. "Cancer genetics" is the assessment type associated with high risk clinic workflows.

9.3 Time Zone

Setting the time zone for your clinic will determine the clock settings for each clinic. Typically, the time zone will be the local time of your corresponding clinic. Clock settings are used in the scheduling system display as well as audit reports.

If you are on the East Coast but reviewing or editing data for your clinic in the Midwest that is on Central Time, the timestamps will be based on Central Time.

Return to Table of Contents



10. USER ROLES AND PERMISSIONS

10.1 Two Roles

With the release of v4.200517, CRA reduced the user profiles to two types of roles: 'Administrator' and 'Clinician'.

The role of Administrator in CRA v4 is generally someone on staff who should have full access to all CRA v4 <u>Utilities</u>. This staff member may be considered a 'superuser', a clinical application manager. Table 9-1 below describes both roles and their associated permissions within CRA v4.

The clinician role may be anyone else who is not a CRA administrator. The screenshot to the right reveals the different utilities a CRA clinician has access to.



Role Name	Provider Application Access	Denied Permission To	Patient Clipboard Access
Administrator	Full	None	Full
Clinician	Partial	 <u>Audit Report</u> Manage Clinics Manage Providers Manage Users 	Full

Table 10-1 CRA Health Application Roles

In prior CRA v4 releases, other roles such as 'Tablet', 'Technologist', 'Administrative Staff' existed and may have been previously assigned to staff. Their workflows **are not** affected by the recent change. The retired roles now take on role of clinicians. The CRA Administrator can go to <u>Manage Users</u> and update these role types. However, this is not necessary.

10.2 Ability To Edit Clinical Data

Currently both user roles can edit clinical data within the CRA v4 Provider Application or sign into the Patient Clipboard application.

Return to Table of Contents



Only superusers have access to the Manage Users utility.

During the planning phase, your institution's representative provided CRA's project manager with a list of approved users: any staff member within your institution that would need access to either the Provider Portal or Patient Clipboard. The names were preloaded before going live with the system.

1. Select Utilities icon from the toolbar, and then select Manage Users from the menu

Schedule						🖺 Audit Reports	d Appointments 🔁 Refresh Appointme
Appt Date/Time +	Name 🕈	MRN \$	DOB¢	Appt Provider 🗢	Visit Number¢	Clinic Reports	Quick Actions
			N	o records found.		Manage Clinics	
						🤱 Manage Providers	
						≜ + Manage Test Patients	
						💄 Manage Users	
						A Reset Password	
						🔲 Web Tablet	

2. A new page will launch titled, "Manage Users"

CRA	Health			Lisa Simpson Logout G 🕐
i de la come de la com	Manage Users			
%				Search by Name
*				٩
æ	♣• Add New User C Refresh			17 Users 🔹 1 2
M	Username \$	First Name \$	Last Name *	Quick Actions
-	jwiison	Jenna	Wilson	Clinic Reset Password 🗹 🛅 💌
	zlefebvre	Lefebvre	Zach	Clinic Reset Password 🗹 💼 💌

3. Each column on the Manage Users page can be sorted. This feature may be especially helpful for clients at large institutions with many CRA users

Manage Users					L	Add New User
Username¢	First Name¢	Last Name*	Quick Actio	ons		
thedude	Dude	Abides	Clinic	Reset Password	Î	×

4. You can now perform many tasks such as create new accounts, delete retired accounts, or add clinic profiles to specific users.



11.1 Creating New User Account/s

If a new staff member joins your institution and is authorized to access the system, you or someone with permissions will need to add the person through this utility.

If your CRA v4 system is configured with Lightweight Directory Access Protocol (LDAP), you will also need to inform your IT department that new staff members need to be part of your institutions security group or active directory for CRA Health v4. LDAP is one way that allows CRA v4 users to sign in with their existing institution credentials rather than maintain a separate username and password.

- 1. Launch Manage Users
- 2. Click the Add New User button in the upper right corner



Add New User

User Name*

First Name

Last Name*

Indicates required fields

- 3. A new form will appear requesting:
 - a. Username of the individual, used within your institution
 - b. Full first name
 - c. Full last name
 - d. Email (optional)
- 4. Click 'Save'
- 5. Return to the Manage Users page, then select "Clinic" button
- 6. A new form, "Edit Clinics" with the new username will appear. By default, a new user will be granted access to all clinics in your institution and will be assigned the roll of 'Clinician'.

Clinic	Role		Actions
Azeroth	Clinician	~	Ê
Clinic6	Clinician	~	Ť.
Clinic7	Clinician	~	Û
Clinic8	Clinician	~	Û
Multidisciplinary Breast Care Clinic	Clinician	~	Ŵ
South Park's Grace Hospital	Clinician	~	Ē
Stars Hollow Genetics Clinic	Clinician	~	Ô

7. You can take away access to specific clinics by clicking on the trash can icon.





- 8. You can change the new user's role by using the dropdown. Please see <u>User Role Permissions</u> in this guide to learn about the different roles.
- 9. Click on 'Save and Close'

11.2 Deleting A User



You can delete a user by clicking the trash can icon under the Quick Actions button. The user will no longer have access to CRA v4; however, their previous interactions will be retained for audit reports.

11.3 Edit Or Disabling A User



If you made a misspelling with the first or last name, you edit the user profile. You can also disable their log in.

Currently, you cannot edit a username in CRA v4.

Manage Users					
				Sea	rch by Name
C Refresh 💄 Add New User 🏦 Upl	oad Users				9 Users
Username 🗢	First Name 🗢	Last Name 🔺	Login Enabled	Quick Ac	tions
vapgar	Virginia	Apgar	Yes	Clinic	Reset Password 🗹 🛍 🖂
bdrohan	Drohan	Brian	Yes	Clinic	Reset Password 🗹 前 🖂
gchin	Gary	Chin	No	Clinic	Reset Password 🗹 🛍 🖂

11.4 Reset Password

Note: if your institution has agreed to authenticate users through <u>LDAP</u> or SAML, then this section is not relevant since passwords for CRA 4.0 will be managed through your IT department and not by the CRA 4.0 system.

Any user in CRA 4.0 can reset his/her own password.

- 1. Click on Utilities
- 2. Click on Reset Password
- 3. Complete the form by entering your current password, then entering your new password and

set Password Change Password			confirming it by retyping it
Password requirements:			again
 Must be at least 8 characters long Must contain at least one upperce Must contain at least one lowerca Must contain at least one digit; an Must contain at least one of the sp Must contain the username, fi Must not contain the username, fi 	; and ise letter; and d pecial characters ~ ! @ # \$ % ^ * () _ + = rst name, last name, or email address; a as P@ssw0rd123!, Qwerty123\$, Spring2	. and ind 0211, Clinician1231, etc.	
Current Password*	New Password*	Retype New Password*	
			50



Setting temporary passwords for others (Administrator only)

Only CRA v4 administrators can reset passwords for other authorized users.

If your institution uses CRA's standard login, authorized users can always update their own password.

The "Reset Password" button can establish a password for a new user or reset an existing user's password. The current v4 Manage Users utility currently does not have a feature to force users to change their password upon sign in.

- 1. Select Utilities from the toolbar, and then select Edit User from within the menu
- 2. For the appropriate user, click on the Password button

Manage Users			Lo Add New User
Username	First Name	Last Name	Quick Actions
service	service	account	Clinic Reset Password 🛍 🔀
mbsmrtic	Smrtic	Mary Beth	Clinic Reset Password 🛅 🔀
bdrohan	Drohan	Brian	Clinic Reset Password 🛅 🔀
zlefebvre	Lefebvre	Zach	Clinic Reset Password 🛅 🔀
bsimpson	Bart	Simpson	Clinic Reset Password 🕅 🐱
Reset Password Please confirm password reset:	Generate Temporary Password		

3. New instructions will appear under the username titled: Reset Password. You will need to scroll down to see these instructions, if the user of interest is listed near the bottom of the Manage Users page.

Manage Users			Add New User
Username	First Name	Last Name	Quick Actions
service	service	account	Clinic Reset Password 🖮 🔀
mbsmrtic	Smrtic	Mary Beth	Clinic Reset Password 💼 🔀
bdrohan	Drohan	Brian	Clinic Reset Password 🛅 🔀
zlefebvre	Lefebvre	Zach	Clinic Reset Password 🛅 🔀
bsimpson	Bart	Simpson	Clinic Reset Password 🗰 🔀
Reset Password Please confirm password reset:	Generate Temporary Password		

4. Click "Generate Temporary Password" and a new field will appear for the user. CRA v4.0 will randomly generate a strong password that is 8 characters long, contains a combination of at least one (1) special character, capital and lowercase letters and numbers. Special characters used by the password generator include: ~!@#\$%^*()_+=.



Return to Table of Contents



12. APPOINTMENTS ON THE WORKLIST

This section describes how to manually add or import appointments to create a worklist in your CRA v4 Dashboard.

If you are using CRA in women's imaging or in a high-volume clinic setting, your institution likely purchased an HL7 appointment feed to deliver appointments from your clinic's scheduling or ordering system to CRA v4. An HL7 appointment feed removes the need for staff to manually create appointments. Even if you did not purchase an appointment feed, you can import a group of appointments into CRA rather than adding individual appointments.

Once you've created an appointment on your worklist, you can edit, copy or delete appointments at any time.

12.1 Manually Add Appointments

To add an appointment, click on the 'Add Appointment' icon found below the and Appointment search filters but above the dashboard columns.

CC	ho	d.	o d	0
SU	ПE	:u	u	E

Appointment Date	Clinic South Park Grace Hospital	and 1 more	Assess	ment Status and 2 more •						Search by r Name / N	name or MRN
C Refres 📑 Add Ap	opointment Upload Appointments									34 Appts	67 K 1 2 3 9 90
Date and Time -	Patient Name 🗢	MRN ¢	DOB	Appointment Provider ¢	Visit Number ≑	Accession Number 🗢	Clinic Name ¢	Referring Provider ¢	Status	Has Pre Assess	Quick Actions
10/31/2020 08:01 AM	TestBreastRisk, Kayley	9991031200	2 09/23/19	70			South Park Grace Hospital		Completed	No	
10/31/2020 08:00 AM	TestBreastRisk, Amanda	9991031200	1 09/23/19	70			South Park Grace Hospital		New	No	
10/17/2020 08:00 AM	TestBreastRisk, Mackenzie	9991017200	1 09/23/19	70			South Park Grace Hospital		New	No	
08/07/2020 08:00 AM	TestPhxBrCa, Amanda CE3640	9990807200	1 09/23/19	70 Roche, Constance A			South Park Grace Hospital	Rivera, Walter	Completed	No	

A new window will launch titled "New Appointment."

inner left corner on the
inner left corner on the
inner left corner on the
apper left contret of the

Enter the patient medical record number (MRN), which can be alphanumeric. The MRN should be consistent with the main patient identifier used at your facility.

A new, larger window will launch with available fields for patient demographic information. See Figure 12.1

If the patient MRN already exists in your database, their prior demographic details will pull forward into this form.



Figure 12-1 New appointment form

Z Test Appointment	Exclude from Tablet	109	Cancel Save
MRN *	Last Name *	First Name *	Middle Name
99907102101	TestGroupEdit	Clare	CommentVital
Display Name (Read Only Fie	eld)	DOB *	Gender *
TestGroupEdit, Clare Com	mentVital	09/23/1970	F 🗸
Appointment Date *	Time *	Survey *	Clinic *
07/10/2021	● ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■ ■	Breast Risk •	Stars Hollow Clinic 🗸
Assessment	Referral	Language	Race
Cancer Genetics 🔹 🗸	~		× ·
Nationality	Occupation	Education	Marital Status
Insurance Patient is related to anoth Opt out Patient Portal inv	ner patient in program itation for all future appointments		
Insurance Patient is related to anoth Opt out Patient Portal inv Opt out Patient Portal inv Address 1	ner patient in program itation for all future appointments itation for this appointment	Address 2	
Insurance Patient is related to anoth Opt out Patient Portal inv Opt out Patient Portal inv Address 1 10 Broadway	ner patient in program itation for all future appointments itation for this appointment	Address 2	
Insurance Patient is related to anoth Opt out Patient Portal inv Opt out Patient Portal inv Address 1 10 Broadway City	ner patient in program itation for all future appointments itation for this appointment	Address 2	Country
Insurance Patient is related to anoth Opt out Patient Portal inv Opt out Patient Portal inv Address 1 10 Broadway City Cambridge	her patient in program itation for all future appointments itation for this appointment State	Address 2 Zip	Country
Insurance Patient is related to anoth Opt out Patient Portal inv Opt out Patient Portal inv Address 1 10 Broadway City Cambridge Email Address	her patient in program itation for all future appointments itation for this appointment State MA	Address 2 Zip 02473 Work Phone	Country Mobile Phone
Insurance Patient is related to anoth Opt out Patient Portal inv Opt out Patient Portal inv Address 1 10 Broadway City Cambridge Email Address test@CRAHealth.com	er patient in program itation for all future appointments itation for this appointment State MA Home Phone 6175551212	Address 2 Zip 02473 Work Phone	Country Mobile Phone
Insurance Patient is related to anoth Opt out Patient Portal inv Opt out Patient Portal inv Address 1 10 Broadway City Cambridge Email Address test@CRAHealth.com Appointment Provider	her patient in program itation for all future appointments itation for this appointment State MA Home Phone 6175551212 Referring Provider	Address 2 Zip 02473 Work Phone PCP	Country Mobile Phone Ordering Provider
Insurance Patient is related to anoth Opt out Patient Portal inv Opt out Patient Portal inv Address 1 10 Broadway City Cambridge Email Address test@CRAHealth.com Appointment Provider	er patient in program itation for all future appointments itation for this appointment State MA Home Phone 6175551212 Referring Provider	Address 2 Zip 02473 Work Phone PCP	Country Mobile Phone
Insurance Insurance Patient is related to anoth Opt out Patient Portal inv Opt out Patient Portal inv Address 1 10 Broadway City Cambridge Email Address test@CRAHealth.com Appointment Provider Visit Number	her patient in program itation for all future appointments itation for this appointment State MA Home Phone 6175551212 Referring Provider Accession Number	Address 2 Zip 02473 Work Phone PCP Appointment Status	Country Country Mobile Phone Ordering Provider



Fill in the patient information in the corresponding new appointment fields. Fields with a red asterisk (*) are required and must contain a valid entry.

The Appointment Date defaults to the current day, and by selecting the appointment icon you have access to an interactive calendar to select a past or future appointment date.

You can select the clinic where the appointment will occur. This is important for comprehensive medical centers that offer services at multiple locations, as well as medical centers that offer breast imaging and high risk/genetic counseling.

You can also decide if this appointment is for a test patient.

The "Exclude from Tablet" checkbox allows you to exclude a particular appointment from the Patient Clipboard worklist.

The green number on the top row is the 'ApptID', a unique number that tracks each clinical encounter for a given patient. (

You can simply enter an eight-digit number in the appointment or date of birth field (below) without the need to enter slashes.

Edit Appointment												
 Test Appointment 	Exclude from Tablet		85							Cancel Save		
MRN *	Last Name *	Fir	rst N	lam	e *					Middle Name		
99903052101	TestShatner		Willi	iam								
Display Name (Read Only Field	Display Name (Read Only Field)									Gender *		
TestBreastRisk, Madison	TestBreastRisk, Madison				03221931					M ~		
		ſ	<		Mar	ch 20	021		>			
Appointment Date *	Time *	9	Su	Мо	Tu	We	Th	Fr	Sa	Clinic *		
03/05/2021	08:00 AM 🗸	2	28	1	2	3	4	5	6	Stars Hollow Clinic 🗸		
			7	8	9	10	11	12	13			
Assessment	Referral	1	14	15	16	17	18	19	20	Race		
Concor Constice		2	21	22	23	24	25	26	27			
	•	2	28	29	30	31	1	2	3	•		
Nationality	Occupation		4	5	6	7	8	9	10	Marital Status		
~												

12.2 Import Appointments

If you do not have an appointment feed, CRA v4 allows you to import appointments from your scheduling system using a CSV or XML file.

As a starting point, open <u>Edit Appointment</u> screen to review the possible fields that can be imported into CRA.

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Click on the Upload Appointments from the dashboard.

Schedule					
Appointment Date	Clinic		Assessment Status		
8/19/2020	- 🗯 South Park Grac	e Hospital and 1 more	New and 2 more	•	
C Refresh 🛱 Add /	Appointme 🕇 🤹 Upload Appo	intments			
C Refresh 🛱 Add /	Appointme 1 🔹 Upload Appo Patient Name 🗢	MRN ¢	DOB	Appointment Provider \$	Visit Numb
C Refresh 🛱 Add / Date and Time 🗸 08/21/2020 08:00 AM	Appointme 🔹 Upload Appo Patient Name 🕈 TestMinus, Christine	MRN + 99908072003	DOB 09/23/1970	Appointment Provider 🕏	Visit Numb
C Refresh 🛱 Add / Date and Time - 08/21/2020 08:00 AM 08/14/2020 08:00 AM	Appointme () Upload Appo Patient Name + TestMinus, Christine TestBreastRisk, Hayley	intments MRN ¢ 99908072003 99908142002	DOB 09/23/1970 09/23/1970	Appointment Provider 🕈	Visit Numb
C Refresh to Add / Date and Time - 08/21/2020 08:00 AM 08/14/2020 08:00 AM 08/07/2020 08:00 AM	Appointme (2 Upload Appo Patient Name + TestMinus, Christine TestBreastRisk, Hayley TestPhxBrCa, Amanda CE3	intments MRN ÷ 99908072003 99908142002 . 99908072001	DOB 09/23/1970 09/23/1970 09/23/1970	Appointment Provider \$ Roche, Constance A	Visit Numbe

Your scheduling file must contain the following columns:

- Patient first name
- Patient last name
- Date of birth: must be in mm/dd/yyyy format. E.g. 03/03/2020
- Appointment date: must be in mm/dd/yyyy format. E.g. 03/03/2020
- Appointment time: must be four digits long with a ':' in between hour and seconds. E.g. 08:00 is acceptable value but 8:00 is not an acceptable value
- Clinic, if your institution uses CRA in more than one clinic
- Survey type, if your institution utilizes more than one survey

If adding other fields like zip code, make sure your values include leading 0. No data shall include special characters such as &, % or commas.

12.3 Creating Test Patient Appointments

You can mark any existing appointment as a test patient.

You can <u>create a test patient using any MRN</u> but a best practice would be to start your MRN with '999' or some prefix that will be clearly visible to other users at your institution.³

Test patient appointments will not appear in the <u>high-risk queues</u>.

Test Appointment	Exclude from Tablet	25	Cancel Save
MRN *	Last Name *	First Name *	Middle Name
99905191902	Test	Daenerys	
Display Name (Read Only F	ield)	DOB *	Gender *
Test, Daenerys		09/23/1970	F
Appointment Date *	Time *	Survey *	Clinic *
05/19/2019	08:01 AM	FMH •	South Park Grace He
Assessment	Referral	Language	Race
Cancer Screening	•		
Nationality	Occupation	Education	Marital Status
٣			

³ Previous versions of CRA v4 used as a rule MRNs starting with 999 to designate test patient appointments. With v4.190519, clients with patients using the older designation were updated to reflect the new method to designate test patient appointments.

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12.4 Edit Appointments

To edit an appointment, select the appointment you want to modify from the worklist, and then click on the Quick Action Edit Appointment icon located on the right side of the worklist

This action will open the Edit Appointment window which includes the same fields as the New Appointment <u>window</u>.

Once you have made the desired modification/s, click the save and close button.

Changing patient's date of birth or gender

You can edit a patient's date of birth (DOB) or gender though the 'Edit Appointment' form at any time, but ideally before running risk calculations.

If you have already run a risk assessment then subsequently make a DOB or gender edit, you will receive a warning message to re-run the risk assessment.



12.5 Copy Appointment

The 'Copy Appointment' feature is useful for institutions that do not have an appointment feed going into CRA. An initial appointment can be copied to create a follow-up appointment.

To copy an appointment, select the Additional Quick Action icon for the appointment you want to copy.

Now choose from the dropdown, Copy Appointment.



This will launch the Copy Appointment window. The contents of this form are like the form for <u>creating</u> or editing an appointment. The Appointment Date defaults to today's date and should be modified by selecting the Appt Date field.

Once you have made the desired modification/s, click the save button and the form closes.



Patient data follows each new appointment

CRA v4 tracks each clinical encounter for the patient. Whether you create a follow up appointment <u>manually</u>, through the <u>copy appointment function</u> or from <u>an appointment feed</u>, all patient data from a previously completed appointment will be pulled forward into the new appointment. For the patient, this means prior years data will be available to review when the patient returns to complete another health questionnaire. Data that follows the patient includes patient demographics, personal risk factors, family health history and prior gene panels documented as part of the patient record.



For Risk Clinic users, pedigree comments will be carried into the new appointment unless you do not wish for this to happen.

12.6 Delete Appointment

To delete an appointment, select the <u>More Actions</u> icon for the appointment you want to delete.

Then choose from the dropdown, Delete Appointment.



An additional window will launch, asking if you are sure you want to delete the appointment.

Selecting 'Cancel', will leave the appointment unchanged. Selecting 'Yes', will delete the appointment.

Exceptions- appointment with clinical information



Users will be asked twice if they wish to delete an appointment that has data entered, even if risk scores have not been calculated.

In this case, CRA v4 will generate the following message:



If you wish to delete an appointment that has clinical data, you will be given a second warning message:

Confirm Operation			
• This appointment contains data enter you want to delete this appointment with o	ered by the patie data?	ent or the provider.	Are you sur
		Cancel	Yes



If you need to retrieve a deleted appointment with clinical data, please contact CRA support.

Return to Table of Contents



13. HEALTH QUESTIONNAIRES FOR CANCER RISK ASSESSMENT

CRA v4 offers a selection of health questionnaires for both screening and high-risk clinic settings. You may offer your patients the opportunity to <u>take a survey in clinic as part of the check-in process</u> (<u>CRA</u> <u>Patient Clipboard</u>) or invite your patients to <u>complete a survey prior to their appointment</u> (<u>CRA Patient</u> <u>Portal</u>).

CRA health questionnaires

- are available in other languages such as Spanish, Portuguese, and French;
- include skip logic based on gender of patient and specific responses to personal and family history questions

Prior to going live, your institution will have decided on a survey that best suits your risk assessment program.



If you would like to create a custom survey by adding new questions or rephrasing questions, please contact your CRA Project Manager. An additional cost may apply based on the scope of work.

13.1 Screening

Women's imaging health questionnaires vary in length and content based on the goals of your screening program. The most popular screening survey is called 'Super Short Breast' which typically takes 3-5 minutes to complete, depending on the patient's family health history. Other CRA surveys elicit additional information depending on the needs of the screening program. Survey variations include sections such as:

- Family size questions such as the number of unaffected siblings, maternal and paternal aunts and uncles based on specific family cancer history triggers. 'Breast Risk' is commonly used survey that includes family size questions (5-7 minutes)
- Mammography intake questions such as 'Where was your last mammogram?' (6-8 minutes)
- Asking for the patient's consent to be assessed for risk (3-5 minutes)
- Accepting the patient's recall of her BRCA1/2 genetic test results, without having to confirm at a high-risk clinic visit
- Consenting the patient to be contacted by a breast health specialist if she is determined to be at high risk (3-5 minutes)
- Asking additional questions that will produce a lifetime colon cancer risk score



CRA Analytics has compared average survey times between two imaging centers. One center used 'Breast Risk' which took patients an average of 6 minutes to complete and the other center used 'Super Short Breast', which took about 4.5 minutes for patients to complete.



Asking about unaffected family members at the time of screening

Some screening centers are willing to provide patients additional time to elicit additional information about family size. Two CRA health questionnaires, 'Breast Risk' and 'Breast Colon Risk', will ask about additional family members based on the patient's unique family health history.

Family health history red flags that will prompt CRA questionnaire to ask about family size:

- More than one family history of Brain/Colon/Uterine Cancer
- Family history of Breast Cancer and Ashkenazi
- More than one family history of Breast Cancer
- Family history of Ovarian cancer
- Family history of Male Breast Cancer
- Any family history with bilateral breast cancer.
- Any family history with breast cancer diagnosed before age 50

If any of the above criteria is met, the questionnaire will ask the patient about the total number of

- sisters
- brothers
- children
- aunts (by bloodline)
- uncles (by bloodline)

Table 13-1 Comparing Select CRA Questionnaire for Screening Settings

Survey feature	'FMH'	'Breast Risk'	'Supershort Breast'
Consent to assess risk and reasons for declining	Yes	No	No
Personal risk factors	Yes	Yes	Yes
Family history - relatives cancer	Yes	Yes	Yes
Family size – unaffected relatives	Yes	Yes	No

13.2 High Risk Clinic

High risk clinics typically will choose a survey, 'Risk Clinic' or 'Risk Clinic Breast Colon', that take on average 25-35 minutes to complete. A more enhanced version of this survey is 'Patient Portal Form' but requires the patient to complete on a desktop machine. Table 13-2 outlines the differences between the three surveys.

One noteworthy difference between these surveys is that 'Patient Portal Form' allows the patient to link affected cousins, nieces/nephews to a maternal/paternal bloodline. While 'Risk Clinic' or 'Risk Clinic Breast Colon' does ask about affected cousins, nieces/nephews, the resulting pedigree will show these affected individuals as <u>floating relatives</u> (untethered to a specific bloodline).

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Table 13-2 Comparing CRA's Questionnaires for High-Risk Clinics

Survey feature	Risk Clinic	Risk Clinic Breast Colon	Patient Portal Form
Duration (without breaks)	25-35 minutes	30-40 minutes	20-30 minutes
Complete on mobile smartphone	Yes	Yes	No
Complete on tablet or desktop	Yes	Yes	Yes
Asks about affected and unaffected family members	Yes	Yes	Yes
Asks if patient's siblings are twins	Yes	Yes	Yes
Asks about patient's half siblings	No	No	Yes
Asks about demographic information and vital status of family members	Yes	Yes	Yes
Asks if patient is adopted	No	No	Yes
Asks about cousins, nieces/nephews	Yes	Yes	Yes
Patient can link cousins, nieces/nephews to a maternal or paternal bloodline	No	No	Yes
Asks about frequency of vegetable intake, exercise, and NSAID/Aspirin use	No	Yes	Yes

When a patient returns to clinic the following year and is asked to update her risk factors or family history using any CRA health questionnaire, her prior years response will be prepopulated into the survey.

Patient Portal Form has a 'Submit' button

In contrast to other health questionnaires, 'Patient Portal Form' requires patients to explicitly declare they are ready to submit answers as part of the questionnaire flow.

CRA Health	TestSubmit, Raven	4 of 5	Back Next Logout ?
Are you ready to submit your answers?			●English ○Spanish [^]
 Yes, I'm ready to submit No, I'm not ready to submit 			
Select Yes if you are ready to submit your answers and click the Next button above to continue	e. Select No if you want to come back and complete your answers.		





Return to Table of Contents

14. EDIT SURVEY

The feature is designed for screening center workflows where a user may wish to quickly review patiententered responses to a CRA health questionnaire. However, risk clinic staff who are not as familiar with pedigree drawing may find the family history presented in a table format just as helpful for their workflow.



To edit a patient's <u>health survey</u> responses, select the patient appointment and click on the Edit Survey Icon located under the set of <u>Quick Action icons</u>.

Across the top, there are four tabs within the Edit Survey selection: <u>Family History</u>, <u>Cancer Risk Factors</u>, <u>Imaging Study</u>, and <u>Documents List</u>. If you use a set of CRA health questionnaires that also as mammography intake questions, you will see a fifth tab- "Mammo Intake"

CRA Health

Family History	Cancer Risk Fac	tors Imaging S	itudy Document	s List Followup	05		Relation	٠	ଯ 🕢 Add R
Family Member	Relative Age	VILAI SLALUS	HIST UX	Age Onset	Second Dx	Age Onset	Third Dx	Age Onset	Actions
Self	47								۲
Mother									۲
Father									۲
Maternal Grandmot									\odot
Maternal Grandfath									۲
Paternal Grandmot									\odot
Paternal Grandfath	er								۲
Maternal Aunt		Alive	Breast Cancer	30					۲
Spouse of Aunt									۲
Maternal Cousin (Fe		Alive							۲
Maternal Uncle		Alive							۲
Spouse of Uncle									۲
Maternal Cousin (M		Alive							۲
Maternal Other		Alive							۵

14.1 Family History

Family history is the default view after clicking on Edit Survey. The table-based view contains information on the patient and her/his family members based on what the patient entered through the survey. You can use the Actions buttons to remove family members or modify a family member's disease and age of onset.

Family History	Cancer Risk Factors	Imaging Study	Documents List	Followups			Relation	*	u Add Relative
Family Member	Relative Age	Vital Status	First Dx	Age Onset	Second Dx	Age Onset	Third Dx	Age Onset	Actions
Self	49								۲
Mother									۲
Father			Colon Cancer	57					0
Maternal Grandmot	her								۲
Maternal Grandfath	er								۲
Paternal Grandmoth	her								۲
Paternal Grandfathe	er								۲
Maternal Aunt		Alive	Breast Cancer	56					Ø 🗊
Cousin (Female)		Alive	Breast Cancer	45					Image: A state of the state



Add a new relative:

- 1. Click Relation drop down to reveal a list of relatives
- 2. Click on Add Relative

Aunts and uncles will be connected to a specific bloodline. However, cousins, nieces/nephews or other relative will not. On the pedigree, these relatives will appear as unattached relatives.

Relation	~	u Add Relative
Third Dx	Daughter Son Brother Sister Aunt - Maternal Aunt - Paternal Uncle - Maternal Uncle - Paternal Cousin Cousin (Male) Cousin (Female) Niece Nephew Other Other (Male) Other (Female)	Actions

Add or edit up to three diseases

You can edit or add common cancers through the Family History form.

Select the Quick Action Edit button for the relative of interest.

A new form will appear that allows you to choose a common cancer and age of onset.

Family History	Cancer Risk Factors	Edit Family Llisto	no Colf			ation	•	🏨 Add Relative
Family Member	Relative Age	Vital	ry - Sell			rd Dx	Age Onset	Actions
Self	48	Vital Status	•	Relative Age	48			0
Mother		First Dx	Atypical Hyperplasia	Age Onset				۲
Father		Second Dy	Atvoical Hyperplasia	Age Onset				۲
Maternal Grandmot		Second BX	Brain Cancer	Alle Onsee				۲
Maternal Grandfath		Third Dx	Cervical Cancer	Age Onset				۲
Paternal Grandmot.		_	Colon or Rectal Cancer					\odot
Paternal Grandfathe			Kidney or Bladder Cancer		Cancel Save			۲
			LCIS Leukemia Liver Cancer Lung Cancer Lymphoma (Non-Hodgkins) Melanoma Other Ovarian Cancer Parceatic Cancer Prostate Cancer Sarcoma Stomach Cancer					
			Copyright © 2018 CRA	Health. All rights reserved				

If you need to add other cancers or want to specify a disease that is not listed, you can <u>to do so through</u> <u>the Risk Clinic module</u> if you are unsure of the **exact** spelling of the disease or condition used in CRA v4.

However, if you are familiar with how diseases are defined in CRA v4, you can type in the disease into the diagnosis box. Examples include:



• Type 'Usual Breast Hyperplasia' to assign hyperplasia (not atypia)

Family History			×
Edit Family Histor	y - Self		
Vital Status	Alive 🗸	Relative Age	50
First Dx	Usual Breast Hyperplasia	Age Onset	
Second Dx	~	Age Onset	
Third Dx	~	Age Onset	
			Cancel Save

14.2 Cancer Risk Factors

Cancer Risk Factors allows you to review or edit patient risk factors. Risk factors are divided into separate sub tabs for breast or colorectal cancer risk factors.

Breast risk

The Breast cancer risk sub tab includes data fields that are <u>incorporated into leading breast cancer risk</u> <u>models</u>. You can view all possible data fields in <u>Figure 13.2</u> by scrolling through to each section. A black information icon next to the risk factor will indicate that a breast cancer model utilizes the risk factor. Not all fields are <u>required to run a risk model</u>. Hover over the icon to see which models utilize the risk factor of interest.

Data is prepopulated if a patient has taken an in-clinic tablet survey or a survey through CRA's <u>Patient Portal</u>.

Data fields include:

- Physical Data: Height and weight
- Breast Density and Polygenic SNP Score
- Social History: Smoking and alcohol consumption
- Ethnicity/Race: Race and two ethnicity categories
- Patient Reported Procedural Hx: Past chest wall radiation treatment, biopsies
 - ✓ If a patient has had a previous biopsy and you enter or edit AH, LCIS data a warning message will appear.
 - The data in these fields will be used in risk model calculation



✓ Note: If you wish to document additional hyperplasias, you can do so using the Risk Clinic pedigree tool

66



- Patient Reported Genetic Testing: BRCA1 or BRCA2 mutation findings, if known
 - ✓ Note: This field is not incorporated into risk model calculation. If you agree with the patient's recall, you must add BRCA1/2 genetic test results through the <u>Risk Clinic pedigree tool</u>.
- Childbirth History: Gravidity, parity, age at first birth, childbearing status
- Birth Control: Number of years taken, age started, continuous usage
- Menstrual History: Age of menarche, menopause status, hysterectomy, oophorectomy
- Hormone Replacement Therapy (HRT):
 - ✓ combined (if hormones were used)
 - ✓ number of years taken
 - ✓ additional years of intended future use (number of years remaining if the patient is currently using)
 - ✓ years since taking

A risk factor such as intended HRT usage is used by the Tyrer-Cuzick model but is not strictly required.

• Chemoprevention: Tamoxifen, Raloxifene usage

Notes:

- 1. As you enter or edit information, the data is automatically saved.
- The data described on this form only represents common risk factors collected by a screening survey, whether it is a disease or procedure that impacts risk models used at your institution. More specific disease types can be documented using the <u>Risk Clinic pedigree tool</u>. Examples include:
 - a. <u>Hyperplasia</u> type
 - b. Prostate cancer, metastatic, intraductal, high Gleason score

67



Figure 14-2 Breast Cancer Risk Factors

Physical D	ata	Breast Density and Polygenic SNP Score
Height	feet inches	BI-RADS Atlas Category
Weight	Ibs Weight Change v	· · · · · · · · · · · · · · · · · · ·
		Volpara VBD % [1-100] BI-RADS Category from Volpara
Ethnicity/I	Race	
Ashkenazi Jewis	th •	Hologic VBD % Hologic ABD % BL-RADS Category from Hologic
Hispanic	•	VAS % [0-100]
	African American or Black American Indian/Alautian/Felvimo	
Race	Asian or Pacific Islander	Polygenic SNP Relative Risk
	Caribbean/West Indian	
Patient Re	ported Genetic Testing	
Has Had Cancer	Genetic Testing	Social History
		Smoking
Result		Alcohol
Genetic Testing	Has Been Done in Family	Patient Reported Procedure History
	Contan multima Aneximates 100,000.00	Chest Wall Radiation < 30 yo
Description		
		Breast Left When Right When
Birth Conti	rol & Fertility Drugs	Ever had a Breast Biopsy? # of Biopsies
sinth Control Us	· ·	
# years taken	Age Started	Biopsy w/ Atypical Hyperplasia Biopsy w/ LCIS
Continuously	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·
Fertility Drug U	ie	Broast Curranias
Hormone F	Replacement Therapy	Implants Left When Right When
Used Hormones	Combined	
# Years Taken	Additional Years	Reduction Left When Right When
	Intended Future	· · · · · · · · · · · · · · · · · · ·
Years Since Tak		Reconstruction Left When Right When
Estrogen	v # Years Taken Still Taking v	Mastectomy Left When Right When
Premarin	• # Years Taken Still Taking •	
Provera	# Years Taken Sbill Taking	r r r r r
		Other Description
		•
		Left When Right When
		· · ·
		Childbirth History
		e or Pregnancies
		# of Children Age at First Birth
		Currently Nursing * Nursing the Last 3 Months *
		Done Childbearing
		Menstrual History
		Age At First Period Menopausal Status +
		Still Having Periods V Age Periods Stopped
		LMP Confident of LMP +
		Hysterectomy + Age of Hysterectomy
		Path Durvier Remand
		ovur overles nemoved
		Chemoprevention
		Tamoxifen v ≠ Years Taken Still Taking v
		Raloxifene 🔹 🕈 Years Taken Still Taking 💌
		Other



Breast density

Breast density can be entered or edited manually, but you have other options if manually entry is not possible (or ideal). Below is a list of options.

- Mammo tech enters data using prior years BiRad value before the appointment begins
- Import a list of breast density values from prior years based on patient MRN
- An inbound <u>ORM interface</u> with prior years breast density value while creating an appointment in CRA v4 Dashboard
- An inbound <u>ORU interface</u> with the BiRad value after the mammogram is read
- An inbound interface with Volpara ScoreCard after the mammogram is read. This the best option to get the most accurate Tyrer-Cuzick 8 score.

Colorectal risk

The colorectal risk factor sub tab shares common risk factors; however, the 'Medications', 'Lifestyle' and 'Procedures' sections are unique and relevant for colorectal models such as CRATT.

Lancer Risk Facto	rs - Breast Cancer Risk Factors - Colorectal		
Physical Data		Menstrual History	
Height	feet. inches	Still Having Periods	
Weight	Ibs Weight Change		
		Hormone Replacement Therapy	
Ethnicity/Race		Used Hormones 🗸	
Ashkenazi Jewish	Ť	Years since Taken	
Hispanic	*		
	African American or Black	Medications	
0	American Indian/Aleutian/Eskimo	Regular Aspirin User 🗸 👻	
Race	Asian or Pacific Islander	Regular Ibuprofen User	
	Caribbean/West Indian		
		Colonoscopy and Polyps	
Lifestyle		Ever had Colonoscopy or Sigmoidoscopy	

14.3 Necessary vs sufficient data

In general, the more data you enter into a risk model, the more accurate the risk calculation will be. However, a potential tradeoff exists- the more data you ask users to enter, the less likely they may be to use the model for all the patients who need the calculation.

Thus, while Tyrer-Cuzick and BRCAPRO both use the age and vital status of every relative, this need for excessive data entry typically results in these models being used only in high-risk clinics and only with the highest risk individuals.



The most common <u>CRA health questionnaire</u> used for screening clinics takes about three to five minutes depending on the complexity of the patient's personal or family history. Read Dr. Hughes' blog, <u>Lyte</u> <u>Breast Cancer Models</u>, to learn more about implementing these Lyte models in a screening setting⁴.

The screenshot below presents risk factors that are captured by the three to five-minute survey, enough for developing a screening score for breast/ovarian cancer.

Physical Data		Social History			
Weight 159	lbs	Smoking No, never \$			
Height 5	feet 8 inches	Alcohol 10 - 19 drinks per week			
Ethnicity/Orig	in .	Patient Reported Procedure Hx			
Ashkenazi Jewish	No	Chest Wall Radiation < 30 yo			
Hispanic	No				
African American or Black		Biopsy w/ Atypical Hyperplasia Yes			
Race	American Indian/Aleutian/Eskimo	Biopey w/1/7/5			
	Asian or Pacific Islander				
	Caribbean/West Indian	Childbirth History			
Patient Repor	ted Genetic Testing	# of Pregnancies 3 Currently Pregnant No \$			
Has Had Cancer G	Senetic Testing	# of Children Age at First Birth 26			
No	\$	Currently Nursing			
Result					
ţ		Menstrual History			

14.4 Imaging Study

Nurse navigators or quality coordinators can record in CRA v4 when patients comply with recommendations by documenting when an MRI, ultrasound was completed or when a genetic test was ordered.

Family History Cancer Risk Factors Imaging Study Documents List			New Mammogram			
	Type ¢	Date≑	Value \$	Result¢	Statusŧ	Quick Actions
	MRI	3/1/2017			Pending	۵

For tracking purposes, you can enter results of imaging studies such as mammograms or MRI through the Quick Action from <u>high or moderate risk queues</u>.

⁴ Biswas S, et. al. Simplifying clinical use of the genetic risk prediction model BRCAPRO. Breast Cancer Res Treat. 2013 Jun;139(2):571-9. Epub 2013 May 21

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14.5 Documents List

Within the Documents List tab, you can view a historical list documents for your patient or <u>create a new</u> <u>document</u>. You can also create new documents directly from the landing page, under <u>Quick Action</u> <u>icons</u>.

Family History	Cancer Risk Factors	Factors Imaging Study Documents List		
Nameŧ			Date Modified \$	Quick Actions
TestSuperShortBreastElizabeth_99902151701_SurveySummary_02152017 21:00:46		02/15/2017 09:00:46 PM	۵	

14.6 Follow Ups

Users can use CRA v4 to track and <u>manage</u> your patient's compliance with recommendations or encounters by phone, email or when letters have been sent. Go to the <u>section</u> on <u>Patient Management</u> <u>Using Risk Queues</u> to learn more.

14.7 Returning To The Work List

For Women's Imaging clients or Risk Clinic clients who have patient clipboard, where automation is included:



Once you have updated the patient data, created a new document, and/or reviewed the patient information, select the Scheduling icon in the left navigation pane.

An additional window will launch, seen below, asking, "Do you would like to calculate risk and generate documents?"



Select Yes

..... this will run the v4 <u>Automation program</u>. Automation runs the risk models and re-prints any documents or letters which are generated once the patient completes the patient survey.

?

If you are unsure of the materials included in your automation workflow, please check with your project manager.

Select No



..... <u>CRA v4 Automation</u> will **not** be run: the risk models will **not** be processed, documents will **no**t be generated.

Return to Table of Contents


15. RUN AUTOMATION DOCUMENTS

CRA v4 Automation can be run as part of a pre-designed workflow or staff can trigger automation on demand.

A typical automation configuration within a women's imaging clinic may be:

- a. Survey summary and Patient letter is printed at the designated point of care printer;
- b. PCP letter is put on the batch list for staff to print at a later time.



From the work list found on the landing page, you can re-calculate risk scores and generate designated documents automatically on demand.



If you are editing clinical data through <u>Edit Survey</u>, you will be asked whether or not you'd like to run automation when you exit.

The specific automation documents that will be generated depend on the configuration and workflow you requested for your institution.

A sample workflow with CRA v4 Automation

- 1. Patient completes risk assessment at home
- 2. Patient then checks into the front desk for their screening mammography appointment
- 3. A survey summary and patient letter are automatically generated at the local printer

You can review <u>elsewhere in this user's guide how v4</u> <u>Automation</u> can facilitate screening workflows.

If you are unsure of the documents included in automation or when automatic is triggered, please check with your CRA project manager.

15.1 Automation document filename

CRA can customize your automation filename by the following

- FormID: your own document identifier. This should be an integer.
- MRN: patient's medical record number. This can be alphanumeric.
- PatientLastName: patient's lastname

ABOUT CRA AUTOMATION

Automation refers to a program within the CRA v4 system that facilitate high volume screening clinics using tablet surveys or Patient Portal. CRA v4 can accommodate several triggers that will drive a variety of automation events. Triggers can include:

- When a staff member manually initiates automation though a quick action
- 2. When a patient completes a survey in the clinic
- 3. When patient checks into the clinic
- 4. When breast density value is sent to CRA
- 5. When a mammography report is completed by the radiologist

Automation events include but are not limited to:

- 1. Risk scores are calculated
- 2. Documents are generated either at the point of care printer or placed on the CRA batch list to be printed later
- A message is sent from CRA to your institution's electronic health record



- DOB: patient's date of birth. This should be an integer that looks like yyyymmdd
- Visitnum: patients visitnumber. This should ben integer
- ApptDate: Appointment date. This should be an integer that looks like yyyymmdd
- LocalProviderID: Your institutions own provider identifier if you are not using NPI. This can be alphanumeric.
- CurrentDateTime: Date, time when automation generated the file. This should be an integer that looks like yyyymmddHHmmss

Suppose you wanted to generate a provider letter through CRA automation for a patient named Marge Simpson whose appointment date was June 24, 2020, date of birth was 09/23/1970 and who has a referring provider with an identifier of XQ644. Marge completed the survey around 8:02 AM. Automation created an referring provider letter as a PDF 24 seconds later. A sample filename that uses all the above fields may look like:

72094_999200624_SIMPSON_19700923_219824525_20200624_XQ644_20200624080224.PDF

Return to Table of Contents



16. CREATE DOCUMENTS

Any Provider Portal user can create new documents on demand in three ways:

- 1. You can quickly create a document by clicking on the "New Document" quick action icon associated with your patient's recent appointment;
- If you are a Breast Imaging user <u>reviewing survey responses</u>, use the <u>Document tab</u> to generate new documents or view archived documents;
- 3. If you are a <u>Risk Clinic</u> user working on a pedigree, use the <u>Document drop down</u> to generate new documents or view archived documents.

CRA can also work with you to generate documents automatically through our <u>automation process</u>.

Pedigree Risk Factors Mutation Risk Cancer Risk Recommendations Documents Imaging Studies Followup

16.1 Standard Templates

The Provider Portal includes several templates for screening (e.g. breast imaging) and high-risk clinic workflows. CRA's "<u>Survey Summary</u>" is the most used template.

CRA provides the following stock templates designed for screening centers:

- 1. "MRI LMN": Letter of medical necessity (LMN) for an MRI.
- "Screening mammography letter" for patients and PCP: Relay results of risk assessment for breast/ovarian or colon cancer at the time of screening. Based on your screening program, these letters will dynamically generate risk recommendations that are tailored to your patient's risk level.

In addition to the survey summary, the high-risk clinic module offers the following templates:

- a. "Consider Testing Relative Letter"
- b. "Known Mutation Relative Letter"
- c. "Letter of Medical Necessity for genetic testing"
- d. "Risk Clinic New Patient PCP Letter"
- e. "Risk Clinic Test Results PCP Letter"





"Survey Summary," a clinical note

The "Survey Summary" is a clinical note that displays clinician decision support messages at the top, patient risk factors including family history in tabular form, risk scores in an easy-to-read grid, and a pedigree. CRA v4 users often import the survey summary into their electronic medical record as a clinician note or as an attachment within an existing progress note.

The document is often two pages but can be longer based on the complexity of your patient's family health history and whether additional features or adjustments are made at your institution.



You will find the following predefined sections within the survey summary:

1. Header: patient demographic information along with referring physician;

2. Clinical decision support messages: see <u>detailed discussion</u> within the user's guide;

3. Risk factors: patient self-reported or clinician-entered cancer and non-cancer risk factors including family history affected relatives in tabular format;

4. Risk calculation or risk score grid: display of your patient's risks cores based on the models used in your risk assessment program;

5. Imputed Tyrer-Cuzick (TC) 8 scores: a series of different TC8 scores based on breast density Bi-RAD value. A radiologist will find this useful as they're reading the mammography images;

6. Pedigree image: a snapshot of the pedigree is generated after the Patient Clipboard survey is complete.



16.2 Customizing Templates

You can work with your CRA Project Manager to customize standard templates or create new templates that best suits your workflow. Typically letter templates, including changes to the survey summary, are defined prior to the 'Go Live' process. However, as your communication needs change, CRA can work with you to support your goals.

Keeping letters to just one page

In addition to concise wording, margin alignment and font size, CRA can offer different strategies to help you keep risk communication letters to be one page. However, the task becomes more difficult if your



€

letter needs to meet envelope requirements or multiple paragraphs are used to convey risk to your patient or referring physician. Furthermore, family health history can vary from patient to patient.

Below are three strategies to consider when designing your CRA letter template

- 1. "play the odds" and anticipate a typical family health history will be three rows. You can then decide to minimize font size and widen margins. This may result in a one-page letter 90% of the time. However, if a patient's health history breaks this rule, the letter will go to two pages;
- 2. define a consistent page break on page 1 and always expect the document to be two pages. This strategy allows letter font to be normal size and more legible;
- 3. don't use window envelopes and capture some line rows back but that still does not guarantee one page. This strategy may result in one-page letters 95% rather than 90% of the time.

16.3 Download A PDF On Demand

From the landing page that displays your patient work list, you can create a new document on demand for an appointment by clicking on the New Document icon under Quick Action section.

An additional window will launch titled: New Document

New Document	
MRN: 999201612121	
Suggested Documents	* Select a document to view it.
MRI LMN	
Screening Mammogrpahy Patient Letter	
Screening Mammogrpahy PCP Letter	
Survey Summary	
Other Documents	
Consider Testing Relative Letter	
Known Mutation Relative Letter	
Letter of Medical Necessity	
Risk Clinic New Patient PCP Letter	
Risk Clinic Test Results PCP Letter	
l	

The available correspondence is listed within the Suggested Documents and Other Documents section, located in the left panel of the New Document window.

Select the document you would like to generate for the patient, and a preview will display in the right panel of the New Document window.



Suggested Documents	Survey Summary		
MRILMN	Clinic 1		Concor Dick Accoccmont Survey
Screening Mammogrpahy Patient Letter	child I	(a	Concer Risk Assessment Survey
Screening Mammogrpahy PCP Letter	TestSuperShortBreast, Elizabeth DOB Unit #: 99902151701 Provi	: 09/23/1970 Age: 46 ider: Gender: F	02/15/2017
Survey Summary			
Other Documents	It is suggested that Breast/Ovarian The patient's risk of mutation is 10% or g The ACS* suggests MRI screening 31 The lifetime risk of breast cancer is 20%.	Cancer genetic testing be considered greater by BRCAPro. hould be considered in people with a 2	for a risk of mutation of 10% or greater. 20% or greater lifetime risk of breast cancer by BRC
	The meane tak of breast cancer is 2070	or greater by Tyrer/Guzicki	
Consider Testing Relative Letter	*ACS = American Cancer Society	or greater by Tyner/Cubick.	
Consider Testing Relative Letter	*ACS = American Cancer Society	or greater by Tyter/Cuzick.	
Consider Testing Relative Letter (nown Mutation Relative Letter .etter of Medical Necessity	*ACS = American Cancer Society		
Consider Testing Relative Letter	ACS = American Cancer Society <u> DEMOGRAPHIC</u> Age: 46 Height: 5-9	LIFESTYLE Smoking: Alcohol:	No, never More than 19 drinks per week
Consider Testing Relative Letter Anown Mutation Relative Letter etter of Medical Necessity Patient Portal Login Email Patient Portal Registration Email	ACS = American Cancer Society PEMOGRAPHIC Age: 46 Height: 5-9 Weight: 147 BMI: 21.7 Conduc Excelo	LIFESTYLE Smoking: Alcohol: ETHNICTY Jewis	No, never More than 19 drinks per week h: No
Consider Testing Relative Letter Known Mutation Relative Letter Letter of Medical Necessity Patient Portal Login Email Patient Portal Registration Email Patient Portal Thank You	*ACS = American Cancer Society *ACS = American Cancer Society DEMOGRAPHIC Age: 46 Height: 5-9 Weight: 147 BMI: 21.7 Gender: Female Phone: 6175551212	LIFESTYLE Smoking: Alcohol: ETHNICITY Bevis Hispan Beckcroun	No, never More than 19 drinks per week h: No 6: No 6: Caribbean/West Indian
Consider Testing Relative Letter (nown Mutation Relative Letter Letter of Medical Necessity Patient Portal Login Email Patient Portal Registration Email Patient Portal Thank You Patiere	*ACS = American Cancer Society *ACS = American Cancer Society <u>DENOGRAPHIC</u> Age: 46 Height: 5-9 Weight: 147 BMI: 21.7 Gender: Female Phone: 6175551212	LIFESTYLE Smoking: Alcohol: ETHNICITY Jewis Backgroun	No, never More than 19 drinks per week h: No d: Caribbean/West Indian
Consider Testing Relative Letter Known Mutation Relative Letter Letter of Medical Necessity Patient Portal Login Email Patient Portal Registration Email Patient Portal Thank You Pedigree	*ACS = American Cancer Society *ACS = American Cancer Society <u>PEMOGRAPHIC</u> Age: 46 Height: 5-9 Weight: 147 BMI: 21.7 Gender: Female Phone: 6175551212	LIFESTYLE Smoking: Alcohol: ETHNICITY Jewis Hispani Backgroun	No, never More than 19 drinks per week h: No d: Caribbean/West Indian

The document can be saved or immediately downloaded as a PDF.

Saving the document serves two purposes:

- 1. you can print it to your local printer;
- 2. you begin a document library for your patient that will build up over time.

The purpose of this Quick Action is to simply create a document. You will need to enter the Edit Survey workflow or launch the Risk Clinic module to view archived documents or <u>edit your documents</u>.

Return to Table of Contents



17. RISK SCORES ON DEMAND

To review, calculate or recalculate patient risk scores, select the patient appointment and click on the Risk Calculation icon from the <u>Quick Action icons</u>.

An additional window will launch titled: Risk Score

lisk Score					
IRN: 999201612121 Preast/Ovarian			Colorectal	Close	n Risk Models
Risk of BRCA1 or BR	CA2 Muta	tion	Risk of Lynch	Syndrome Muta	ation
BRCAPro		MMRPRO			
Myraid			PREMM2		
Tyrer-Cuzick			Colon Conc	5 years Disk	Lifatima Dick
Tyrer-Cuzick v7			MMRPRO	J YEARS RISK	Lifetime Risk
Breast Canc 5 ye	ars Risk	Lifetime Risk	CCRAT		
BRCAPro			Endometri	5 years Disk	l ifatima Pick
Claus				5 years Risk	Lifetime Risk
Gail			MMRPRO		
Tyrer-Cuzick					
Tyrer-Cuzick v7					
Ovarian Ca 5 ye	ars Risk	Lifetime Risk			

Selecting the 'Run Risk Models' button will process the risk models and display risk calculations for the patient.

To close the Risk Scores window, select the Close button.

Return to Table of Contents



18. PATIENT CLIPBOARD



CRA v4 Patient Clipboard allows patients to take a cancer risk assessment survey **in clinic** prior to seeing the provider. Staff can quickly see whether a returning patient was previously identified as high-risk for breast cancer or BRCA1/2 mutation or if a new patient was just identified as high-risk.

Patient Clipboard is:

• included as part of your institution's CRA v4 configuration at no additional cost;

• a separate web-based program that can run on tablets, patient kiosks or on a designated workstation that provides

privacy for the patient⁵.

You will need to work with your IT department to ensure tablets are maintained, cleaned and 'locked down' so patients cannot perform other functions with the tablet.



If you would like to avoid maintaining patient facing devices at your institution, talk to your CRA Project Manager about <u>Patient Portal</u>, which gives patients the opportunity to complete a survey prior to an appointment or with their own mobile device while in clinic.

18.1 Workflow: Staff to Patient

The typical workflow in a clinic where tablets are used would be:

- 1. Staff launches Patient Clipboard in the tablet's browser and logs in;
 - Note: Based on how you <u>securely log into the Provider Portal</u>, staff will log into Patient Clipboard the same way
- 2. The Patient Clipboard worklist only shows today's appointments;

		Clinic:	BWH Imaging		~		
Appt Time	MRN	Patient	Name	DOB	Survey Type	Visit Num	Accession Nun
08:00 AM	99907292001	TestBreastRisk, Mary		09/23/1970	Breast Risk		
08:00 AM	99907292002	TestSuperShortBreast,	Anna	09/23/1970	Super Short Breast		
08:01 AM	99907292004	TestSuperShortBreast+	Consent, Mary	09/23/1970	SuperShortBreast +Consent		
08:03 AM	99907292006	TestSuperShortBreast+	Consent, Brandy	09/23/1970	SuperShortBreast +Consent		
08:04 AM	99907292007	TestSuperShortBreast+	Consent, Jasmine	09/23/1970	SuperShortBreast +Consent		
08:05 AM	99907292008	TestSuperShortBreast+	Consent, Elizabeth	09/23/1970	SuperShortBreast +Consent		
08:07 AM	99907292010	TestSuperShortBreast+	Consent, Grace	09/23/1970	SuperShortBreast +Consent		
08:08 AM	99907292011	TestSuperShortBreast+	Consent, Daniela	09/23/1970	SuperShortBreast +Consent		
08:09 AM	99907292012	TestSuperShortBreast+	Consent, Carla	09/23/1970	SuperShortBreast +Consent		

3. Staff can change the worklist for today by clinic

⁵ Clients are expected to provide their own devices.

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- 4. Staff can quickly determine if a return patient on today's worklist was previously identified as high-risk.
 - A pink ribbon indicates if patient was previously identified has having a high lifetime breast cancer score based on the risk models used at your institution's screening program.
 - A pink DNA strand indicates if patient was previously identified as high risk for BRCA1/2 mutation (not shown).

A return patient may have both icons or have no icons next to their name. No icons next to the patient's name means the patient is a new patient that has never completed a risk assessment or a return patient who was previously at average risk (<20% lifetime score and does not meet your institutions threshold for BRCA1/2 mutation risk);

- Staff identifies the patient from a worklist and moves to the next page by clicking 'Next' button to confirm patient's identity;
 - If your institution would like to document that a patient has declined the risk assessment questionnaire, please go to this article, 'Patient declines risk assessment'
- Staff, without clicking the 'Next' button, then hands the tablet to the patient in front of them;

	Н	ealth Questic	nnaire	
If the information reception de	n below is not you, ple esk. If this is you, plea	ease click the ' ise click the 'N	Not Me' button a ext' button to be	nd return the tablet to th gin the questionnaire.
	MRN:	9990729200	7	
	Patient Name:	TestSuperSh	ortBreast+Conse	nt, Jasmine
	Date of Birth:	09/23/1970		
		Not Me	Vext	

- 7. Patient starts the survey at the confirmation screen and has the option of clicking 'Not Me' if staff accidentally handed off the wrong tablet;
- 8. Patient completes the survey and hands the tablet back to clinic staff after reaching the 'Thank You' screen;
- 9. The patient who just completed the survey will no longer appear on the Patient Clipboard worklist.

18.2 Protecting Patient Information

- No data is stored on devices that delivers CRA's Patient Clipboard survey.
- Staff will always be required to sign back into Patient Clipboard if the program times out or after the last "Thank You" screen.
- A patient will only see his or her own survey questions and can never see the list of other patients in the clinic.



Clients who elect to use tablets in the clinic to deliver a CRA Patient Clipboard survey should not utilize the save username and password feature offered by the major web browsers. After a patient reaches the end of the survey, the Patient Clipboard is designed to return the patient to a login screen. However, if the web browser is saving a staff member's username and password, the patient may be able to click further to see the Patient Clipboard worklist.

		CRA Health
Hea	alth Questionnaire	
Please login to see	the list of appointments t	for today.
Username:	hsimpson	
Password:	•••••	
		Next

18.3 Review the Patient's Breast and BRCA1/2 risk status

Sites also have an option to configure their Patient Clipboard with a feature, "Show High Risk," that lets staff immediately see the results of the risk assessment.

When staff clicks on the "Show High Risk" button, the worklist will reveal only those patients who had completed a risk assessment in their respective clinic and were identified as high risk (based on lifetime breast cancer and/or BRCA1/2 mutation score).

18.4 Putting a Patient Back On The Worklist

If you need to hand a tablet back to a patient after she has completed a survey, you will need to log into the Provider Portal and use a quick action to <u>mark her appointment as incomplete</u>. Your patient's appointment will reappear on the Patient Clipboard worklist. (In addition, the <u>appointment status on the dashboard</u> will be marked as 'In Progress.')

Repeat the steps described above if you would like the patient to restart the survey. The patient will be able to review questions she has already answered and finish the rest of the survey.

18.5 Patient Declines Risk Assessment

If your institution wishes to document patients who decline risk assessment, you will need to sign into the v4 Provider Portal.

- 1. Click on Edit Survey icon
- 2. Click on the Followups tab
- 3. Add new Followups
- 4. The new pop-up screen will indicate a disposition of 'Declined'
- 5. Return to the CRA v4 Dashboard
- 6. You will be asked if you would like to 'Run automation and calculate risk scores'
- 7. Click 'No'
- The patient's appointment status will be marked as 'Complete'. However, you can choose to 'Mark as incomplete' using the v4 Dashboard Quick Action



82



Return to Table of Contents

19. POPULATION SCREENING WORKFLOWS AND INTERFACES

In addition to the <u>right CRA survey</u> for your clinic population, a typical workflow that utilizes CRA Health v4 for screening high patient volumes (e.g. within a Women's Imaging clinic) will include Patient Portal, inbound and outbound interfaces.

<u>Patient Portal</u> allows patients to spend less time in clinic by completing a health questionnaire prior to the appointment. If the patient does not complete the health questionnaire at home,

If your institution chooses not purchase Patient Portal, then <u>Patient Clipboard</u> can elicit risk factors responses in the clinic with a tablet for automatic risk calculation.

CRA <u>v4 Automation</u> can create documents at different points of the workflow.

A common workflow for a busy screening clinic may be:

- 1. Patient appointment is created by an HL7 feed
- 2. Patient is invited through v4 Patient Portal to complete a health survey prior to the appointment
 - a. Patient is automatically reminded to complete the questionnaire if she has not done so
- 3. Patient complies and completes the questionnaire in advance
- 4. Patient checks into the front desk on the day of her appointment
 a. This event triggers CRA <u>v4 Automation</u> to print a survey summary to the local printer
- 5. Patient completes her mammogram
- 6. CRA automation recalculates risk scores and now triggers a final survey summary when the breast density is known
 - a. This event can also generate patient and provider letters, whether they print to a local printer or drop into a <u>batch queue</u> for staff to print later

19.1 Overview of Interfaces

Inbound

An appointment feed from your clinic's scheduling system to CRA v4 using Health Level 7 (HL7)⁶ standards creates a worklist. This removes the need for staff to <u>manually create appointments</u>. Your IT department will work with CRA implementation and service engineers (ISE) to exchange SIUs and ADT messages. When an appointment is scheduled, the information will quickly appear in CRA Dashboard. If the appointment is cancelled or rescheduled, the information will be quickly updated in the dashboard as well.

⁶ HL7 is an standards organization to facilitate health information data exchange between information systems. <u>https://www.hl7.org/about/index.cfm?ref=nav</u>

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Another way to create appointments in CRA is through an HL7 order entry message (ORM) feed. The order includes information about the patient and can include whether the patient has a personal history of breast cancer or the patient's breast density from last year.

Another type of interface is to bring in Volpara Health Volumetric Breast Density value after the mammogram is read to get the most accurate Tyrer-Cuzick 8 score.

Outbound

Your patient's personal and family health history can be shared with your electronic health record, RIS or PACS system via an outbound interface through a HL7 observation result (ORU) message.

19.2 Clinical Decision Support Messages

CRA v4 provides various clinical decision support messages at the top of the survey summary that are unique to each patient's risk profile.

Breast/Ovarian

The messages below appear if a patient meets <u>your institutions breast/ovarian threshold</u> for risk-based interventions. The relevant risk model is cited as part of the message.

This patient meets breast/ovarian mutation and lifetime risk thresholds for 10% and 20%, respectively.

Clinic		Cancer Risk Assessment Surve		
TestBreastRisk, Johanna	DOB: 01/11/1970	Age: 45	11/16/2015	
Unit #: 99911161502	Provider:	Gender: F		
It is suggested that Breast/Ovaria The patient's risk of mutation is 10% or	n Cancer genetic testing be considered	l for a risk of mutation of	10% or greater.	

The ACS* suggests MRI screening should be considered in people with a 20% or greater lifetime risk of breast cancer by BRCAPRO, Tyrer-Cuzick or Claus.

The lifetime risk of breast cancer is 20% or greater by Tyrer/Cuzick. *ACS = American Cancer Society

DEMOGRAPHIC
Age: 45
Gender: Female
Phone: 6175551212

ETHNICITY

Background: African American or Black

The patient below meets National Comprehensive Cancer Network guidelines for BRCA1/2 testing and breast/ovarian lifetime risk threshold.



TestNCCN, Laura Unit #: 201806291 DOB: 09/23/1970 Appointment Physician: Age: 47

Gender: F

06/29/2018 Referring Physician:

The NCCN* suggests that Breast/Ovarian Cancer genetic testing for people meeting the following criteria: Close relative with breast cancer diagnosed <= 45 years old

The ACS* suggests MRI screening should be considered in people with a 20% or greater lifetime risk of breast cancer by BRCAPRO, Tyrer-Cuzick or Claus.

The lifetime risk of breast cancer is 20% or greater by Tyrer-Cuzick v8: 25.86%, Tyrer-Cuzick v7: 25.86%.

*NCCN = National Comprehensive Cancer Network. Referenced with permission from the NCCN Guidelines (R) for BRCA-Related Breast and/or Ovarian Cancer Syndrome V1.2018.

*ACS = American Cancer Society

Lynch Syndrome

It is suggested that Colon Cancer genetic testing be considered for a risk mutation of 5% or greater. The patient's risk of mutation is 5% or greater by MMRPRO.

Chest wall radiation

When the patient self-reports they've had chest wall radiation under the age of 30, the following message is shown:

The ACS* suggests MRI screening in people who have received chest wall radiation under the age of 30. The patient indicates she had chest wall radiation under age 30.

Average risk

No clinical decision support messages appear for an average risk patient.

Clinic	Cancer Risk Assessment		Assessment Surve
TestBreastRisk, Jane	DOB: 09/23/1970	Age: 45	11/16/2015
Unit #: 99911161508	Provider:	Gender: F	
DEMOGRAPHIC Age: 45	<u>ETHNIC</u> Backgro	<u>CITY</u> bund: Unknown	

19.3 Patient Reports Atypia, LCIS and/or Genetic Testing

CRA v4 treats self-reported biopsy results and genetic testing results very cautiously in the screening setting. Presence of atypical hyperplasia (AH) and/or lobular carcinoma in situ (LCIS) can significantly increase a patient's lifetime risk for breast cancer based on the Tyrer-Cuzick model. A patient who



reports having had a prior genetic test should have a follow-up with a genetics professional to understand the nature of the test.

The messages below are warnings that CRA v4 generates on top of the survey summary.

The patient states they have LCIS.

Refer for full evaluation OR confirm and run risk calculations before making management decisions.

The patient states they have Atypical Hyperplasia. Refer for full evaluation OR confirm and run risk calculations before making management decisions.

TestCO1574, SavannahGtest	DOB: 09/23/1970	Age: 48	10/30/2018
Unit #: 99910301801	Provider:	Gender: F	

The patient has indicated they have had genetic testing in the past.

Refer for full evaluation OR confirm and run risk calculations before making management decisions.

DEMOGRAPHIC	LIFESTYLE
Age: 48 Height: 5-9	Smoking: No, never Alcohol: 10 - 19 drinks per week
Weight: 123 BMI: 18.2 Gender: Female Occupation: Military Marital Status: Widowed Education Level: Some college Phone: 6175551212 Email: test@hughesriskapps.com	<u>ETHNICITY</u> Jewish: No Hispanic: No Background: Asian or Pacific Islander

No risk scores on survey summary

The survey summary that is initially generated after a patient reports AH, a LCIS biopsy result or that she previously had genetic testing presents decision support messages that asks the user to confirm or make a referral. On this initial survey summary, no risk scores are presented. In addition, the self-reported risk factor is NOT saved as a risk factor until staff confirms the information.

Verify self-reported pathologies

Staff should confirm the responses with the patient, then produce a new survey summary with risk scores.

1. Launch the Provider Portal interface, highlight the patient from the worklist;



2. Click the Edit Survey button;



 You will see a pop-up indicating the patient has self-reported AH, LCIS or prior genetic testing;



- 4. Select the Cancer Risk Factors tab;
- 5. Exit out of Edit Survey mode
- 6. Click "Yes" when asked to <u>Re-Run Calculations and Generate Documents;</u>
- 7. An updated Survey Summary with risk scores can now be saved and/or printed.

You can watch a video to learn more about the workflow described in this section.

Health Edit Survey TERpende Data		Bruto Mayre Logost G
wighten and a state of the second state of the		
ange 112 au	(manual) in and	
mpt (s) ma (s) mm	And The Party of Barrier and T	
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An	a submer an an an a	
and a second sec	Transferred (1) and (1) and (1)	
	* presente presente	
	Renderman Security 17	

Notes:

After confirming self-reported pathologies, the resulting risk scores will take into account the patient's response.



If the patient reported prior genetic testing, the risk scores that are produce do NOT consider the patient's response. If the gene panel or mutation is known, screening center staff can add the <u>genetic</u> test results through the Pedigree tool and re-run risk models.

If you would like to opt out of this standard feature and always accept what the patient reported as true without having staff confirm the veracity of the patient's response, contact your CRA Project Manager to have your system configured.

Return to Table of Contents



20. PATIENT MANAGEMENT USING RISK QUEUES

Screening center staff can manage their high and moderate risk breast/ovarian cancer patients identified by CRA v4 through the <u>queues</u> feature. Staff can enter follow-up actions including whether a patient has received enhanced screening or visited a genetics professional.

Note: Your institution can define which patients appear in your CRA v4 risk queues by limiting or expanding on <u>the standard models used to define high risk</u>.

For example, sites have opted to configure CRA risk queues in the following ways:

- use only the Tyrer-Cuzick 8 model for both lifetime and mutation risk
- use NCCN HBOC guidelines rather than risk models to define patients who fall into the high mutation risk queue
- lower the mutation risk threshold from 10% to 5% to define patients who fall into the high mutation risk queue
- add Gail model to define patients who fall into the high lifetime risk queue⁷

As of this release, CRA v4 does not have a Lynch Syndrome or chemoprevention queue. If your screening center would like to manage this population of patients in CRA v4, please contact your CRA project manager.

20.1 Managing High-Risk Patients

CRA v4 presents three high-risk queues for patients who may develop breast/ovarian cancer. The queues are available to meet the needs of different screening programs. You may prefer to work in just one queue.

The three high-risk queues are:



1. Lifetime or BRCA1/2 mutation risk. This queue is suitable for screening programs that are identifying patients who qualify for enhanced screening by MRI and/or qualify for genetic counseling and testing



- 2. Lifetime only
- 3. BRCA1/2 mutation risk only

Note: A patient may appear on all three queues if both their lifetime and mutation scores meet your institution's <u>risk thresholds</u>.

⁷ Given that the Gail model does not meet NCCN or American Cancer Society criteria for familial based risk assessment, it should not be utilized to assess lifetime risk. Nonetheless, if your institution would like the GAIL model scores to be included in your high-risk criteria (e.g. based on the insurance guidelines in your area), please contact our CRA project manager.

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This section focuses on the "Lifetime or BRCA1/2 mutation risk' queue but the features are similar for individual lifetime and BRCA1/2 mutation risk queues.

Patients who are high lifetime breast cancer or high BRCA1/2 mutation risk

This combined queue is the most commonly used queue for screening centers whose clinical objectives are to identify and triage high-risk patients who benefit from enhanced screening and/or genetic counseling.

Figure 20-1 Patients with an Elevated Lifetime Risk of Breast Cancer or an Elevated Risk of BRCA Mutation

Patients with an Ele	vated Lifetim	ne Risk of Br	east Cancer C)r an Elevated	Risk of BRCA Mutati	on								
Assessment Date Ass	essment Type	Clinic			Referring Provider Type	Gene Tested	Follow-up Type					Search by name, M	RN, gene, significance or disease	
All Time 👻 🛛 Al	ny 🕶	South Park (5race Hospital an	d 2 more 👻	All 👻	No 👻	High Risk Clinic a	nd 18 more	•					Q
C Refresh														7 Patients
Name 🕈	MRN ¢	DOB	Last Assessm	Assessment T	Lifetime Risk 🕈	Mutation Risk 🕈	NCCN	Genes	Disease Hx	Ref Provider 🕈	Clinic 🕈	Followup	Quick Actions	
TestFutureCE4166, Myra	99901092101	09/23/1970		Cancer Screening	TC7 67.35%		Yes		Atypical Hyperp		South Par.		∥⊿ % (? (? 🖪 ⊙	
TestFMH, Brittany	10041801	09/23/1970	10/4/2018	Cancer Screening	TC7 33%						South Par.	7/2/2019 (MR scheduled)	🛷 🗹 🐮 🚱 📿 🗟 ອ	
TestBreastRisk, Alexandra	99901241901	09/23/1970	1/24/2019	Cancer Screening	TC7 20.09%	BRCAPro 19.2%	Yes				South Par.		∥⊿ # 0: Q ⊡ ⊙	
TestSelfReportAHLCISGT,	99902042002	09/23/1970	2/4/2020	Cancer Genetics	TC7 40.32%				Atypical Hyperp		Stars Holl.		# 🗹 ∺ 🚱 🔾 🗟 🔿	
TestBreastRisk, Theresa	99903202001	09/23/1970	3/20/2020	Cancer Genetics	TC7 28.19%						Stars Holl.		∥2 % (0 ⊑ ⊙	
TestSSMHC, Felizia Mobile	99904042001	09/23/1970	4/16/2020	Cancer Screening	TC8 35.36%	BRCAPro 32,48%	Yes				South Par.		∲ZX CQ Q B ⊙	
TestCE3853, Jasmine Clip	99911142001	09/23/1970	11/13/2020	Cancer Screening	TC8 23.13%		Yes				South Par.		∥⊿ ೫ 🚱 🖓 🖪 ⊙	

Quick Actions for high-risk patients



Once a patient is placed on either high-risk queue for breast cancer, staff can begin <u>documenting</u> <u>Follow-up actions or events</u>.



CRA v4 also provides navigators with the ability to email patients to elicit their intentions to comply with recommendations. Once the patient responds, a Follow-up action is automatically entered into the patients record. Please contact your CRA Project Manager to configure this

feature.

Filtering by Follow-up actions or events

The most recent follow-up action that nurse navigation staff documents for patients shall appear on high-risk queue.

Staff can filter the high-risk queue based on documented Follow-up actions or events. The screenshot below shows patients on the high-risk queue who are scheduled for MRI. For this subset of patients,

Patients at an El	atients at an Elevated Lifetime Risk of Breast Cancer												
Assessment Date All Time 🔹 C Refresh	Assessment Type	Clinic Azeroth and	4 more 👻	Referring Provider	Type Gene Tested	Follow-up Type MR scheduled 👻					Search by patient name or MRN		Q 2 Patients
Name 🕈	MRN \$	D	OB	Last Assessment A	Assessment Type	Risk Score 🗢	Gene Tested	Last US/MRI	Ref Provider \$	Clinic 🕈	Followup	Quick Actions	
Test, Three	9999999	99903 01/	/01/1972	4/26/2017	Cancer Genetics	TC7 40.75%	No			Multidisciplin.	10/1/2018 (MR scheduled)	* 🛛 🛪 🚱	Q⊠ ₿
TestBreastRisk, UAB2	9990414	42101 09/	/23/1970	4/30/2021	Cancer Genetics	TC8 25.6%	No	4/15/2021 (Schedul		Stars Hollow .	6/1/2021 (MR scheduled)	*Z # 6	Q⊠ 🖪

90



nurse navigation staff can now enter MRI findings when available and document the follow-up as "MRI Completed."

Document follow-up encounters or patient's disposition

Nurse navigators using the CRA's v4 Provider Portal can track whether above average risk patients for breast cancer are complying with enhanced screening or genetic testing recommendations.

Staff can document a follow-up encounter for patients who have been identified as high or moderate risk from queues or when charting the patients record using the Risk Clinic module or when Edit Survey workflow.

The following describes each field in the Follow-up record.

- a. date of the follow-up encounter or event;
- b. the type of interaction. One interaction type, 'HL7 ORM,' is automatically recorded if your workflow includes <u>sharing data with a genetics</u> <u>laboratory partner to</u> <u>generate a test request form;</u>

Date	Who	Туре
08/21/2021		
Disposition	Reason	Email from patient
Will consider	~	Face-to-Face Letter from patient
Comment		Phone Call
		HL7 ORM
		Other

c. the patient's disposition towards a recommendation or an action the patient has taken;





d. the patient's reason or rationale

ute	Who	Туре
02/23/2018		
isposition	Reason	
Made appointment *		*
	Already had ge Already had ris Not interested Not needed Personal reaso Patient wishes Other	way with own oncologist mentic testing sk assessment in risk assessment ns no further contact

When the nurse navigator returns to the queue, she can filter by the follow-up. For instance, she can filter by patients whose disposition is 'Will Consider' and reach out to the patient to determine if a decision was made about the patients care.

20.2 Managing Moderate Lifetime Risk Patients

The moderate risk queue functions the same way as the high-risk queue with one exception: users can indicate whether the patient has dense breasts.

0	Patients at a	a Modera	te Lifetime	e Risk of B									
R	Include rows with:		Exclude:	Cancer Geneti	cs Patients 🕑 Do No	ot Call Patients	🗷 Genetic Testi	ng Patients				Q Search	Clear
•	any reterring physician in office referring physicians												
ś	only	,											
8	Name¢	MRN≎	DOB¢	BC Risk ¢	Last Assessme	Last US/M	US/MRI Sta	Ref Dr. \$	Clinicŧ	Followup¢	Dense Bre	Quick Actions	
	ModeRiskTEST, Ella	201707031	07/01/1970	15.61	7/3/2017 10:15:0	7/27/2017	Awaiting Auth	Jennifer C. Mo	BWH Imaging		0	\$° 🛛 🕷 🕞 🔾	
	LowTestrisk, Cath	201706072	06/01/1952	19.54	7/6/2017 11:00:0			Dr. Marissa B	BWH Imaging			*Z # @ Q	
	TestReportPlus, C	201712201	09/23/1970	15.32	12/20/2017 8:00:				BWH Imaging			*Z # @ Q	
	TestSSBCE1943, J	10081801	09/23/1970	19.75	10/8/2018 8:00:0				BWH Imaging			*Z # @ Q	
	4 Patients											BWH	I Imaging:

Return to Table of Contents

21. BATCH PRINTING

Batch printing is typically deployed in a high volume setting such as women's imaging. The batch list allows staff to select multiple documents that can be downloaded as a single PDF for printing.

21.1 Common Documents

In women's imaging, clients typically place high risk letters for patients or referring providers on the batch list, rather than have these documents come out of the local printer each time a patient completes a risk assessment survey.

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The practice manager at your institution can work with your CRA project manager to decide which documents and when they should appear on the batch list based on your clinic's workflow.

21.2 Put On Hold

The batch queue allows you to put a hold on a specific document from being part of the batch process. For example, you wish to put a hold on a specific patient because her mammography findings have not been finalized or you are awaiting biopsy results.

- 1. Click on the Quick Action icon to mark the document to be 'On Hold'
- 2. See the 'On Hold' column change from No to Yes
- 3. Click on the Quick Action icon again to unmark the document

21.3 Sort, Filter, Then Generate

You can sort your batch print list by a variety of filters

- Assessment date
- Assessment type
- Document type e.g. if you want to print referring provider letters first before printing the patient letters
- Clinic
- Referring provider type e.g. if you want to print in-network referring provider first before out-ofnetwork providers
- Print status

Batch Pr	rint										
Assessment Date Last Week 🕶	Assessment Type Cancer Screening 🕶	Document Type	Clinic Multidisciplinary Breas	st Care Clinic and 2 more 🕶	Referring Provider Type All 🗸	Print Status New 🗸				Search by patient name	or MRN
🖶 Generate Bat	ch Document 🖪 Remove D	ocument 🗆 :	Save a Copy in Patient Re	ecord C Refresh							0 Documents
Select Narr	ne ¢	MRN	¢ DOB	Assessment Date •	Assessment Type ¢	Docume Type \$	ent Referring Provider¢	Clin	Last ic Printe	On d≑ Hold	Quick Actions

- 1. Use filters to establish your desired list of documents that you wish to print in a batch
- 2. Select documents
 - a. Click on individual documents of interest or
 - b. Click on "Select" checkbox to select all 20 documents on the current page (See Figure 21-3)
- 3. Option: Click 'Save a copy in Patient Record'. This will show in the patients <u>document</u> <u>archive list</u> that a document was created.
- 4. Click "Generate Batch Document"
 - a. Recall any documents that have been <u>placed 'On Hold'</u> will be part of your batch document
- 5. A single PDF file will download onto your designated download folder.
- 6. The file name will be 'Batch_document_6_17_2020.PDF'. The date reflects the day you generated the document.



Quick

♨

Actions



Figure 21-3 Selecting All Documents Applies to the Current Page

essment	Date Assessment Type	Document Type		Clinic	Referring Pr	ovider Type Print Status		Search	by patient name or N	VIRN	
Time 🔸	Any 👻	Screening Mammography	PCP Letter 👻	BWH Imaging and 2	emore • All •	New -					
Refresh	Generate Batch Docume	ent 📓 Remove Document 🗔	Save a Copy in Pa	itient Record					43 Doci	uments 🛛 🗤	« 1 2 3)
✓ elect	Name ¢	MRN ¢	DOB	Assessment Date *	Assessment Type ¢	Document Type ¢	Referring Provider ¢	Clinic	Last Printed ¢	On Hold	Quick Actions
•	FestSTRIC, SusanneTab	99909151701	01/25/1970	9/15/2017	Cancer Screening	Screening Mammography i	P	BWH Imaging		No	٩
	festSTRICEdit, Elizabeth	99909151702	01/25/1970	9/18/2017	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٩
-	festTC, Phil	99909271703	09/23/1970	9/27/2017	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٩
	FestTCEditSurvey, AshleyPhil	99909271704	09/23/1970	9/27/2017	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٩
	FestiBIS6, Ashley	99909281701	09/23/1970	9/27/2017	Cancer Screening	Screening Mammography I	P	BWH Imaging		No	٩
2	festReportPlus, Christine	201712201	09/23/1970	12/20/2017	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٩
	festTimeStamp, Kendra	99912221701	09/23/1970	12/22/2017	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٩
	FestiBIS7, Zen1330	01051803	09/23/1975	1/5/2018	Cancer Genetics	Screening Mammography R	P	BWH Risk Clinic		No	٩
2	festTemplate, Hope	99901101801	09/23/1970	1/10/2018	Cancer Genetics	Screening Mammography I	P	BWH Risk Clinic		No	٩
	festFlexSurvey, Genesis	99901231801	09/23/1970	1/23/2018	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٢
	FestHiHiDontCall, Jacqueline	18013001	09/23/1970	1/30/2018	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٩
	FestBreastRisk, April	99902281801	09/23/1970	2/28/2018	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٩
2	festBreastRisk, Erica	99902281803	09/23/1970	2/28/2018	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٩
	festPtPortal, Laura	99905071802	09/23/1970	5/25/2018	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٩
	FestMutQueue, Aubrey	2018070202	09/23/1970	7/2/2018	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٢
	FestMutQueueBrCa45, Justine	2018070201	09/23/1970	7/2/2018	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٩
	festSuperShortBreast, Clare	99909201801	09/23/1970	9/20/2018	Cancer Screening	Screening Mammography I	P	BWH Imaging		No	٩
	FestSuperShortBreast, Destiny	99910051801	09/23/1970	10/5/2018	Cancer Screening	Screening Mammography R	P	BWH Imaging		No	٩
2	FestSSBCE1943, Jasmine	10081801	09/23/1970	10/8/2018	Cancer Screening	Screening Mammography R	P.o.	BWH Imaging		No	٩
	FestFMH, Leah	99910151801	09/23/1970	10/17/2018	Cancer Screening	Screening Mammography I	P	BWH Imaging		No	٩

Note:

The 'Select' check boxes selects all 20 documents on the current page of the queue. It does not select all documents that are in your queue. So, if your queue includes more than 20 documents and you wish to generate a batch document for all documents, you will need to go to the next page and click on the 'Select' check box for each page.

C Refresh 🖨 Generate Batc	h Document 🔋 Remove Document 📋 Save a C	opy in Patient Record			43 Documents 🐭 🕛 1	2 3 + 10
All Time • Any •	Screening Mammography PCP Lett	er 👻 BWH Imaging and 2 more	- All -	New 👻		٩
Assessment Date Assessme	nt Type Document Type	Clinic	Referring Provider Type	Print Status	Search by patient name or MRN	
Batch Print						

Return to Table of Contents



22. GENETIC TESTS QUEUE

The Genetic Tests Queue is a unique list of patients who have at least one genetic test result or a test request form that was electronically delivered to CRA v4 Provider Portal by a telegenetics education program.

Genetic Tests									
Assessment Date Assessment Type	Status	Clinic		Referrin	g Provider Type Appt Provider			Search by name or MRN	
All Time 🔹 🛛 Any 👻	TRF Received and 6 more	South Park Grac	e Hospital and 2	more • All •	All 👻			Name / MRN	Q
C Refresh									15 Tests
Name •	MRN ¢	DOB	Assessment Date ^	Assessment Type	Genetic Tests	Ref Provider 🗢	Clinic 🕈	Appt Provider 🕈	Quick Actions
TestTwoPanels, Autumn	99905142103	09/23/1970	2/1/2016	Cancer Screening	Complete, Preexisting Result (5/.		South Park G	ace Hospital	Z 🗹
TestGeneTestedYES, Rene Screening	99901271901	09/23/1970	1/7/2019	Cancer Screening	Complete (5/14/2021)		South Park G	ace Hospital	X 🗹
Stark, Eddard Ned	201903204	03/01/1980	3/21/2019	Cancer Genetics	Complete (2/4/2020)		Stars Hollow (linic	z c
TestCE2841, Chive	201908241	07/23/1975	8/24/2019	Cancer Screening	Complete (8/25/2019)		South Park G	ace Hospital	X C
TestMedStar, Brenda	99912161901	09/23/1970	2/4/2020	Cancer Genetics	Complete (2/4/2020)		Stars Hollow (Ilinic	X C
TestPending, Sierra	99904302001	09/23/1970	4/30/2020	Cancer Genetics	Pending		Stars Hollow	Ilinic	X C
TestGeneticTestQ, Victoria	99905012001	09/23/1970	5/1/2020	Cancer Genetics	Complete (5/1/2020)		Stars Hollow	Ilinic	X Z
TestQCallback, Autumn	99905112001	09/23/1970	5/11/2020	Cancer Genetics	Complete (5/11/2020)		Stars Hollow	Ilinic	X C
TestATMmutation, Justine	99905142002	09/23/1970	5/14/2020	Cancer Screening	Complete (5/14/2021)		South Park G	ace Hospital	X C
TestFamilial, Johanna CE3815	99908212001	09/23/1970	8/21/2020	Cancer Genetics	Pending and 1 more test	Sweet, Amy	Stars Hollow (Ilinic Roche, Constance A	X C
TestTRFReceived, Jasmine	99904302101	09/23/1970	4/30/2021	Cancer Genetics	Pending		Stars Hollow	Ilinic	X C
TestQPtInformed, Diana	99904302102	09/23/1970	4/30/2021	Cancer Genetics	Complete, Pt Informed (4/30/20		Stars Hollow	Ilinic	X C
TestManyPanels, Christine	99904302103	09/23/1970	4/30/2021	Cancer Screening	Pending and 1 more test		South Park G	ace Hospital	X C
TestTwoPanels, Autumn	99905142103	09/23/1970	5/14/2021	Cancer Screening	Complete (5/14/2021) and 1 mo		South Park G	ace Hospital	X C
TestGeneTestedYES, Rene Screening	99901271901	09/23/1970	5/14/2021	Cancer Screening	Complete (5/14/2021) and 1 mo	F	South Park G	ace Hospital	X C

If a patient has more than one gene panel documented, the 'Genetic Tests' column within the queue will indicate the status of all gene panels. You can hover over the 'Genetic Tests' field to quickly review a history of panels associated with the patient.

TestQPtinformed, Diana	99904302102	09/23/1970	4/30/2021	Cancer Genetics	Complete, Pt Informed (4/30/20	Stars Hollo	w Clinic	ZC
TestManyPanels, Christine	99904302103	09/23/1970	4/30/2021	Cancer Screening	Pending and 1 more test	1	Grace Hospital	z c
TestTwoPanels, Autumn	99905142103	09/23/1970	5/14/2021	Cancer Screening	Complete (5/14/2021) and 1 mor	myRisk V4 Complete (5/14/2021) BBCA1/2 Complete Preevisting Result	Grace Hospital	Z C
TestGeneTestedYES, Rene Screening	99901271901	09/23/1970	5/14/2021	Cancer Screening	Complete (5/14/2021) and 1 mor		Grace Hospital	Z C

22.1 Filtering Genetic Tests Queue

Many of the filters on the Genetic Tests Queue are similar to filters found on the <u>high and moderate risk</u> <u>queues.</u>

One filter that is unique to this queue is the 'Status', which reflects the status of the genetic test described <u>here</u> in this user guide. As CRA expands its connections to telegenetics and/or laboratory information management systems (LIMS), new statuses for genetic tests have been introduced:

- 'TRF Received' indicates CRA received a test request form from the telegenetics education system
- 'Pending w/Lab Results' indicates CRA has received a result (PDF or gene specific data) from the genetic testing company's LIMS



These statuses can be used to filter the Genetic Tests Queue. The screenshot below shows how to quickly find patients who have at least one completed genetic test as part of their patient record.

Genetic Tests										
Assessment Date Assessment Type	Status	Clinic		Referring	Referring Provider Type Appt Provider			Search by name or MRN		
All Time 👻 🛛 Any 💌	dl Time 🔹 🛛 Any 🔹 Complete and 2 more 👻		ospital and 2 mo	re • All •	All 👻		Name /	Name / MRN		
C Refresh	- All								8 Tests	
Name +	TRF Received	DOB	Assessment Date •	Assessment Type	Genetic Tests	Ref Provider	Clinic ¢	Appt Provider	Quick Actions	
TestGeneTestedYES, Rene Screening	Pending	09/23/1970	1/27/2019	Cancer Screening	Complete (11/22/2019)		South Park Grace Hospita		4	
Stark, Eddard Ned	Pending w/Lab Results	03/01/1980	3/21/2019	Cancer Genetics	Complete (2/4/2020)		Stars Hollow Clinic		4	
TestCE2841, Chive	Complete	07/23/1975	8/24/2019	Cancer Screening	Complete (8/25/2019)		South Park Grace Hospita	r -	4	
TestMedStar, Brenda	Complete, Pt Informed	09/23/1970	2/4/2020	Cancer Genetics	Complete (2/4/2020)		Stars Hollow Clinic		4	
TestGeneticTestQ, Victoria	Complete, Preexisting	09/23/1970	5/1/2020	Cancer Genetics	Complete (5/1/2020)		Stars Hollow Clinic		4	
TestQCallback, Autumn	Result	09/23/1970	5/11/2020	Cancer Genetics	Complete (5/11/2020)		Stars Hollow Clinic		2	
TestATMmutation, Justine	Cancelled	09/23/1970	5/14/2020	Cancer Screening	Complete (5/14/2020)		South Park Grace Hospita	1	4	
TestFamilial, Johanna CE3815	99908212001	09/23/1970	8/21/2020	Cancer Genetics	Pending and 1 more tests	Sweet, Amy	Stars Hollow Clinic	Roche, Constance A	4	

23. RISK CLINIC MODULE

To initiate the Risk Clinic module, select the patient appointment and click on the Risk Clinic Icon under the <u>Quick Action icons</u>. The Risk Clinic is typically used by High Risk/Genetic Counselors to enter patient data, build out pedigrees, review risk graphs, record follow up actions or manage documents.

A new window will launch in under 30 seconds that brings you to the pedigree drawing workspace. Wait for the spinning hourglass in the upper left-hand corner of the pedigree workspace for the pedigree components (e.g. Title Box, Legend and Comment box) to complete loading.



If this is the first time the appointment is opened and your patient has not completed a survey in advance, a basic seven-person, three generation pedigree will be displayed.

- CRA v4 prepopulates all relatives a patient must have (e.g. parents, grandparents)
- Your patient will be outlined in Red with an arrow pointing to them



• You can <u>click on the green arrow</u> on the right to reveal patient details (e.g. demographics, disease, genetic testing)

23.1 Navigating Within Risk Clinic

While in the Risk Clinic mode, the patient's name and demographic information is presented in the top navigation banner.



Note: The age of the patient shown in the top navigation banner is based on the date of the appointment, **not** the day you are viewing the record.

Click on the triangle next to the Risk Clinic label in the top banner to navigate within the module.



There are eight dropdown choices within the Risk Clinic module that lead to new views: Pedigree (default view), Cancer Risk Factors, Mutation Risk, Cancer Risk, Recommendations, Documents, Imaging Studies and Followup.

Pedigree	
Risk Factors	
Mutation Risk	
Cancer Risk	
Recommendations	
Documents	
Imaging Studies	
Followup	

The descending order of the dropdowns reflects a typical genetic professional's workflow. However, you can move to any of the views at any point. Both <u>Mutation Risk</u> and the <u>Cancer Risk</u> views will allow you to calculate risk scores for the patient.

23.2 Updating Patient Demographics

You can update patient demographics using the 'Edit Appointment' quick action.

The gender field in CRA v4 refers to the patient's gender assigned at birth. Currently CRA v4 does not have functionality to designate gender identity. Please contact your CRA project manager to discuss risk assessment cases if you have a transgender patient.

23.3 Pedigree Drawing

The pedigree drawing tool begins with a three-generation pedigree. Your patient will be outlined in red with an arrow pointing to him or her. A proband's parents and grandparents can never be deleted from the pedigree.

This document is proprietary and confidential. No part of this document may be disclosed in any manner to a third party without the prior written consent of CRA Health LLC.



If your patient has not completed a <u>Patient Portal</u> or <u>Patient Clipboard</u> survey, you can begin <u>adding</u> <u>family members</u> to build out the pedigree.

If your patient has completed a <u>Patient Portal</u> or <u>Patient Clipboard</u> survey, the information about the family will be pre-populated into the pedigree.

You can begin manipulating the pedigree by using your cursor to highlight family members or <u>lasso</u> a group of relatives for further action.

Hover above each icon across the top to reveal descriptions of pedigree drawing tools that help format and make the pedigree, especially complicated ones, more presentable.

Discuss with your CRA project manager if you would like default pedigree configurations, such as:

- Having all <u>in-laws hidden</u>
- Defining which labels are used and where they are placed around pedigree symbols
- Defining the color annotation used for diseases

Top tool bar overview

The following are brief descriptions of each tool. A series of five-minute training videos are available to see how these tools are used in constructing a new pedigree or organizing an existing pedigree. <u>Click here to view videos</u>.

No need to frame your pedigree

Your pedigree will <u>automatically be framed</u> as a landscape image based on the positions of the title box, legend, comment box, and pedigree width.

Printing your pedigree



Print: You can print a snapshot to your local printer. Since pedigrees can vary widely by family, use your local printer's layout to either print a profile or landscape picture.



Create PDF: Generate a PDF of the pedigree that includes the title box, comment box and legend.



Save the Pedigree Diagram: Click on this button to ensure your changes are being saved when multiple users are accessing the patient record



accessing the patient record at the same time.

The 'Save the Pedigree Diagram' button is also useful when <u>sharing updates with a patient during a</u> <u>telegenetics call</u>.

Organizing your pedigree

Zoom pedigree: The first horizontal bar to the right of the snapshot



button allows you to adjust the sizing of the pedigree by zooming in or out. Click on the button and drag to the right to zoom in or to the left to zoom out.



Do not use your browser's zooming settings as this may cause elements of the pedigree to appear cut off. Use the zoom bar instead to resize your pedigree view.

Vertical Spacing Pedigree: The second horizontal bar allows you to expand the generation lines for the entire pedigree. Click on the button and drag to the right to expand the vertical space between generations or to the left to reduce the vertical space.



Wand: This is an important button to help you clean up or re-organize complicated pedigrees as you create them. The feature allows you to adjust the pedigree layout, spreading apart relatives and generation lines evenly. However, for large pedigrees (>200 family members) that are derived from a <u>CRA survey</u>, you will need to resolve manually.



Center parents over the selected children or **align children under selected parents**, respectively: Draw a lasso around members of the family. Parents will be in the midpoint between children. Or children will evenly distribute themselves underneath their parents.



Layout changes can be undone or redone. These buttons do not undo or redo an action like adding relatives.

Undo: Click the button with the clockwise arrow to undo a previous pedigree layout change



For example, you accidentally moved the mother to the extreme right (below)





Click the "Undo Layout Changes" button to bring the mother back to her original position.



Center the pedigree: Click the button to center the pedigree into the allotted desktop

Re-do: Click the button with the counterclockwise arrow to repeat a pedigree layout change





Make horizontal spacing equal: Lasso a group of relatives in the same generation (e.g. brothers and sisters, then click this button to make spacing among them evenly distributed.



Increase or Decrease horizontal spacing: Lasso a group of relatives in the same generation, then click these buttons to increase or decrease the space between relatives, respectively.



Align relatives vertically or horizontally: Lasso a group of relatives across generations (e.g. grandmother, mother, daughter) or in the same generation (e.g. brother and a sister). Then click on the Align relatives vertically to center relatives are a lign relatives and the same brain and the sam

across generations or Align relatives horizontally to center relatives on the same horizontal line.

Pedigree features





<u>Pedigree settings</u>: Click on this button to reveal pedigree annotations configurations and customize how you want to label your pedigree.



Snap: This button helps you maintain the horizontal position of relatives within a generation. The feature is checked off by default.



Hide In-Laws: Click this box to hide family members that are not related to the proband by blood. If you would like to have this box checked by default for all pedigrees, please contact your CRA Project Manager. Read more about hiding in-laws

here.

o'clock.



indicates who the proband is.

Rotate Proband Symbol: The horizontal bar on the far right end of Pedigree drawing tools allows you to move the position of the triangular icon on the pedigree that

Test.Ju

The default position for the Proband Symbol is in the lower left-hand corner or around 8



Click and drag to the left, and the Proband Symbol will move counterclockwise to about 1 o'clock.

Click and drag to the right and the Proband Symbol will move clockwise.

v4 Automatically frames your pedigree for printing

Pedigrees will automatically be sized to maximum fit onto the page and presented in **landscape**. Users simply click the <u>PDF icon</u> or the <u>printer icon</u> to generate the image.

Notes:

- 1. By exiting the appointment, CRA saves the pedigree snapshot. This image will also be used in the CRA template Survey Summary and <u>Mutation Risk tab</u>.
- 2. If you do not choose to frame and snap the Pedigree, the system will use a default setting that best centers the existing pedigree.

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Add Children

Add Parents

Add Other Delete Person

Adopted Vital status

Fertility

Grouping

Link To Relative Consanguineou≩

Twins

Hide

 \geq

>

>

>

>

>

>

Quick actions: adding/deleting relatives, multiples, grouping, consanguinity

1. Clicking on any individual within the family will result in a red halo



2. Then right click to reveal quick actions that will help you establish demographic information about the relative or construct and organize your pedigree.

-		
Add <u>C</u> hildren	>	1 •
Add Parents		female v
Add Other	>	
Delete Person		Grouped
Adopted	>	Half siblings
Vital status	>	Add
Fertility	>	
Twins	>	
Grouping	>	
Hide	>	
Link To Relativ	ve	
Consanguined	ษษ	

Adding children to create siblings or half-siblings

If you want to add a sibling to a family member, add a son or daughter to the respective parents. (Currently there is no method to add a sister/brother directly from the person of interest.)

- 1. Click on 'Add Children' to see additional menu choices
- Choose the number children. (You can add up to 15 or an "Unknown" number of children)

Add Children	- 1	1	
Add Parents		1	
Add Other	- 5	3	
Delete	•	5	
Adopted	- 1	7	
Vital Status	- 2	8	
Fertility	- 2	10	
Twins	- >	11	
Grouping	5	12 13	
Hide	•	14	
Link To Relative		unknown	
Consanguineous			

- 3. Decide if you wish to group if >1 child
- 4. Decide if you wish to make child a half-sibling
- 5. Click 'Add'

102



Adoption status

You can define any relative as adopted in or adopted out. Clear the adoptions status by selecting 'Not adopted.'



0

Half siblings

Select the appropriate parent (outlined in red) to whom you want to add children.

For example, if you are adding a maternal half sibling, select the proband's mother (if adding paternal half sibling, then select the father).

Review how to "Add Children" from the previous section.

Use the dropdowns to choose:

- the number of half-siblings, if more than one
- gender of the half siblings
- whether you want to group half-siblings, if more than one

Click on "Add"

If you need to add more half siblings after the fact, as a best practice, select the 'other parent'. The screenshot on the right indicates the other parent is the mother's other male partner.

Now add as full siblings to the patient's existing half sibling.

If you check off "Half Siblings" while selecting the 'other parent', you will create another female partner and a non-blood relative to the proband.





If a parent has multiple partners, you can always add additional children by '<u>lassoing</u>' the father and mother of interest and add children as full siblings. The screenshot on the left shows a mother of the proband with three partners: father, partner 2, partner 3. To add a half sibling with partner 3, lasso the mother and partner 3 (colored blue) then add children.

103



"Lasso" family members ...

Many of the actions that affect a group of family members require you to lasso the individuals first. The lasso function is a click and drag function.

- 1. Click on an open space near the group of individuals you want to act on.
- 2. Then drag a circle around the group of individuals.
- 3. When you unclick, the group of interest will turn a shade of blue.

...to create twins

For example, to create twins, lasso two children on your pedigree. Both children in the pedigree will become shaded blue. However, if their pedigree symbol is already shaded, you will not see the blue hue. Right click on either child and see the choice 'Twins'. The > symbol opens more actions and allows you to specify fraternal or identical twins.

...to define a consanguineous relationship







3. The couple relationship line is now a double line



...to group siblings

You can group unaffected siblings of the same gender that have demographic details entered such as name, age or free-text comment. The grouping will hide all the member's demographic details. You cannot group affected and unaffected siblings or siblings of different genders.

Tips for organizing pedigrees



Use the <u>organize wand</u> after every three or four actions as you construct a complicated pedigree or as you organize an existing pedigree. For best results, use the wand button after each time you add a family member.

Hiding in-laws



You may choose to hide all in-laws (non-blood relatives) on the pedigree by checking the box or have this checked by default as part of your <u>system configuration</u>. Even if you use the <u>organize wand</u>, in-laws shall remain hidden.

When you construct a pedigree from scratch, the <u>hide in-laws' checkbox</u> will not hide the parent of a half-sibling that is NOT related to the family. The screenshot below shows the mother's partners and the patient's half siblings from each of those partners.







Pedigree settings

You can change pedigree labels and their positions for any given pedigree. You can also hide borders around title box, legend and comment box.

😝 🔯 🕼 🕼 💷 💶 💶 💷 💷 👘 🖏 🕼 🕼 🖓 🛛 😕 🥂 👘 🎊 👷 👘 🎊 🖓 🖓 🕹 🖓 🖓 🕹 👘 🖓		
	< ☆ \$# 1 ♥ ♥ ♥ ₩ ₩ ₩ ₩ ₩ ▲	👖 🎲 👌 🗛 🖕 🖾 Snap 🗖 Hide In-Laws 🧰 🔲

Click on the gearbox icon found at the top navigation bar.

A new pop up will appear (next page).



Pedigree Settings	
 Show title box border Show legend box border Show comment box border Show comment box 	8.25Title box name font size8.25Title box MRN and DOB font size8Legend box font size10Comment box font size10Pedigree annotation font size
Variable Accession # Age Brca Score Comment Date Of Birth Disease List Dx + Comment Ethnicity First Name Last Name MMR Score Name and Age Heritage Panel Name Relationship Test Result	Area Order not shown on pedigree ▼ 0 ▼ lower list 1 ▼ not shown on pedigree ▼ 0 ▼ lower list ▼ not shown on pedigree ▼ 0 ▼ not shown on pedigree ▼ 0 ▼ lower list ▼ not shown on pedigree ▼ 0 ▼ lower list ▼ not shown on pedigree ▼ 0 ▼ lower list ▼ not shown on pedigree ▼ 0 ▼ lower list ▼ not shown on pedigree ▼ 0 ▼ lower list ▼ not shown on pedigree ▼ 0 ▼ lower list ▼
Variant	Done



Contact your CRA Project Manager if you would like to have default pedigree settings established for all pedigrees in your database. You can always change the settings on individual pedigrees as needed.

23.4 Pedigree examples

"Floating" cousin, niece/nephew

On occasion, you may see an unattached relative on your pedigree. This occurs in two ways: when a patient has completed a CRA mobile survey and indicated she had an affected cousin, niece/nephew or when a colleague in women's imaging added a relative through the Edit Survey feature.

107



Figure 23-4 Floating or unattached cousin

		🍾 🔒 FHx - Cousin (Fe	male)	
TestBreastRisk, Emma	1	Details Diseases	Genetic Testing	
MRN: 99907172001 DOB: 09/23/1970	Col - Colon or Rectal Cancer 🕙 Br - Breast Cancer	First Name	Middle Name	Last Name
		Title	Maiden	Suffix
		Age	Gender	Vital Status
		Comments		
	Col 57 Br 56	Adopted	Adopted I	FHx known
Created by web session	49 TestBrea	Date of Birth	Confidence	Update Age
		Date of Death	Confidence	Cause of Death
		City	State	Zip Code
		🗸 Ashkenazi	Hispanic	

You will need to connect the relative to the correct bloodline by using the 'Link To Relative' feature.

Currently only one CRA survey- 'Patient Portal Form'- allows a patient to link cousins, nieces/nephews to the correct bloodline. However, this survey is not designed for mobile devices and must be completed on a laptop or desktop. <u>Review Table 13-2 to learn more</u>.

Family tested for same gene but found different variants

Review the pedigree on the right for a case in which members of a family had the same gene tested but resulted in different variants. The pedigree shows a proband who does not carry the familial CHEK2 mutation but does carry a VUS in the CHEK2 gene. Results on the pedigree say 'VUS' and '-' for the proband. For the relative, who had the CHEK2 mutation, the pedigree test results show a '-' for the VUS and '+' for the mutation.



Return to Table of Contents


23.5 Family History Details

Add information about the proband or a family member

Click on the family member of interest. The family member will have a red halo around their pedigree symbol when selected.



Then click on the icon on the far-right side of the pedigree desktop to expand and reveal additional information.

Comment Comment Concert Ov-Ovarian Cancer			\sim
Comment Br 63 Tests Br 50 Det 55 Br 62		🖤 Oth - Other 🍼 Br - Breast Cancer 🍞 Ov - Ovarian Cancer	- (
Comment Br 63 46 Br 50 Teestope Br 62 out see			
	Comment	Br 63 H 6 Br 50 TestSupe Oth 55	÷

At the top of the expanded Details form will be a label indicating the relationship to the patient.



If the relative's <u>name is entered</u>, the relationship label will switch to the first name.

🔈 💄 FHx - I	Noni			
Details	Diseases	Genetic Testing		
First Name		Middle Name	Last Name	^
Noni				

109



Demographic details

Follow the above steps to reveal the form that allows you to add demographic details.

The 'Details' subtab is the default view. Demographic details about a family member, if known, can be entered, including

- Name
- Age
- Gender
- Vital status
- Comments about the relative
- Adoption: adopted in or adopted out
- Date of Birth
- Date of Death
- Cause of Death
- City, state or zip code
- Ethnicity
- Race
- Nationality/Ancestry

The figure below indicates demographic details for the patient's Grandmother. Use the vertical scroll bar on the right and scroll down to show all the fields.

Details Diseases	Genetic Testing	
First Name	Middle Name	Last Name
Title	Maiden	Suffix
Age	Gender	Vital Status
Comments	Female	· · · ·

Current Age

Enter the relative's age in the 'Age' field.



CRA v4 can calculate current age if needed.

- 1. Vital Status field must be 'Alive'
- 2. Enter date of birth
- 3. Click on "Update Age" button
- 4. The age will calculate based on date of birth and the appointment date

Age of death

If you do not know the relative's date of birth and date of death, you can:

- 1. Mark vital status as 'Dead'
- 2. Enter age of death in the 'Age' field

Details Disea:	ses Genetic Testing	g
First Name	Middle Name	Last Name
Title	Maiden	Suffix
Age	Gender	Vital Status
79	Male	Dead 🗸

111

For a deceased relative, you can enter both date of birth and date of death (DOD) and click on 'Update age'. The age at death will automatically calculate and display in the age field and on the pedigree. The screenshot below shows the patient's sister was 52 at the time of death based on her DOB and DOD.

· · · · · · · · · · · · · · · · · · ·	📀 💄 FHx - Sister		
	Details Diseases	Genetic Testing	
)	litle	Maiden	Suttix
	Age	Gender	Vital Status
	52	Female 🗸	Dead 🗸
	Comments		
	green		
	Adopted	Adopted FF	łx known
		◄	~
	Date of Birth	Confidence	
FO red F3 blue	03/30/1969	~	Update Age
TestOrde green	Date of Death	Confidence	Cause of Death
Other -	05/28/2021	~	~



Ethnicity, race, nationality/ancestry

You will see fields for ethnicity, race, nationality/ancestry near the bottom of the details form. The combination of these fields <u>can be displayed in the pedigree if you wish</u>.



<u>Gender</u>

Sometimes a family member's gender is reported or entered incorrectly. You can change the gender for both the patient and all family members except core family such as the patient's parents and both set of grandparents.

You can even change the gender of multiple family members at once if they are already <u>grouped</u>. The screenshot below shows a group of three sisters and the details form. Note that only the gender field is editable while other demographic fields are disabled.



112



You can change the gender of the patient through the pedigree Details form or using <u>Edit Appointment</u> form.

Diseases, procedures

Follow the previous instructions to reveal the details form that allows you to add one or more diseases.

Note: CRA v4 also allows clinicians to add procedures, including those that impact risk scores.

Click on the subtab 'Diseases' to see a new view.

Adding a disease/procedure

- 1. You can click 'Add New Disease' and a new row will form.
- Start typing the disease of interest. As you type the letters of your disease, any diseases with the same set of letters will appear in the dropdown list. See <u>Figure 21-4.1</u> to see what appears if you type 'bre'.
- 3. Click on the dropdown to choose from the list of diseases.
- 4. Add age of diagnosis for the disease.
- 5. Add comments about the disease.
 - a. If your comment is very long, use a comma to create a line break that will appear on the pedigree. See <u>Figure 21-4.2</u> to see the difference between a comment that uses a line break and one that does not.
 - b. Simply adding a comment is not sufficient to incorporate relevant data into risk models. Please review the section on <u>breast cancer triple-negative</u> and <u>MSI/IHC</u> results
- 6. Click on
 - a. ..the edit icon to add details to breast, uterine or colon cancer diagnoses.



As of this release, the edit icon is only unique to these three conditions. Other diseases will not have an additional details form.

b. ...the X icon to delete a disease if you've made a mistake.

Details Diseas	ses Genet	ic Testing			
Name:		Age:	Relation:	Grandmother	
Breast/Ovarian		• Add N	lew Disease		
Disease	Age	Comments	()		
Breast Cancer	• 45			⊘ ×	
4				•	

The screenshot to the left shows a grandmother who has breast cancer diagnosed at age 45.



Figure 23-5.1 Drop down choices when user types 'bre'

Details Di	seases	Genetic Testing			
ame: TestBrea	astRisk, The	eresa CE3436	Age: 49	Relation:	Self
Add New D	isease				
lisease		Age	Comments		
bre					×
Benign breas	t condition				
Breast (cytolo	gic atypia)			
Breast Cance	r				
Breast Cance	r (DCIS w	ith microinvasion)			
Breast Cancer (DCIS with suspicion of invasion)					
Breast Cance	r (DCIS)				
Breast Cance	r (Invasive	e Ductal)			
Breast Cance	r (Invasive	<i>.</i>		-	

Figure 23-5.2 Using a comma to break up a disease comment for pedigree display





Breast cancer

CRA v4 does not track recurrence of breast cancer. If you enter second breast cancer diagnosis, CRA v4 assumes this is a second primary cancer.

You can enter and track breast cancer details by clicking on the edit icon.

e			Month Diag	tnosis	Year Diagno	osis			
		~		*		*			
Summary of Def	initive Sur	gery-							
Month Year		Breast			Axillary			Reconstruction	
v	~			~			~		
ER	~ % Ir	tensity	~	PR		95	Intensity	~	
			~			•		~	
mments									



You can enter as much details as you want for tracking or reporting purposes.

Under pathology, you can select a type of invasive breast cancer (ductal, lobular, etc.). As an alternative, you can select <u>specific breast cancer types from</u> <u>the disease dropdown</u>. E.g. 'Breast Cancer (invasive ductal)'

Receptor status

You should switch ER/PR/HER2 to "Negative," to indicate triple negative breast cancer which will be used in model calculation.

As an alternative, you can select '<u>Breast Cancer (triple-negative</u>)' from the disease drop down and the receptor status will be pre-set for you.

If you add comments using the Breast Cancer Details form, they will appear in the disease summary as well.

Breast cancer (triple negative)

If you choose from the disease dropdown 'Breast Cancer (triple-negative)', CRA v4 will automatically enter negative receptor status and addend the comment box with '-/-/-'. If you click on the <u>breast cancer details</u>, you will NOT be able to change the receptor status.

Add New Disease		
isease	Age	Comments
BRea		
Breast Cancer (DCIS)		•
Breast Cancer (Invasiv	e Ductal)	
Breast Cancer (Invasiv	e)	
reast Cancer (Lobula	r)	
reast Cancer (Medull	ary)	
Breast Cancer (Triple)	legative)	
Breast Cancer (Tubula	r)	
Isual Breast Hynernia	sia	-



Colon cancer

You can find various colon cancer outcomes by typing 'C-o-I'.

Add New Disease		
Disease	Age	Comments
col		
Adenomatous Colon Po	lyps 100 or mo	re 🔺
Adenomatous Colon Po	lyps 10-100	
Colon Cancer		
Colon or Rectal Cancer		
Colon Polyp Adenomate	ous	
Colon Polyp Hamartom	atous	
Colon Polyp Inflammate	ory	
Colon Polyn Villous		~

MSI/IHC results

Click on disease details to enter additional information about colon cancer.

Colon Cancer	
Month Diagnosis Year Diagno	sis
~	v
MSI	IHC
~	~
BRAF V600E	MLH1 Promoter Methylation Location
~	· · · ·
Comments	
	Close

MSI and/or IHC must be entered as outlined below for the data to be integrated properly in the risk models⁸. This function is currently only available for colon and uterine cancer.

Colon polyps

There are two ways to describe colon polyps:

- You can choose a disease that includes the count such as '...Polyps 10-100' or '...Polyps 100 or more.' The advantage of using this disease is that poly count will appear in the CRA documentation such as the survey summary.
- 2. You can choose disease 'Colon Polyp...' then add the polyp count as a comment. See Figure 21-4.3 describes what a patient with 60 polyp count may look like on the pedigree and survey summary.

⁸ Sining Chen et. al. JAMA. 2006 Sep 27; 296(12): 1479–1487. doi: 10.1001/jama.296.12.1479 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2538673/

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Figure 23-5.3 Pedigree and survey summary view of two family members with polyp count

	Details Diseases	Genetic Testing	
egend	Name:	Age: Relation: Mother	
Polyp-Adm - Colon Polyp PolypAC10+ - Adenomatous Colon Polyps 10-100	Add New Disease		
	Colon Polyp Adenor	Age Comments	
	F	MILY HISTORY	
JlypAC10+ 52 Polyp-Adm 52 60	M	other Colon Polyp Adenomatous age 5 ather Adenomatous Colon Polyps 10-	;2 100 age 5
49 TestBrea			

S . FHx - Mother

Endometrial cancer

As of this release, the disease list does not include 'Endometrial Cancer.' Clinicians can enter 'Uterine Cancer' instead.

Endo			×
Endocarditis			
Endocrine Cancer			
Neuroendocrine Cancer			

Hyperplasia

CRA surveys allow <u>patients to self-report biopsy results as atypical hyperplasia or lobular carcinoma in</u> <u>situ (LCIS)</u>. However, pathology findings may be more specific. You can enter specific types of hyperplasia such as 'Atypical Lobular Hyperplasia' or 'Usual Breast Hyperplasia.'

Add New Disease			
Disease	Age	Comments	
hyperplasia			
Atypical Ductal Hyperpl	asia		
Atypical Hyperplasia			
Atypical Lobular Hyperp	lasia		
Ductal Hyperplasia (no	atypia)		
Usual Breast Hyperplas	ia		



Additionally, you can enter 'benign breast disease' as a disease option. See Figure 21.4-1.

Review CRA's guidance on which breast cancer risk assessment models use benign pathologies. Go to the References section on the <u>CRA help page</u>.

Prostate cancer

Prostate cancer types that impact NCCN hereditary breast/ovarian testing guidelines are available as drop-downs:

- prostate cancer (metastatic)
- prostate cancer aggressive (Gleason score >7)
- prostate cancer (intraductal)
- prostate cancer (cribriform histology)
- prostate cancer (high-risk group)
- prostate cancer (very-highrisk group)

Add New Disease						
Disease	Age	Comments				
prost						
Prostate Cancer						
Prostate Cancer (Cribrif	orm Histology)					
Prostate Cancer (High-F	Risk Group)					
Prostate Cancer (Intradu	uctal)					
Prostate Cancer (Metastatic)						
Prostate Cancer (Very-High-Risk Group)						
Prostate Cancer Aggres	sive (Gleason	score >= 7)				

As NCCN HBOC testing guidelines change, relevant diseases will be added.

<u>Unknown cancer</u>

Patients may not know cancer health history of family members. You can still enter a disease using 'Unknown Cancer.'



🔊 💄 FHx -	Grandfather				
Details	Diseases	Genetic Te	sting		
Name:			Age:	Relation:	Grandfather
Add New I	Disease		- · ·		
Cancer - u	inknown ty	Age	Comments		×
unk					×
Unknown	Cancer	í			
Unknown (Unknown [Unknown [Unknown Unknown	Clotting Disorder Diabetes Disease Gastrointestinal D Heart Disease Gidney Disease	isorder			
•					

Uterine cancer

If patients are completing a CRA v4 survey at home or in clinic prior to seeing the provider, they have the option of entering 'Uterine Cancer.'

Click on disease details to enter additional information about uterine cancer.

	Î.	🔈 💄 FHx - I	Mother				
		Details	Diseases	Genetic Te	esting		
		Name:			Age:	Relation: Moth	er
Legend		Add New I	Disease				
Ute - Uterine Cancer	÷	Disease Uterine C	ancer	Age 45	Comments		⊘×
Ute 45 Ute 45 Ute 45 TEST, Li							



MSI/IHC results

Colon Cancer	
Month Diagnosis Year Diagno	sis
✓	v
MSI	IHC
~	~
BRAF V600E	MLH1 Promoter Methylation Location
~	v v
Comments	
	Close

MSI and/or IHC must be entered as outlined below for the data to be integrated properly in the risk models⁹. This function is currently only available for colon and uterine cancer.

23.6 Genetic Testing

Genetic test results can be added to the patient or a family member.

Follow the steps for <u>'Add information about the proband or a family member'</u> to reveal the details form.

Click on the subtab for "Genetic Testing". The choice will be underlined with a black strip and the elements that describe genetic testing results will appear, including column headings for panel of interest and the result or finding.



The v4 system allows you to enter more than one gene panel for any given patient or relative.

Minimal steps are needed for a genetic test result to be assessed by risk models.

⁹ Sining Chen et. al. JAMA. 2006 Sep 27; 296(12): 1479–1487. doi: 10.1001/jama.296.12.1479 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2538673/

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 choose your lab of interest. Generic single site or multi-gene panels that are not affiliated with a specific lab will fall under the 'Other' category;



- 2. click on the green button, 'Add New Genetic Test';
- 3. search by typing in a few letters of the panel
- 4. select a panel from the dropdown list;

Name: Age: Relation: Mother Breast/Ovarian Add New Genetic Test Choose A Panel Choose A Panel Obligate Familial Mutation Other p16 Sequencing & Deletion/Duplication P53 Deletion/Duplication p53 Full Gene Sequencing p53 Sequencing & Deletion/Duplication Pop Health Screen v1 (59 genes)	Details	Diseases	Genetic T	esting			
Breast/Ovarian Add New Genetic Test Choose A Panel Image: Choose A Panel Obligate Familial Mutation Image: Choose A Panel Obligate Familial Mutation Image: Choose A Panel Other Image: P16 Sequencing & Deletion/Duplication P53 Deletion/Duplication Image: P53 Full Gene Sequencing & Deletion/Duplication P53 Sequencing & Deletion/Duplication Image: Pop Health Screen v1 (59 genes)	Name:			Age:	Relation:	Mother	
Choose A Panel Choose A Pan	Breast/C)varian	~	Add Nev	w Genetic Test		
Obligate Familial Mutation Other p16 Sequencing & Deletion/Duplication P53 Deletion/Duplication p53 Full Gene Sequencing p53 Sequencing & Deletion/Duplication Pop Health Screen v1 (59 genes) Total Sequencing Total Sequencing<td>Choose A</td><td>Panel</td><td>•</td><td></td><td></td><td></td><td>×</td>	Choose A	Panel	•				×
Other p16 Sequencing & Deletion/Duplication P53 Deletion/Duplication p53 Full Gene Sequencing p53 Sequencing & Deletion/Duplication Pop Health Screen v1 (59 genes)	Obligate	- Familial Mutati	on				•
p16 Sequencing & Deletion/Duplication P53 Deletion/Duplication p53 Full Gene Sequencing p53 Sequencing & Deletion/Duplication Pop Health Screen v1 (59 genes) T	Other						
P53 Deletion/Duplication p53 Full Gene Sequencing p53 Sequencing & Deletion/Duplication Pop Health Screen v1 (59 genes)	p16 Sec	uencing & Dele	tion/Duplicatio	n			
p53 Full Gene Sequencing p53 Sequencing & Deletion/Duplication Pop Health Screen v1 (59 genes)	P53 Del	etion/Duplicatio	n				
p53 Sequencing & Deletion/Duplication Pop Health Screen v1 (59 genes)	p53 Full	Gene Sequenci	ng				
Pop Health Screen v1 (59 genes)	p53 Sec	uencing & Dele	tion/Duplicatio	n			
	Pop Hea	alth Screen v1 (5	i9 genes)				Ŧ

- a. the summary field will immediately indicate the results are 'Pending'
- 5. click the 'Edit' button;
- 6. the Genetic Testing form appears;
- click on button 'Set All Negative' for expediency. The 'Status' dropdown will be automatically be marked as 'Complete';
 - a. at this point you can stop here if the laboratory does not report any significant variants

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- b. on the pedigree, a shortened version of the panel name will appear with a negative sign.
 You can determine where the gene panel name appears on the pedigree by <u>changing</u> the label positions.
- 8. If a significant finding was reported by the laboratory,
 - a. scroll down to the gene of interest;
 - b. choose the finding under the 'Significance' dropdown;
 - c. enter at a minimum, the DNA change. If DNA change is unknown, you can enter free text 'Unknown'
 - d. Click 'Save and Close' to exit out of the form
- 9. If no significant finding was reported by the laboratory, click 'Save and Close'

If no DNA or AA change is entered for a significant finding, the Pedigree will still display a symbol that a variant was identified. However, you will not be able to add a Familial Known Mutation test for another relative.

You can also start the documentation of genetic test results by first choosing the appropriate 'Status'. If you choose 'Complete', 'Complete, Pt Informed', or 'Complete, Preexisting Result', the significance for each gene in the panel will be set to 'Negative'.

Figure 23-6 Defining status of genetic test

Genetic Testing				Save And Close
Panel myCode GSC v2		Month	Day Year	~ 🛗
Accession Comments	Status Pending Pending Pending Pending Pending Pending Pending Complete Com	~	Lab Result Status N/A	Lab Result Significance N/A
	Complete, Preexisting Result Cancered		Set All Negative	Add New Result

If a significant result is found, you will need to update this for the affected gene.

Adding a gene into existing panel

If the list of genes is incomplete, you can add additional genes as needed.

In the Genetic Testing form,

- 1. click on 'Add New Result';
- 2. Scroll to the bottom of the form to see a new row with no gene name

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Gene	DNA Change	AA Change		Significance	Allelic State	Comments
PMS2	\$	\$	*	*	*	
						×
Gene	DNA Change	AA Change		Significance	Allelic State	Comments
PTEN	\$	\$	\$	\$	\$	
						×
Gene	DNA Change	AA Change		Significance	Allelic State	Comments
RAD50	\$	\$	*	*	\$	
						*
Gene	DNA Change	AA Change		Significance	Allelic State	Comments
RAD51C	\$	\$	*	\$	\$	
						*
Gene	DNA Change	AA Change		Significance	Allelic State	Comments
RAD51D	\$	\$	\$	\$	\$	
						×
Gene	DNA Change	AA Change		Significance	Allelic State	Comments
SMARCA4	\$	\$	*	\$	*	
						×
Gene	DNA Change	AA Change		Significance	Allelic State	Comments
STK11	\$	\$	*	\$	\$	
Gene	DNA Change	AA Change		Significance	Allelic State	Comments
TP53	\$	\$	*	÷	\$	
Gene	DNA Change	AA Change		Significance	Allelic State	Comments
	\$	\$ ye	\$	\$	\$	
				*		

- 3. Choose from the dropdown list or enter a gene symbol;
- 4. If significance has not been set along with other genes, set the significance

'Other' panel

Use the 'Other' gene panel when you have limited panel information but want to enter results of a genetic test.

	invitae Breast/Gyn Guideline vz (19 genes)	
	Invitae Breast and Gyn Cancer Guidelines Panel V2 + Prelim Evidence Genes (20 genes)	
	Invitae CNS V2 (25 genes)	
	Invitae Common Hereditary Cancers Panel V4 (47 genes)	
	Invitae Custom Panel V4 (128 genes)	
	Invitae Experience Panel V1 (28 genes)	
	Invitae Hereditary Prostate V2 (12 genes)	
	Invitae High Risk Breast V3 (9 genes)	
	Invitae Melanoma V2 (9 genes)	
	Invitae Multi-Cancer Panel V4 (83 genes)	
	Obligate Familial Mutation	
Ì	Other	
	nue Sequencing & Deletion/Duplication	
	pro Sequencing & Selection/Duplication	
	PSS Deletion Displication	
	pos rui delle sequencing	
	pss sequencing & Deletion/Duplication	
	PTEN Deletion/Duplication	
	PTEN Full Gene Sequencing	
	PTEN Sequencing & Deletion/Duplication	
	Uwash BROCA V8 (70 genes)	-

123



My patient's maternal aunt tested positive for a BRCA 2 mutation, with a variant of unknown significance in the BRCA 1 gene. I don't have a copy of results so I can't enter – not sure what lab she tested with. How do I enter that info?

Genetic Te	esting					Save And Close
anel				Month	Day Year	-
)ther				~	~	~ 📖
ccession			Status		Lab Result Status	Lab Result
			Complete	*	N/A	Significance
omments naternal aunt teste	ed positive fo	or a BRCA 2 mutation, v	vith a variant of unknown sign	ificance in the BRCA 1 gene. I don	t have a copy of results so I c	an't enter – not sure what lab
omments naternal aunt teste he tested with	ed positive fo	or a BRCA 2 mutation, v	vith a variant of unknown sign	ifficance in the BRCA 1 gene. I don	t have a copy of results so I c	an't enter – not sure what lab
omments haternal aunt teste he tested with	ed positive fo	or a BRCA 2 mutation, v	vith a variant of unknown sign	ificance in the BRCA 1 gene. I don	t have a copy of results so I c	an't enter – not sure what lab Add New Resu
omments naternal aunt teste he tested with Gene	ed positive fo	DNA Change	AA Change	Significance	t have a copy of results so I construction of the source o	an't enter – not sure what lab Add New Resu Comments
Gene BRCA1	ed positive fo	DNA Change	AA Change	ificance in the BRCA 1 gene. I don Significance	t have a copy of results so I constraints of the second seco	Add New Resu Comments
Gene Gene Gene	ed positive fo	DNA Change DNA Change	AA Change	ificance in the BRCA 1 gene. I don Significance VUS	t have a copy of results so I constraints of the set All Negative Allelic State	Add New Resu Add New Resu Comments Comments Comments

		Details Diseases Get Name: Contract of the second sec	netic Testing Age: Relation: Aunt
TestBreastRisk, Brianna MRN: 99906242001 DOB: 09/23/1970	Legend Family Genetic Testing Results BRCA1 unknown VUS BRCA2 unknown Pathogenic	Breast/Ovarian Panel	Add New Genetic Test Result
Created by web session	Vus vus vus vus vus vus vus vus vus vus v	Other 🗸	BRCA1 VUS; BRCA2 Pathogen

Keeping up with the gene panels

CRA Health strives to maintain the most current gene panels; however, currently, we do rely at the community at large.



Each gene panel name is annotated by a CRA version number along with the number of genes in the panel.

Older gene panel names are given a version number and can be found at the bottom of the gene panel dropdown list.

Return to beginning of Risk Clinic Module

Return to Table of Contents



23.7 Cancer Risk Factors

You can enter or edit your patient's personal health history along with common risk factors or procedures. See Edit Survey section, under <u>Cancer Risk Factors</u> for a description.

Important note: The data described on this form represents common risk factors collected by a health questionnaire, whether it is a disease or procedure that impacts a risk model. More specific disease types can be documented using the pedigree tool. Examples include:

- <u>Hyperplasia type</u>
- Prostate cancer, including metastatic, intraductal, high Gleason score

23.8 Mutation Risk

The Mutation Risk view allows you to view the pedigree in a static form, run or re-run risk models, and view results.



Selecting **Run Risk Models** (upper right-hand corner) will process <u>all the risk models</u> available in CRA Health v4 (including <u>lifetime breast cancer models</u>).

126



The "Risk and Recommendations" view is expanded by default. If you wish to review a snapshot of your pedigree, you can collapse the Risk & Recommendation view by clicking on the green arrow next to the checkbox.

TestSuperShortbreast, Elizabeth Moit: 5992153781 Dit: Other ● Dit: ● Dit	E Kun Kisk Models
D08: 69/23/1970 Breast/Ovarian Colon/Endometrial Risk of BRCA1 or BRCA2 Mutation BRCAPro 18,75% Myriad 3,05% Tyrer-Cuzick 6 5,9% Tyrer-Cuzick 7 6,25% NCCN Colon/Endometrial Percommendations & Results Description Description Description	
2% 21% 21% 21% Percommendations & Results Percommendations & Results	
2% 21% 21% 21% Percommendations & Results Percommendations & Results	
2% 2% 21% 21% Percompositions & Decuts	
2% 2% 21% 21% 21% Proceedings Proceedings Proceedings Proceedings	
2% 2% 21% 21% Percommendations & Percuts	
2% 2% 21% 21% Provide the second sec	
Genetic Testing Recommendation	
456 456	T
Breast Density Considerations	
	T

"Risk and Recommendations" details

The expanded view presents two sub tabs: Breast/Ovarian and Colon/Endometrial.

- 1. **Breast/Ovarian** is the default view that displays:
 - a. The proband's BRCA1 or BRCA2 mutation risk results. CRA v4 uses a default threshold of >=10% as high mutation risk. However, <u>you can change this threshold</u> if you wish.



You can quickly determine if your patient meets NCCN guidelines for HBOC testing. If 'Yes', click on the green circle to review what criteria was met. <u>See Figure 21-7</u>;

🖂 Risk & Rec	ommendations
Breast/Ovarian	Colon/Endometrial
Risk of BRCA1 or	BRCA2 Mutation
BRCAPro	4.30%
Myriad	1.50%
Tyrer-Cuzick 6	4.65%
Tyrer-Cuzick 7	2.49%
Tyrer-Cuzick 8	2 600
NCCN	Yes 🔕
Genetic Tecting De	♥
Relatives to Cons	ider Testing
The patient's relat	ives not susceptible to the Risk

- b. "Recommendations and Results" allows you to document the provider's genetic testing recommendations, breast density considerations and genetic testing results, all of which are linked to existing Risk Clinic templates;
- c. "Relatives to Consider Testing", if any, will be displayed based on BRCAPro results. The list is sorted in descending order based on relatives that would most benefit most from genetic testing. Scroll down if necessary, to see a complete list of affected relatives.

If no relatives of the patient benefit from genetic testing, the following message will appear:

100000000	isider resultig			
The patient's rel	atives not susce	eptible to the	Risk	

2. **Colon/Endometrial** displays the risk of MMR Mutation results using two models. The CRA Health system uses a default threshold of >=5% as high risk for Lynch Syndrome.

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🛛 🗹 🛛 Risk & Reco	nmendations
Breast/Ovarian	Colon/Endometrial
Risk of MMR Mut	ation
MMRPro	0.1%
PREMM2	1.1%
Genetic Testing Recommend	ation v
Genetic Testing Results	
	Ŧ
Relatives to Cons	sider Testing
The patient's relatives not s	usceptible to the Risk

Meeting NCCN HBOC v1.2020 guidelines

The screenshot below reveals a patient that meets multiple guidelines.

Figure 23-8 Patient who meets multiple NCCN criteria (in bold) for HBOC testing

No Pi No Pi	
No P	ersonal history of breast cancer diagnosed at age <= 45 y
lo D	ersonal history of breast cancer diagnosed at age 46 - 50 y with a second breast cancer diagnosed at any age
• •	ersonal history of breast cancer diagnosed at age 46 - 50 y with >= 1 close blood relative with breast, ovarian, pancreatic, or high-grade (Gleason score >= 7) or intr
lo Pi	ersonal history of breast cancer diagnosed at age <= 60 y with triple-negative breast cancer
o P	ersonal history of breast cancer diagnosed at any age with Ashkenazi Jewish ancestry
lo P	ersonal history of breast cancer diagnosed at any age with >= 1 close blood relative with breast cancer at age <= 50 y or ovarian, pancreatic, or metastatic or intradu
lo P	ersonal history of breast cancer diagnosed at any age with >= 3 total diagnoses of breast cancer in patient and/or close blood relatives
No P	ersonal history of breast cancer diagnosed at any age with male breast cancer
lo P	ersonal history of epithelial ovarian cancer (including fallopian tube cancer or peritoneal cancer) at any age
No P	ersonal history of exocrine pancreatic cancer at any age
No P	ersonal history of metastatic or intraductal prostate cancer at any age
No P	ersonal history of high-grade (Gleason score >= 7) prostate cancer with Ashkenazi Jewish ancestry
lo P	ersonal history of high-grade (Gleason score >= 7) prostate cancer with >= 1 close relative with breast cancer at age <= 50 y or ovarian, pancreatic, or metastatic or
No P	ersonal history of high-grade (Gleason score >= 7) prostate cancer with >= 2 close relatives with breast or prostate cancer (any grade) at any age
lo Ir	ndividual with a probability greater than 5% of a BRCA1/2 pathogenic variant based on prior probability models
res A	ny blood relative with a known pathogenic/likely variant in a cancer susceptibility gene
res F	irst- or second-degree blood relative with a history of breast cancer diagnosed at age <= 45 y
No Fi	irst- or second-degree blood relative with a history of breast cancer diagnosed at age 46 - 50 y with a second breast cancer diagnosed at any age
lo Fi	irst- or second-degree blood relative with a history of breast cancer diagnosed at age 46 - 50 y with >= 1 close blood relative with breast, ovarian, pancreatic, or high
lo Fi	irst- or second-degree blood relative with a history of breast cancer diagnosed at age <= 60 y with triple-negative breast cancer
√o Fi	irst- or second-degree blood relative with a history of breast cancer diagnosed at any age with Ashkenazi Jewish ancestry
les F	irst- or second-degree blood relative with a history of breast cancer diagnosed at any age with >= 1 close blood relative with breast cancer at age <
res F	irst- or second-degree blood relative with a history of breast cancer diagnosed at any age with >= 3 total diagnoses of breast cancer in relative and/
No Fi	irst- or second-degree blood relative with a history of breast cancer diagnosed at any age with male breast cancer
No Fi	irst- or second-degree blood relative with a history of epithelial ovarian cancer (including fallopian tube cancer or peritoneal cancer) at any age
Yes F	irst- or second-degree blood relative with a history of exocrine pancreatic cancer at any age
No Fi	irst- or second-degree blood relative with a history of metastatic or intraductal prostate cancer at any age
No Fi	irst- or second-degree blood relative with a history of high-grade (Gleason score >= 7) prostate cancer with Ashkenazi Jewish ancestry
	irst- or second-degree blood relative with a history of high-grade (Gleason score >= 7) prostate cancer with >= 1 close relative with breast cancer at age <= 50 y or
No Fi	

Some guidelines require the family cancer history to be on the same side of the family.



Suppose the family health history was the following:

- Mother breast cancer at 55
- Maternal Grandmother breast cancer at 55
- Paternal Grandmother breast cancer at 55

NCCN HBOC criteria states: First- or second-degree blood relative with a history of breast cancer diagnosed at any age with >= 3 total diagnoses of breast cancer in relative and/or close blood relatives.

Since there are two close relatives with breast cancer on the maternal side, and one close relative with breast cancer on the paternal side, the patient's family health history does not meet this guideline.

Return to beginning of Risk Clinic Module

Return to Table of Contents



23.9 Cancer Risk

Selecting Run Risk Models will process all the risk models.

The "Breast" tab displays the Risk of Breast Cancer; 5 year and lifetime risk on the right. The summary page displays the Risk of Breast Cancer by model.



BRCAPro, Gail, Tyrer-Cuzick, and Claus subtabs can be selected to display the risk associated with each specific model.

The "Ovarian" tab displays the BRCAPro Risk of Ovarian Cancer. Both the graph and table, "Risk of Ovarian Cancer" presents risk scores that take into account genetic testing status. CRA v4 will calculate for you the lifetime score if the patient tested positive or negative for BRCA1/2.



The "Colon" and "Endometrial" tab displays the MMRPro Risk of Colon Cancer, CCRAT Risk of Colon Cancer and MMRPro Risk of Endometrial Cancer. The summary page displays the Risk of Breast Cancer by model. BRCAPro, Gail, Tyrer-Cuzick, and Claus tabs can be selected to display the risk associated with each specific model.



Return to Table of Contents

23.10 Recommendations

Users can document recommendations. The choice of dropdowns will define the content of emails sent to patients to help track their interest in complying with recommendations.

Recommendations

CBE	
	•
Chemoprevention	
	٣
MammographyHXView	×
Prophylactic Mastectomy	
	•
MRI	

Return to beginning of Risk Clinic Module

23.11 Documents

The Documents view allows you to view previously generated documents. The list is sortable by Name, Date Modified and represents a longitudinal history of documentation for your patient.

Quick Action buttons are available to edit or delete the existing list of documents.

Documents		New Docume
Name≑	Date Modified	Quick Actions
TESTSCHED_999201612121_SurveySummary_12122016 22:31:55	12/12/2016 10:31:56 PM	۵

New

You can also generate new documents by clicking on the 'New Document' hyperlink in the upper right corner.

Documents		New Document
Name¢	Date Modified 	Quick Actions
TESTSCHED_999201612121_SurveySummary_12122016 22:31:55	12/12/2016 10:31:56 PM	۵

See Create Documents section of this manual for more details.



Make sure you click the "Save the Pedigree Diagram" button *before* generating the CRA Survey summary when multiple users are



editing the same record at the same time.

In Figure 21-10 below, user one (left) is adding a maternal aunt and son to the pedigree while user two (right) is attempting to generate a survey summary.





Editing



You can click on the edit icon, click on an area in the document to drop the cursor and begin adding free text into the document using the built-in html editor. You can quickly print or download the newly edited document. Remember to save your work.



23.12 Imaging Tests

You can document results of mammograms or MRI. See <u>Imaging Study</u> section. Additional test results will be considered in future releases.

23.13 Follow-Ups

Users can use CRA v4 to track and <u>manage</u> your patient's compliance with recommendations or encounters by phone, email or when letters have been sent.

For instance, in a cancer treatment center, staff can document that the genetics patient was referred onto a surgical oncologist within the center (internal referral) or external clinician for follow-up care.

Any CRA v4 Provider Portal user can see a history of Follow-up actions that any member of the care team has documented for the patient. A 'Record Date' column displays when the Follow-up action was entered into CRA v4, not the date of the Follow-up event. Typically, the 'Record Date' and 'Follow-up Date' are the same. However, the 'Record Date' may show that a Follow-up event was entered after the fact. In the screenshot below, the Follow-up event indicates the patient had completed an MRI on July 2, 2019. However, the event was actually recorded on December 12, 2019.

Record Date +	Followup Date +	Who ¢	Type≑	Disposition +	Reason +	Comment+	
12/12/2019 10:31 AM	7/2/2019	MRI feed	Other	MR completed		DB MRI dx Lynette: Breast Screening MRI ac	ĭ ×
12/12/2019 10:32 AM	10/5/2018	Navigator	Phone Call	MR considered		MRI screening needed Patient screened on	B , ×



Go to the user's guide <u>section</u> on <u>Patient Management Using Risk Queues</u> to learn how to enter specific follow-up events or actions.

Return to Table of Contents



24. PATIENT PORTAL

The Patient Portal is an add-on feature of CRA v4. *If your institution does not offer this CRA feature but is interested in implementing, please contact your CRA Project Manager. Note: Even if your institution's electronic health record (EHR) has its own patient portal tool, CRA Patient Portal can integrate with it through a single sign-on connection. The integration allows you to send a CRA survey through your EHR's patient portal tool.*

CRA v4 Patient Portal allows staff at your institution to email or text patients inviting them to complete any <u>CRA survey</u> prior to an appointment.

The email will come from a CRA account called 'DO NOT REPLY <u>notifications@crahealth.com</u>.' If your institution prefers, a CRA Project Manager will work with your institution's IT team to link v4 Patient Portal with your institution's email address system.

Text messages to patients will come from a phone number with a 508 area code.

With the Patient Portal, patients

- 1. will receive an invitation to register;
- 2. will need to register and create a password within 14 days up receipt of the email;
- 3. will automatically enter into Patient Portal after registration is complete;
- 4. can stop and start surveys within Patient Portal;
- 5. can log out and back into the Patient Portal;
- 6. can even finish a survey in clinic that she started at home.

You can access the Patient Portal from the <u>Quick Action</u> set of icons. The Patient Portal icon changes based on the status of the patient's invitation and subsequent actions.



1. The person icon indicates a patient with an appointment who has not been invited but the appointment includes an email;



2. The grey person icon indicates a patient who has not been invited and the appointment includes no email. You can click on the icon and type in the patient's email;

ð	3.	The email icon indicate	es that an invitation	has been emailed.	Clicking on this i	con will
	send ar	nother invitation to the	patient's email;			

¥ 4. may

4. The hourglass icon indicates that the patient is still working on the survey. The patient may have started the survey but has not yet completed the survey. Or it is possible that the patient completed the survey but decided to return to the survey to update her answers before the day of the appointment;



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If you hover over the icon with your mouse, the tool tip text will indicate what the Patient Portal status is. The screenshot on the left shows the tool tip if you hover over the hourglass icon.



Read more <u>here</u> about the different surveys that are available to you from the CRA library.

24.1 Patient Emails or Mobile Number

Patient emails can be manually entered by staff through the <u>Appointment form</u> or may be included as part of your appointment feed. You can also enter emails by simply clicking on the <u>Patient Portal icon</u>. CRA Health assumes that you have your patients' permission to use her personal email to send an invitation to complete a survey.

24.2 Invitation

Patients can be manually or automatically invited to participate in the Patient Portal. Once a patient is invited, no additional action is necessary.

Manual invite

Choose a patient from the worklist and click on the Edit Appointment icon.

Click the person icon.

r	٦		
ς.	4		
	c	3	

A new form will appear that asks the user to confirm the patient's email address. If your institution's deployment of CRA v4 includes an appointment feed, patient emails may be pre-populated into CRA.

Email ID	
Patient's Email ID	
	Cancel OK

After clicking OK, the system will automatically send an email that contains a unique, institution-specific URL, along with anticipatory guidance about registering for the Patient Portal. Keep in mind the email is coming from CRA so let your patients know to check their spam folders.

If an email was successfully sent,

1. You will see a message appearing on the bottom of your screen;





The standard text used in the invitation email can be previewed and edited from the Documents library. Below is a sample email addressed to a Patient named 'Johanna'.

Inbox
Action Items
Dear Johanna,
On behalf of Oncology, and as a part of your upcoming genetics clinic visit, we need you to register on the CRA Health Patient Portal. Once registered, you will receive another email that will provide instructions to access to the ONLINE FAMILY HISTORY questionnaire where you can then enter your personal health and family history information.
Please complete your registration on the patient portal by clicking on the below link. You can also type the exact URL link address or copy and paste into your toolbar web browser.
Family History Questionnaire
The above link will be valid for next 14 days.
You will be prompted to enter your date of birth to register and set up your password. Remember your password as you will need to use it to login once you receive the login information in a separate email. Please note, your password should have at least one special character from ~!@#\$%^*0_+=
Once completed, you will receive a message "You have registered successfully and login url has been sent to your email id!". Follow the instructions from the 2nd email to complete the online questionnaire.
In case of any problems please contact the program's coordinator at: XXX-XXX-XXXX
Sincerely, Your Oncology Genetics Team

As part of implementing the Patient Portal at your institution, CRA can customize the text, <u>how long the</u> <u>survey link will be valid</u> or coordinate use of an email address that is managed by and originates from your institutions email servers.

Automatic invite

If your institution includes an appointment feed, CRA can be configured to automatically send an invitation each time an appointment is created.

Multiple configurations are possible with the automatic invite feature

If you have multiple clinics within your CRA v4 institution, your CRA Project Manager can configure the automatic email invitation to apply to specific clinics. Staff at your remaining clinics will need to invite patients manually.

If you do not want to automatically invite a patient who has already completed a survey in the past, your CRA Project Manager can work with you to define what the timeframe can be.

24.3 Patient Accepts

With the email invitation, the patient is now responsible for registering for the Patient Portal. The patient can click on the unique URL which will then launch a registration page.

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CRA Heal	th
Please enter your email ID, confirm your d /YYYY), and set up your password.	ate of birth (MM/DD
Once done you can proceed to take the su	irvey.
Email Id*	
@	
Password *	
a	۲
Confirm Password*	
A	•

The patient registers by confirming their email, entering their birthdate, and creating a password. Whether you invite the patient by email or text, the patient's username is the patient's email.

If the Patient does not follow the initial email instructions when registering with a strong password, an error message will appear.

Registration	2
CRA Health	
Please confirm your date of birth (MM/DD/YYYY) to re and set up your password.	gister
Once done you can proceed to take the survey using login url sent to your registered email id.	the
Date of Birth*	
9/23/1970	
Password *	
·····	۲
Confirm Password*	
a	۲
S	ubmit
Password should have atleast one special character from $\sim !@#$\%^*0_+=$	



If the patient attempts to register *after* the URL is no longer active, the patient will receive this message:

Registration 🚨
CRA Health
Please confirm your date of birth (MM/DD/YYYY) to register and set up your password.
Once done you can proceed to take the survey using the login url sent to your registered email id.
Date of Birth*
É
Password *
۲
Confirm Password*
Submit
Message: This link is not active. Please contact your administrator.

Welcome page

Once the patient completes registration within the proper timeframe, the Patient Portal URL is now activated for use. The patient will be automatically be taken to her unique Patient Portal landing page, titled 'Welcome'.

Figure 24-3 is a screenshot of the typical 'Welcome' page for mobile friendly surveys. Whether you assigned your patient to take a quick screening survey or a longer high-risk clinic survey, your patient will be able to:

- choose to take the survey in different languages;
- click 'Start questionnaire' to begin the health survey;
- logout at any time;



Figure 24-3 'Welcome' page for mobile friendly surveys



The screenshot below shows the 'Welcome' page for CRA's survey called 'Patient Portal Form', which is designed for desktop use only. The patient will be able to:

- see their name at the top;
- choose to take the survey in English or Spanish;
- click next to begin the survey;
- logout at any time;
- click on the question mark icon to find a simple user's guide.

CRA Health	TestPatientPortalForm, Johanna	1 of 4	Back	Next	Logout ?
					English OSpanish
	Welcome!				
	Please fill out this survey so we can review your personal and family history before your appointment. Th recommendations for your care. The next page will allow you to enter information about yourself and your we ask about each relative includes their name, age, cancer history, relationship to you, and if they are cur family history will ask questions about your personal health history. Prior to your appointment, you can return to the survey using the link in your email to edit Thank you for completing the survey.	is information is family members rently living. Th your responses	s used to m. s. The inform e page follo s.	ake hation wing	

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141



A separate patient friendly guide can be made available to your institution with an example of the final text used in the registration email, reminders about looking for an incoming email in their spam folders and guidance on collecting family health history.

24.4 Completed Surveys

When a patient completes a survey, the results automatically is associated with the patient's appointment. The Patient Portal icon in the Provider Portal worklist for that day changes to box with a check mark.

A staff member can view the data prior to the patient's scheduled appointment. However, if the staff member changes any data, it will overwrite what the patient originally entered through the Patient Portal.

24.5 Timeline

Link expiration

Your patients have a limited amount of time to complete the survey prior to the appointment. By default, the CRA v4 Patient Portal link is set to expire after 14 days. You can configure Patient Portal and invite patients up to six months in advance but CRA recommends, for security reasons, to keep the link valid for 90 days.

Re-invite

For patients who have been invited but not yet started or are in progress, you can re-invite patients to complete the survey.

Staff can manually re-invite patients by clicking on the Patient Portal icon again. A new message will appear to indicate a previous invitation was sent.

If you resend the invitation, the Patient Portal status will be set to 'Invited.'

Patient Portal Invitation Confirmation
The patient has registered or started with the Patient Portal survey. Sending the invitation again will set the status to invited. Are you sure you want send another invitation? Please confirm the patient's email address:
bklin@CRAHealth.com
Please enter the patient's cell phone number:
Cancel Send Email Again Send Text Again

Automatic reminders

Reminders can be automated as well. Contact your CRA Project Manager to help you configure when automatic reminders should be sent.

Clients generally opt to automate reminders either 1, 2 or 3 days in advance. These reminders are sent out at 5pm UTC. For clients in the United States, patients will receive reminders during business hours. Based on your configuration, a patient who has an appointment on Monday morning and has not completed a survey may receive a reminder message over the weekend.

142

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Appointment begins

Once the appointment starts, patients will **not** be able to make any additional changes through the survey. If the patient attempts to log back in the next day, she will see a note that says, "No surveys are found" or "This link is no longer valid."



If you use the 'Patient Portal Form' survey designed for desktops, you can customize what you want the message to say if a patient attempts to be be be be be be be attempts to be a say if a patient of the say want the message to say if a patient attempts to log back into the survey after the link has expired.

24.6 Opt Out of Patient Portal

If a patient has informed you or staff that they would like to opt out of receiving reminders for their current appointment or future appointments, click on the Edit Appointment form.

You will see options to

- opt out of the appointment in question
- opt out of future appointments



Iest Appointment	Exclude from Tablet	105	Cancel Save
MRN *	Last Name *	First Name *	Middle Name
99906112101	TestRelease	Chelsea	
Display Name (Read Only Fi	eld)	DOB *	Gender *
TestRelease, Chelsea		09/23/1970	F
Appointment Date *	Time *	Survey *	Clinic *
06/11/2021	08:00 AM	Breast Risk 🗸	South Park Grace H
Assessment	Referral	Language	Race
Cancer Screening 🗸	~	~	
Nationality	Occupation	Education	Marital Status
Insurance			
Patient is related to anot Opt out Patient Portal in	her patient in program vitation for all future appointments	ר	
Patient is related to anot Opt out Patient Portal in Opt out Patient Portal in	her patient in program vitation for all future appointments vitation for this appointment		
Patient is related to anot Opt out Patient Portal inv Opt out Patient Portal inv Address 1	her patient in program vitation for all future appointments vitation for this appointment	Address 2	
Patient is related to anot Opt out Patient Portal inv Opt out Patient Portal inv Address 1 10 Broadway	her patient in program vitation for all future appointments vitation for this appointment	Address 2	

24.7 Sharing the Pedigree During a Telehealth Session

If you asked your patient to complete the <u>Patient Portal Form</u> in advance, your patient will be able to see the pedigree once your appointment time begins.

You can edit and immediately share a static image of their patient's pedigree while on the phone.

- 1. Patients must register for Patient Portal using instructions you emailed.
- 2. Patients can still complete a survey at home up until the time of their appointment.
- 3. Once the appointment begins, patients who sign back into their Patient Portal account will see a static image of the pedigree.




4. Providers can continue to make edits on the pedigree, then click a new button 'Save the Pedigree Diagram'.



- 5. Once the patient refreshes their browser, she will see updates to the pedigree.
- 6. Patients and providers can continue sharing up until midnight of the patient's appointment.

24.8 Workflows

The figure below shows a typical Patient Portal workflow that includes an appointment feed along with automatic invites and reminders.



Figure 24-8 Automated invitation and reminder workflow



Prior to the appointment

A patient named Johanna is scheduled in advance for a Friday appointment and invited to complete a survey through CRA's Patient Portal. Johanna completes registration process and begins the survey. (The Patient Portal icon on the Clinician Application now shows she is 'in progress' \equiv). She completes the survey the night before, on Thursday. As Johanna answers questions information is saved in real-time and visible through the Clinician Application. The moment she reaches the end of the survey, a 'Thank you' screen, the Patient Portal icon will change to a checkbox. The clinician can review information and calculate a risk score. However, staff should be mindful not to change data until the day of the appointment with Johanna. After the appointment time has started on Friday, Johanna will not be able to go back into the Patient Portal survey to change her answers. Note: If Johanna had a telehealth appointment on Friday, she could <u>log back into the Patient Portal and view her pedigree</u> with the clinician.

In clinic on patient's mobile device

A patient named Eliza is scheduled in advance for an appointment next Wednesday. Leading up to Wednesday, you notice the Eliza has not registered for Patient Portal. When Eliza checks in for her appointment on Wednesday, front desk staff can text an invitation to Eliza's mobile phone to complete the survey in the waiting room. Eliza will still need to register using her email, date of birth and create a password. Once she registers, Eliza can complete the risk assessment survey prior to see the clinician.

Return to Table of Contents

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25. CRA LAB CONNECT

CRA v4 can integrate with clinical laboratories via the Lab Connect feature to enhance your workflow in either women's imaging or high-risk clinic.

Within imaging centers, CRA is currently partnering with Myriad Laboratories to provide telegenetics education immediately after the patient has been identified as high mutation risk for breast/ovarian cancer. Nurse navigators, with the patient's consent can send patient demographic information to initiate a telegenetics education session with an off-site genetic counselor. After the pre-test counseling is completed, a test request form is returned to the nurse navigator for completion.

If you order from Ambry Genetics, CRA can currently provide a test requisition form (TRF) that will prepopulate with patient demographics and family history. Future releases will allow users to place an electronic order for a gene panel.¹⁰

Future enhancements with CRA laboratory partners will allow genetic test results to be populated directly into the <u>genetic test details form within Risk Clinic</u>.

26. QUESTIONS?

26.1 Risk Models

For a review of current risk models available through CRA, go to the section on risk thresholds.

CRA staff has summarized the following section into a single fact sheet. If you are interested in obtaining the sheet as a handout for training purposes, please contact <u>CRA Support</u>.

I get several different risk scores from different tools

Why do I sometimes get a low risk score when I know the patient clearly needs BRCA testing based on family health history?

Please review blog by Dr. Kevin Hughes titled "Many Breast Cancer Risk Models: Which One is Accurate?" which can be accessed at <u>http://www.crahealth.com/cra-blog/2016/1/22/many-breast-cancer-risk-models-which-one-is-accurate-1</u>.

I get 'N/A' (not available) for a model

Models have been developed for various situations and models will not run if they were not designed for the situation presented by your patient. A listing of models that will display as N/A under different situations follows:

Model	Will NOT run and display 'N/A' if	
Gail	Patient has breast cancer, is <35 years old, has LCIS or patient is male	
Tyrer-Cuzick 6, 7 or 8	 patient has breast cancer, patient is male or	

¹⁰ Electronic genetic test ordering for Invitae and Ambry panels will be available in early 2022.

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	 patient is <20 years old or >84 years
Claus	Patient has breast cancer, is <30 years old, or if patient has no family history of breast cancer or patient is male
Myriad	Patient does not have cancer and no family history of breast cancer under age 50 and no family history of ovarian cancer
BRCAPRO	 Will run but not display breast cancer risk over time if patient has breast cancer patient is > 85 years of age Will not run if two first cousins on the pedigree have a child

NOTE: No models will be presented on the survey summary if the patient has self-reported AH, LCIS or genetic testing until verified by the provider through the CRA Health Provider Portal.

Situation	If
No ovarian risk	patient had oophorectomy or ovarian cancer
No breast risk	patient had mastectomy

Help review cases

CRA's medical advisory board can also help review cases on your behalf.

"We have a referring physician inquiring why a patient was not found to be at elevated mutation risk based on hereditary breast/ovarian cancer criteria. The patient scored 37.4% lifetime and has family and personal history inclusive of:

Mother Breast Cancer age 55	Jewish: No
Father Lung Cancer age 71	Hispanic: No
Maternal Grandmother Breast Cancer age 55	Race: Caucasian or White
Paternal Grandmother Lung Cancer age 71	
Paternal Grandfather Stomach Cancer age 55	CHILDBIRTH HISTORY
Paternal Aunt Breast Cancer age 70, Breast	# of Pregnancies: 2
Cancer	Age 1st birth: 30
DEMOGRAPHIC	MENSTRUAL HISTORY
Age: 49	Menarche: 14
Height: 5-6	Menopausal status: Pre
Weight: 156	
BMI: 25.2	BREAST SURGERIES AND TREATMENTS
Gender: Female	Ever had biopsy: Yes
	Number of biopsies: 1
ETHNICITY	Biopsy with Atypical Hyperplasia: No

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Biopsy with LCIS: No

Tyrer-Cuzick (TC) model looks at more than just BRCA1/2 genes when considering family history risk. In this case the TC calculated risk of BRCA1/2 is low but risk of another gene that's involved in this family history is what's elevating the lifetime score. Here is a reference from the TC authors that discusses this other low penetrant, dominant breast cancer gene (other than BRCA1/2): <u>http://www.ems-trials.org/riskevaluator/documents/Breast_cancer_prediction_model.pdf</u>. In contrast if we look at BRCAPro, a low mutation risk score correlates with a lower lifetime score. BRCAPro does not consider any other low penetrant dominant breast cancer gene and is based on probability of carrying BRCA1/2 mutation. NCCN HBOC v1.2020 criteria are not met either. The age of onset for breast cancer among relatives is not low. If the relatives ages were <=50 years, NCCN would be triggered. Also the relatives with breast cancer are not all on the same side of the family.

26.2 Survey Summary Does Not Show Risk Scores

Several reasons can account for this. One workflow-related reason involves <u>patient reported procedures</u> <u>or past genetic testing</u>. If this does not apply to you, please contact CRA Support.

26.3 Published Studies Using CRA

Selected articles

Yin K et. al. Breast imaging, breast surgery, and cancer genetics in the age of COVID-19 Cancer. 2020 Oct 15;126(20):4466-4472.

McCarthy AM et. al. Performance of Breast Cancer Risk-Assessment Models in a Large Mammography Cohort J Natl Cancer Inst. 2020 May; 112(5): 489–497.

Le QP et. al. High-risk for developing breast cancer: Differences between white and African American women. Ann Surg Oncol 2019; 26(Suppl 1):S79.

Ray D et. al. Short-term outcomes of the implementation of a computer-based breast cancer risk assessment program during screening mammography J Community Support Oncol. 2014 Jun;12(6):209-11.

Murphy CD et. al. The American Cancer Society guidelines for breast screening with magnetic resonance imaging: an argument for genetic testing Cancer. 2008 Dec 1;113(11):3116-20.

26.4 Online Help

You can view videos, download fact sheets at <u>http://public.crahealth.com/cra-help/</u>.

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Support line

Email <u>support@crahealth.com</u>. A field engineer will respond within one business day. In the case of an emergency (e.g. where the system is not functional), field service staff will contact you within the hour. **Please note: the support mailbox is for you and your colleagues and is not meant for patients.**

Call 617-631-8174 Extension 2

You Customer Success Manager

Sally Koskinen 617-631-8174 x5100

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