Liverpool Women's
NHS Foundation Trust

Assessing Eligibility for R208

Inherited breast cancer genomic testing for patients with breast cancer

Anna Whaite, Registered Genetic Counsellor, GCRB 229

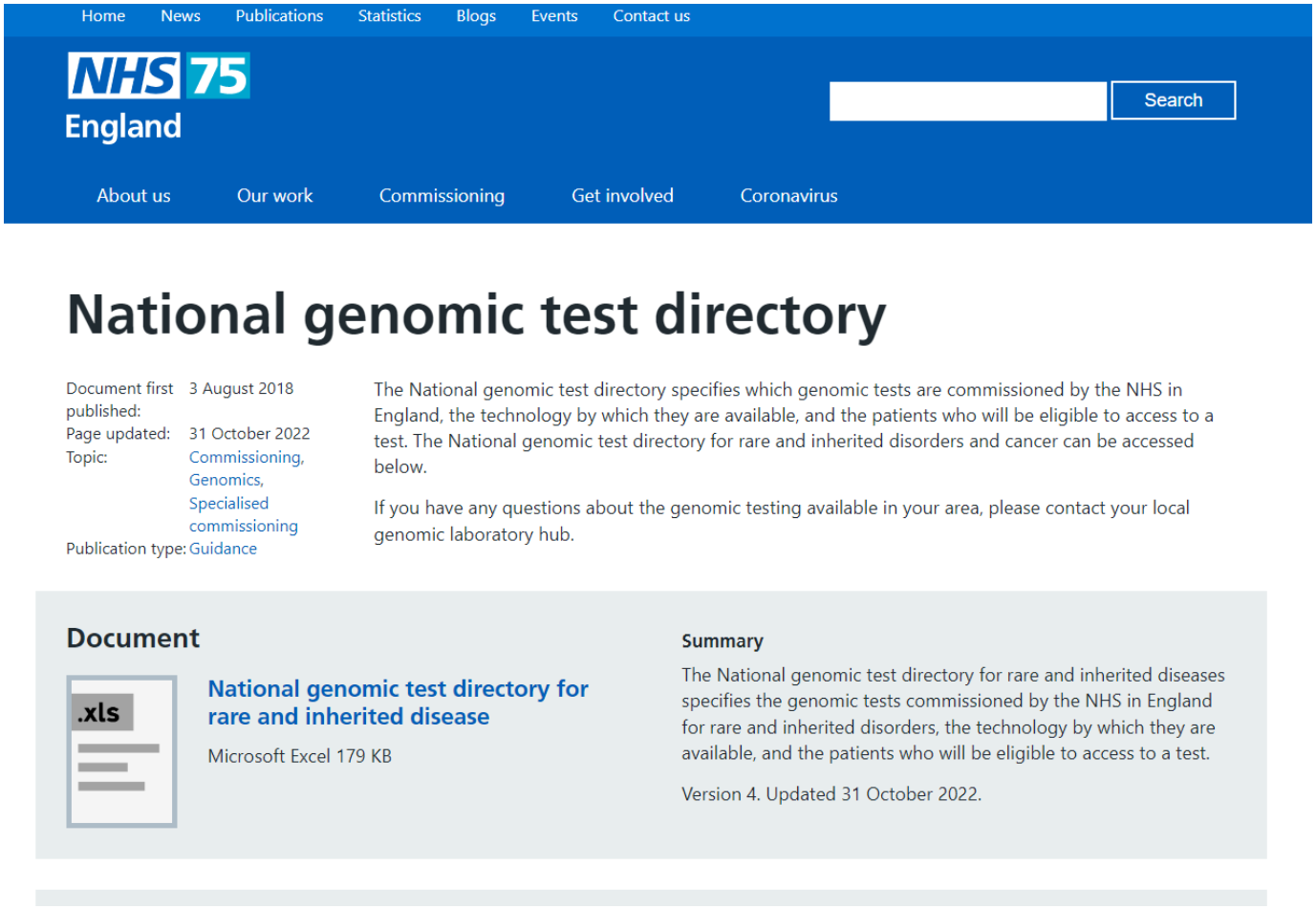
Liverpool Centre for Genomic Medicine

Overview

- Genomic Test Directory eligibility criteria
- Manchester Scoring
- CanRisk

The Genomic Test Directory

https://www.england.nhs.uk/publication/national-genomic-test-directories/



Page updated: 31 October 2022
Topic: Commissioning, Genomics, Specialised commissioning
Publication type: Guidance

test. The National genomic test directory for rare and inherited disorders and cancer can be accessed below.

If you have any questions about the genomic testing available in your area, please contact your local genomic laboratory hub.

Document

National genomic test directory for rare and inherited disease

Microsoft Excel 179 KB

Summary

The National genomic test directory for rare and inherited diseases specifies the genomic tests commissioned by the NHS in England for rare and inherited disorders, the technology by which they are available, and the patients who will be eligible to access to a test.

Version 4. Updated 31 October 2022.

Document

Rare and inherited disease eligibility criteria

PDF 4 MB 405 pages

Summary

This eligibility criteria document supplements the National genomic test directory by setting out which patients should be considered for testing under that indication, and the requesting specialties is a list of the clinical specialties who would be expected to request the test.

Version 4. Updated 31 October 2022.

Document

Summary

The National genomic test directory for cancer specifies the

R208 Inherited breast cancer and ovarian cancer

Testing Criteria

1. **Living affected individual (proband)** with breast* or high grade ovarian cancer where the individual +/- family history meets one of the criteria. The proband has:
   a. Breast cancer (age <40 years,), OR
   b. Bilateral breast cancer (age < 50 years), OR
   c. Triple negative breast cancer (age < 60 years), OR
   d. Male breast cancer (any age), OR
   e. Breast cancer (age <45 years) and a first degree relative with breast cancer (age <45 years), OR
   f. Combined pathology-adjusted Manchester score ≥15 or single gene pathology adjusted score of ≥10 or BOADICEA/CanRisk score ≥10% OR
   g. Ashkenazi Jewish ancestry and breast cancer at any age
2. **Living affected individual with pancreatic cancer** AND family history of breast*/high grade ovarian/prostate cancer with a pathology adjusted Manchester score of ≥ 15/CanRisk score of 10%.
3. **Living affected individual with prostate cancer** AND a family history of breast/ovarian/pancreatic cancer with a pathology adjusted Manchester score of ≥ 15/CanRisk score of 10%.
4. **Deceased affected individual** with breast* or high grade ovarian cancer with:
   a. A stored DNA, blood or tissue sample available for DNA extraction, AND
   b. Pathology-adjusted Manchester score ≥17 or CanRisk score ≥15%, AND
   c. No living affected individual is available for genetic testing
5. **Living unaffected** individual with:
   a. first degree relative affected by breast* or serous ovarian cancer, AND
   b. Combined pathology-adjusted Manchester score ≥20 or BOADICEA/CanRisk score of ≥20% for affected relative or BOADICEA/CanRisk score of ≥10% for unaffected relative AND
   c. No living affected individual is available for genetic testing, AND
   d. No deceased affected individual with tumour material available for testing

   Note for living unaffected individuals:

   Where more than one family member may be eligible for unaffected testing, the residual probability of a causative pathogenic variant in the family should be considered, taking into account prior normal unaffected tests.

NOTES

- ***Breast cancer definition includes high grade DCIS**
- **The proband's cancer and majority of reported cancers in the family should have been confirmed**
- **The pathology adjusted Manchester score involved incorporation of pathology data for the tested proband alone, i.e. pathology need not be sought for other family members.**
- **Ovarian cancer: Fallopian Tube and Primary Peritoneal cancers can be included**
- **BRCA1/BRCA2 testing should not typically have previously been performed. Exceptions may include, for example, patients who have been tested through the Jewish Community's NHS BRCA-Testing Programme for BRCA1/BRCA2 and not received a molecular diagnosis**
- **Testing of unaffected and deceased individuals can only be offered by Clinical Genetics**

Genetic testing may occasionally be appropriate outside these criteria following discussion at a specialist MDT with a cancer geneticist present

R208 Inherited breast cancer and ovarian cancer

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3. **Living affected individual with prostate cancer** AND a family history of breast/ovarian/pancreatic cancer with a pathology adjusted Manchester score of ≥ 15/CanRisk score of 10%.
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R208 eligibility

R208 Inherited breast cancer and ovarian cancer

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   g. Ashkenazi Jewish ancestry and breast cancer at any age

NOTES

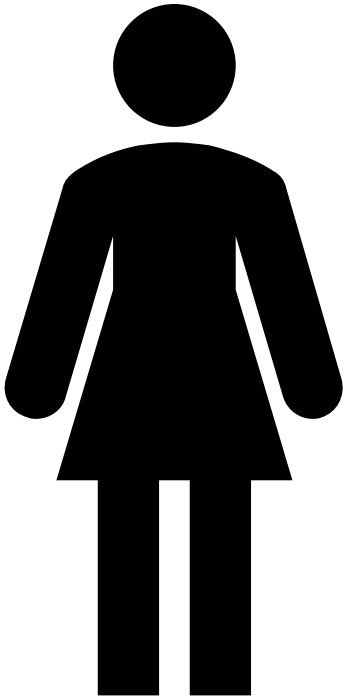
- ***Breast cancer definition includes high grade DCIS**

R208 eligibility – own diagnosis (female)

Breast cancer < 40 years

Updated to include grade 1 breast cancers and high grade DCIS

(if 30 and under, or under 35 with HER2 positive breast cancer please refer directly to Genomic Medicine)

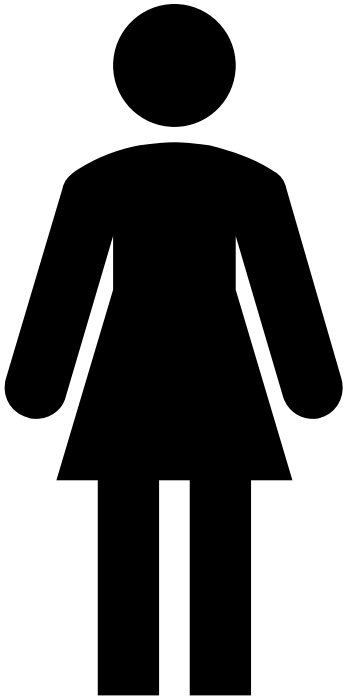


R208 eligibility – own diagnosis (female)

Bilateral breast cancer, both < 50 years

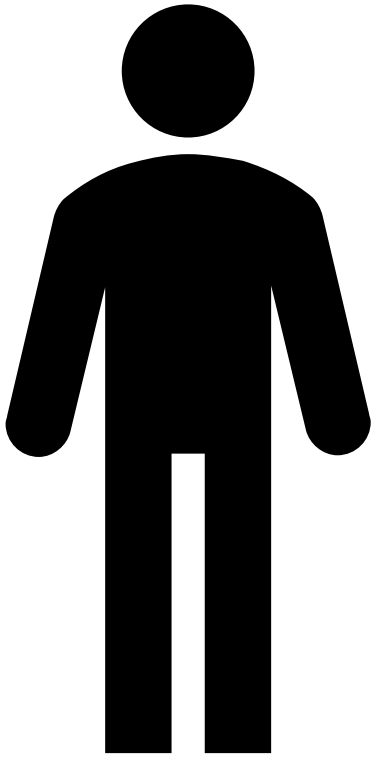
OR

Triple negative breast cancer < 60 years



R208 eligibility – own diagnosis (male)

Male breast cancer at any age

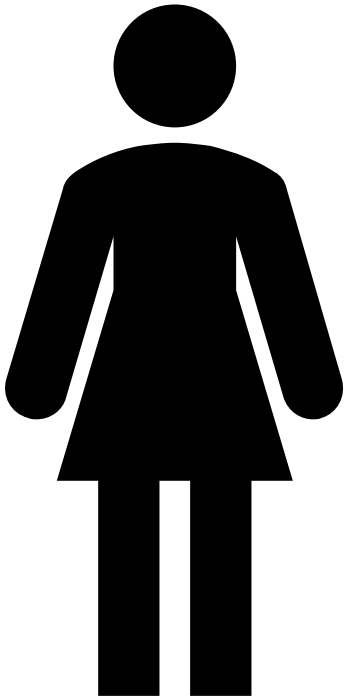


R208 eligibility –simple family history

Breast cancer <45 years and a first degree relative (FDR) with breast cancer < 45 years

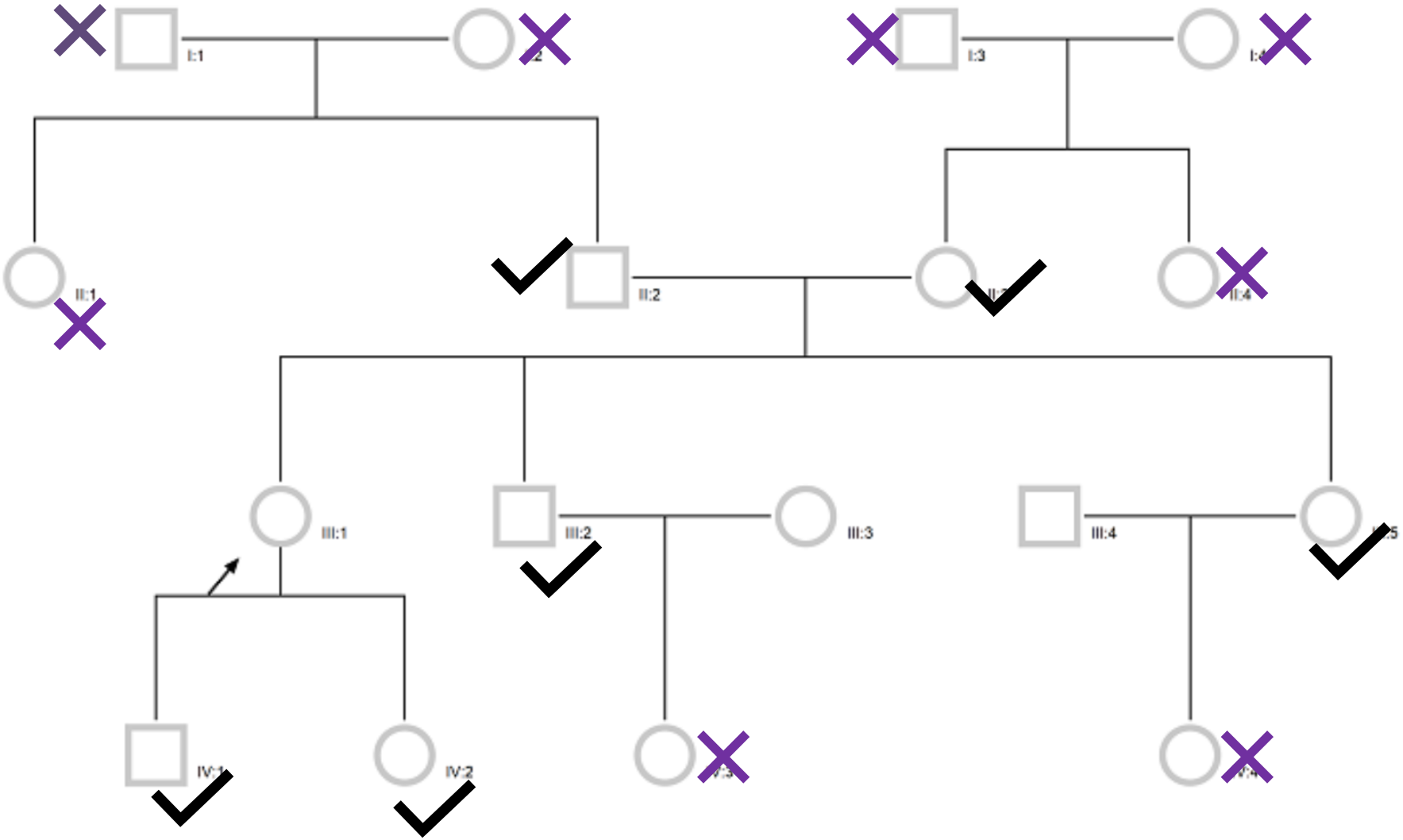
OR

Ashkenazi Jewish ancestry and breast cancer at any age

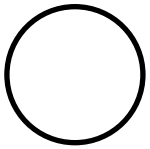


‘Are you aware of any Ashkenzi Jewish ancestry in your family?’

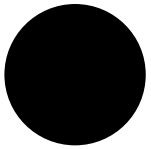
Who is a First Degree Relative?



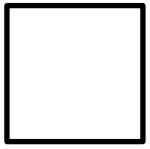
Common Symbols



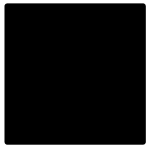
Female



Affected female



Male

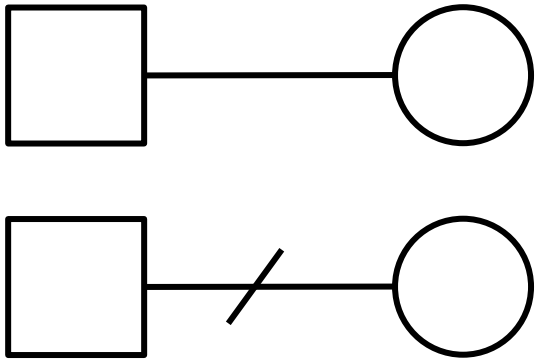


Affected male

Always use a key to show what the diagnosis is e.g.

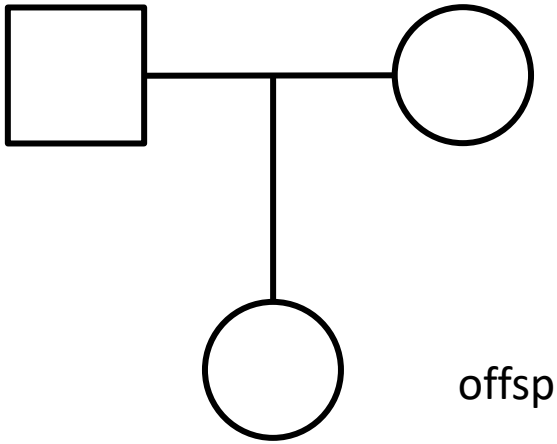
Breast cancer

Relationship lines



A relationship line, between a couple

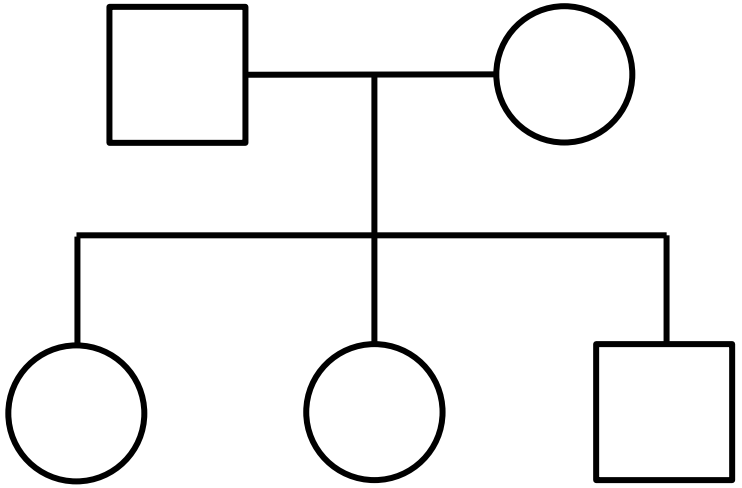
Separated couple



parents

offspring

sibship line



R208 eligibility

R208 Inherited breast cancer and ovarian cancer

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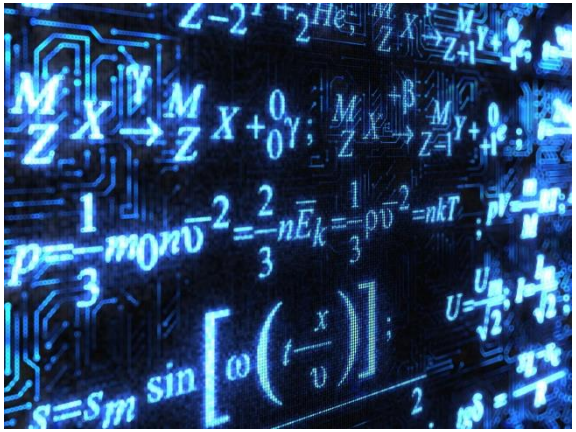
What is a Manchester Score?



Comparative Study > J Med Genet. 2004 Jun;41(6):474-80. doi: 10.1136/jmg.2003.017996.

A new scoring system for the chances of identifying a BRCA1/2 mutation outperforms existing models including BRCAPRO

D G R Evans [1], D M Eccles, N Rahman, K Young, M Bulman, E Amir, A Shenton, A Howell, F Lalloo

Affiliations + expand

PMID: 15173236 PMCID: PMC1735807 DOI: 10.1136/jmg.2003.017996

Free PMC article

Abstract

Purpose: To develop a simple scoring system for the likelihood of identifying a BRCA1 or BRCA2 mutation.

https://pubmed.ncbi.nlm.nih.gov/15173236/

ORIGINAL ARTICLE

Pathology update to the Manchester Scoring System based on testing in over 4000 families

D Gareth Evans,[1,2,3,4,5] Elaine F Harkness,[6] Inga Plaskocinska,[7] Andrew J Wallace,[3] Tara Clancy,[3] Emma R Woodward,[1,3] Tony A Howell,[2,5] Marc Tischkowitz,[7] Fiona Lalloo[3]

Scoring includes family history and pathology of the proband's tumour

https://jmg.bmj.com/content/jmedgenet/54/10/674.full.pdf

Step 1 – score the family history

- For each relative with cancer (including DCIS), assign a score based on the relative's age at diagnosis **(see table 1)**

  Only these cancers count in Manchester Scoring
  - Breast
  - Ovarian
  - Prostate
  - Pancreas

Family history question ideas

Clear intro and first question

Your family tree may alter what testing we can offer. Has anyone else in the family had a breast cancer?

Gentle questioning not interrogation

How are you related? How old do you think they were when it was diagnosed?

Explaining terminology

Is she a full sister, so same mum and same dad?

Clarifying specifics

So your cousin Jane is your dad's sister's daughter?

Summarise details given

So let me check all that: your mum had breast cancer at 52, her mum, your grandmother, had ovarian cancer at 86, is that right?

Final open question

Has anyone else had a cancer that we've not talked about yet? Is there anything else you think I should know?

Acknowledge/thank patient for sharing

Guidance for combined Manchester Score

Table 1: Scoring system for each member of your current patient's family

Gender of relative	Cancer	Age at diagnosis	Score	No of family members affected	Calculation
Female	Breast Cancer	<30	11		
	Breast Cancer	30-39	8		
	Breast Cancer	40-49	6		
	Breast Cancer	50-59	4		
	Breast Cancer	>59	2		
Male	Breast Cancer	<60	13		
	Breast Cancer	>59	10		
Female	Ovarian Cancer	<60	13		
	Ovarian Cancer	>59	10		
Any gender	Pancreatic Cancer	Any age	1		
Male	Prostate Cancer	<60	2		
	Prostate Cancer	>59	1		
			Total		

How to calculate the Manchester Score?

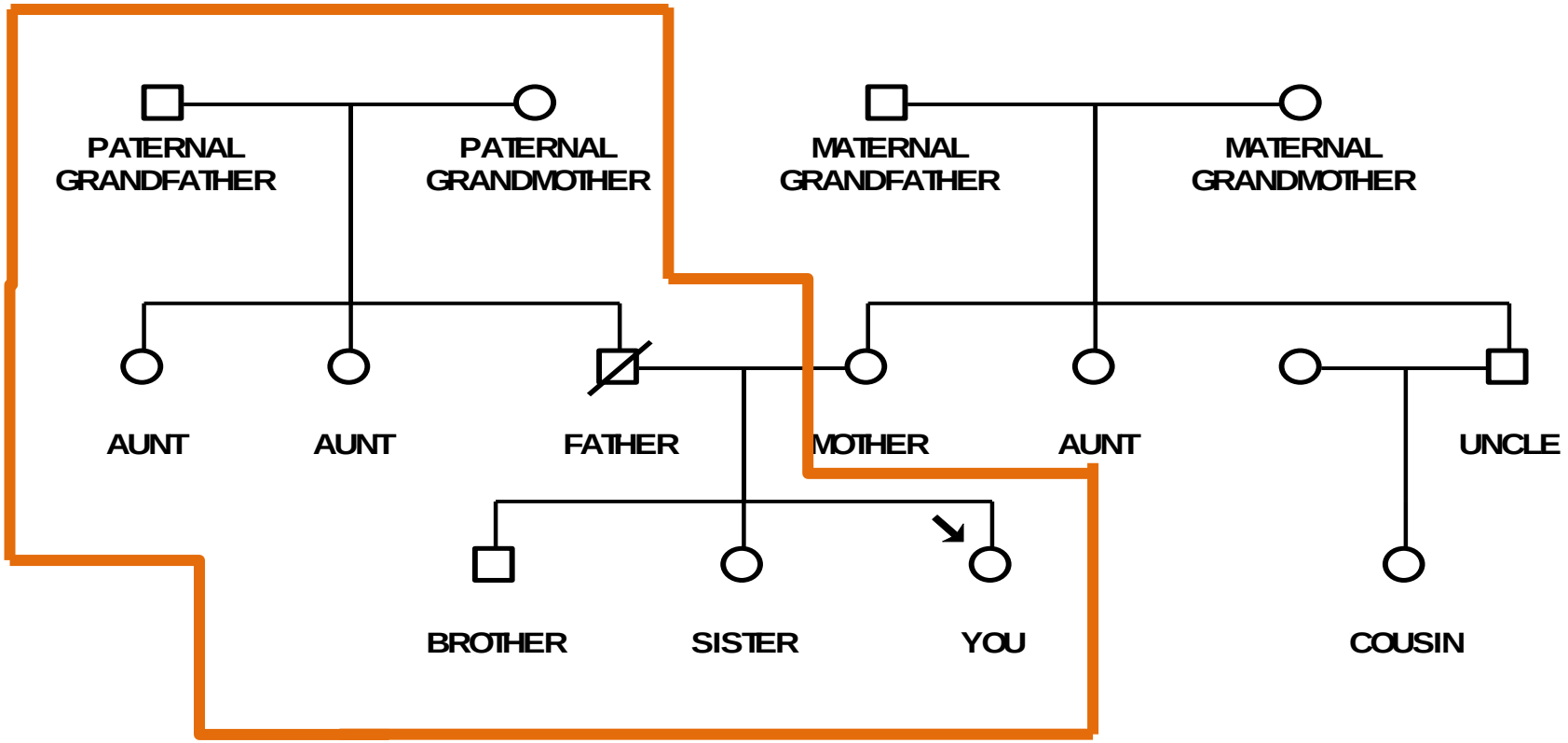
PART ONE – reviewing the patient's family history

To use the Manchester Scoring System you need to know

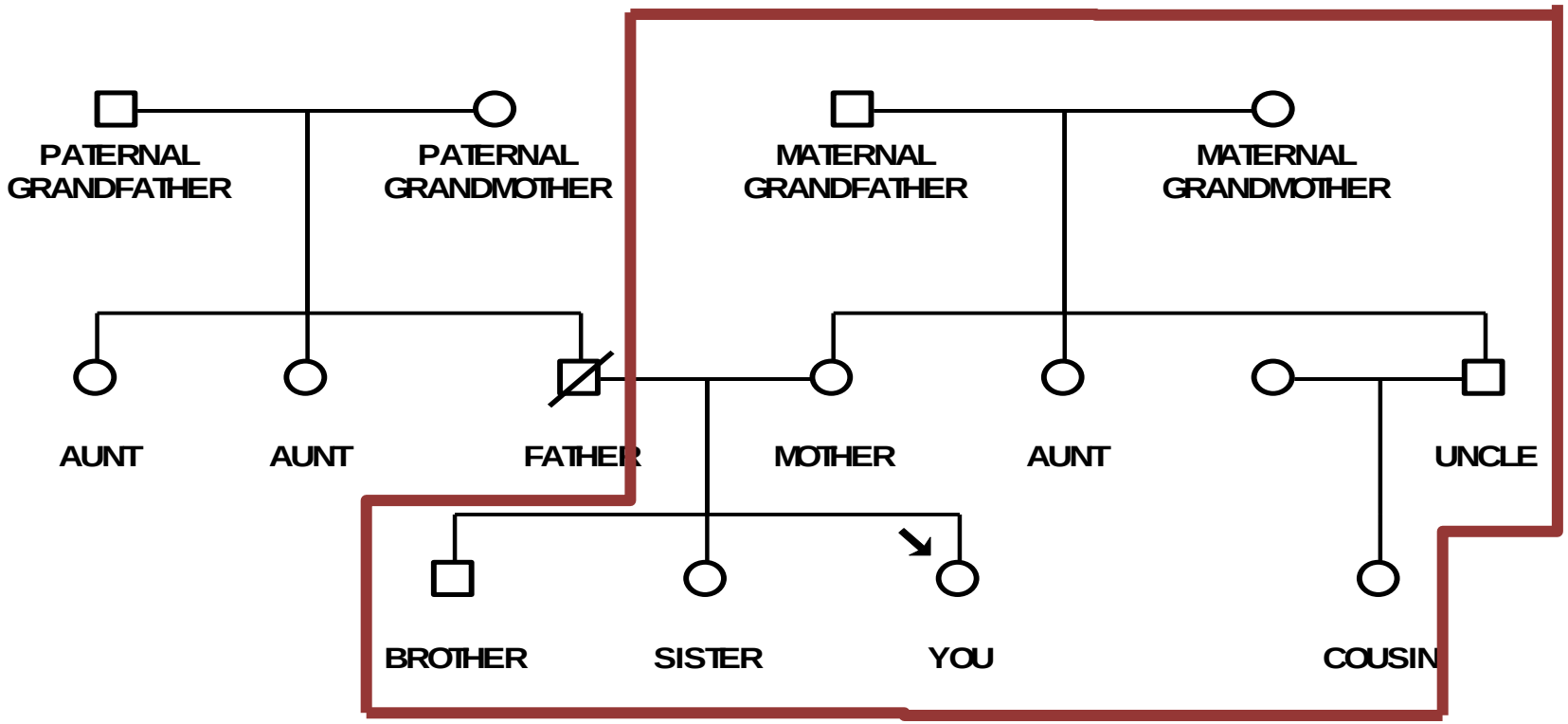
- If any relative has had cancer
- What type
- Age at diagnosis
- WHICH SIDE OF THE FAMILY they were on

    - Assess mum and dad's side separately – do not add scores together for mum and dad's side
    - Include your patient in both assessments

Father's side, inc patient and sibs



Mother's side, inc patient and sibs



Pathology adjustments

Table 2: Adjustments according to your current patient's tumour biology

Patient's tumour biology	Adjustment to Manchester Score	Calculation
Triple negative tumour	+ 4	
ER positive and HER2 negative	-1	
ER positive and HER2 positive	-7	
ER negative and HER2 positive	-5	
Grade 3	+2	
Grade 1	-2	
DCIS only (no invasive disease)	-2	
Invasive lobular cancer	-2	
	Total	

Add/subtract this to each family history score
Total determines eligibility for R208

Guidance for combined Manchester Score

There is an information sheet by Greater Manchester Genomics to guide non-genetic specialists to calculate a Manchester Score for patients with a new diagnosis of breast cancer.

Patients with a Manchester Score ≥ 15 are eligible for R208 testing (over 14)

(single gene pathology adjusted score of ≥ 10 is a new addition to eligiblity, we are not expecting this to be calculated currently)

Family A

Your patient is female with breast cancer aged 65
Her mother had breast cancer aged 79

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	Breast Cancer	50-59	4		
	Breast Cancer	>59	2	**2**	**4**

Do not offer R208

Family B

Your patient is female with breast cancer aged 59
Her mother had breast cancer aged 37
Mother's brother had prostate cancer at 58

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Gender of relative	Cancer	Age at diagnosis	Score	No of family members affected	Calculation
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	Breast Cancer	>59	10		
Female	Ovarian Cancer	<60	13		
	Ovarian Cancer	>59	10		
Any gender	Pancreatic Cancer	Any age	1		
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	Prostate Cancer	>59	1		
			Total		

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	Breast Cancer	>59	10		
Female	Ovarian Cancer	<60	13		
	Ovarian Cancer	>59	10		
Any gender	Pancreatic Cancer	Any age	1		
Male	Prostate Cancer	<60	2	1	2
	Prostate Cancer	>59	1		
			Total		14

Family B

Your patient **GRADE 3, ER negative, PR positive, HER2 negative**

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	Total	

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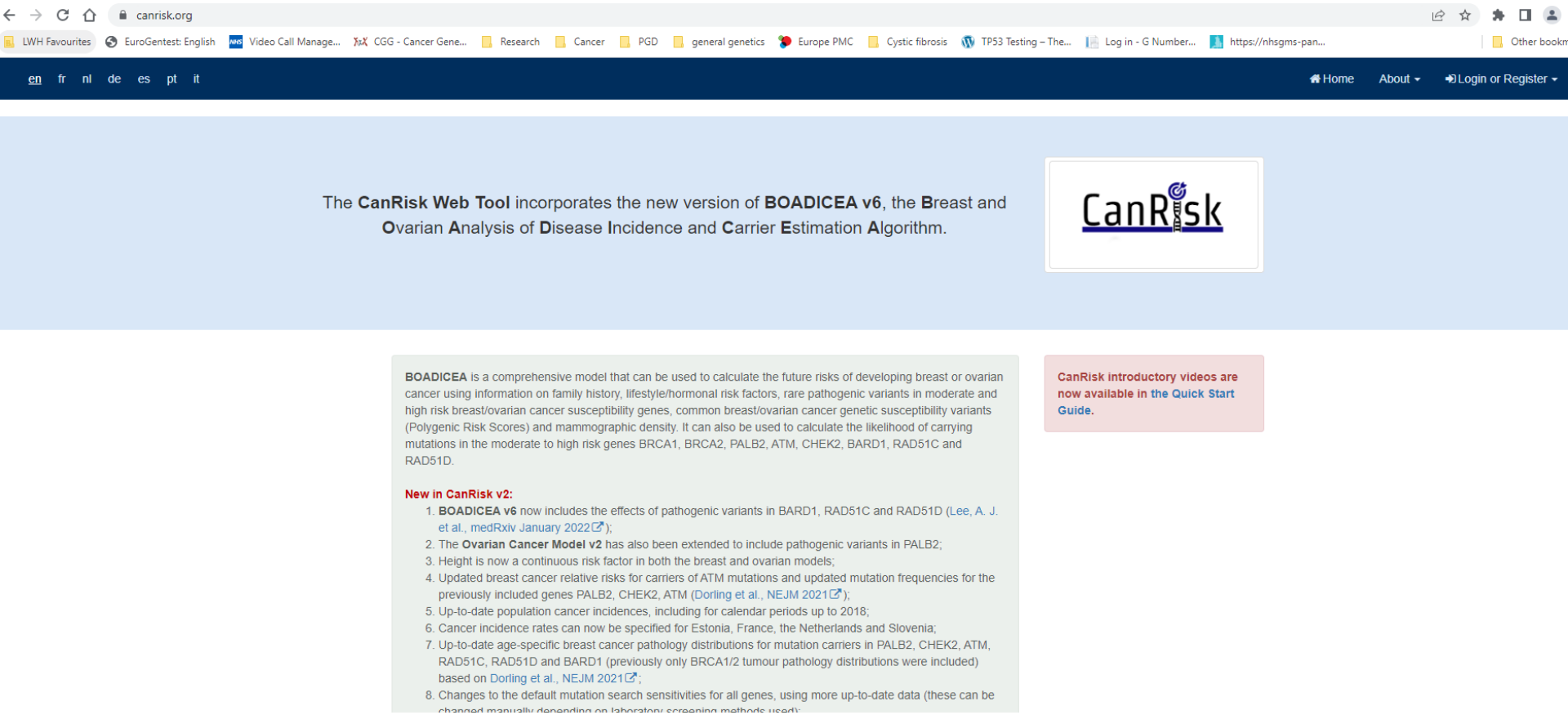
Grade 3	+2	**+2**
Grade 1	-2	
DCIS only (no invasive disease)	-2	
Invasive lobular cancer	-2	
	Total	**+2**

14+2 = 16 Offer R208

CanRisk


canrisk.org
LWH Favourites
EuroGentest: English
Video Call Manage...
CGG - Cancer Gene...
Research
Cancer
PGD
general genetics
Europe PMC
Cystic fibrosis
TP53 Testing – The...
Log in - G Number...
https://nhsgms-pan...
Other bookm
en fr nl de es pt it
Home
About
Login or Register
The CanRisk Web Tool incorporates the new version of BOADICEA v6, the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm.
CanRisk
BOADICEA is a comprehensive model that can be used to calculate the future risks of developing breast or ovarian cancer using information on family history, lifestyle/hormonal risk factors, rare pathogenic variants in moderate and high risk breast/ovarian cancer susceptibility genes, common breast/ovarian cancer genetic susceptibility variants (Polygenic Risk Scores) and mammographic density. It can also be used to calculate the likelihood of carrying mutations in the moderate to high risk genes BRCA1, BRCA2, PALB2, ATM, CHEK2, BARD1, RAD51C and RAD51D.
New in CanRisk v2:
1. BOADICEA v6 now includes the effects of pathogenic variants in BARD1, RAD51C and RAD51D (Lee, A. J. et al., medRxiv January 2022);
2. The Ovarian Cancer Model v2 has also been extended to include pathogenic variants in PALB2;
3. Height is now a continuous risk factor in both the breast and ovarian models;
4. Updated breast cancer relative risks for carriers of ATM mutations and updated mutation frequencies for the previously included genes PALB2, CHEK2, ATM (Dorling et al., NEJM 2021);
5. Up-to-date population cancer incidences, including for calendar periods up to 2018;
6. Cancer incidence rates can now be specified for Estonia, France, the Netherlands and Slovenia;
7. Up-to-date age-specific breast cancer pathology distributions for mutation carriers in PALB2, CHEK2, ATM, RAD51C, RAD51D and BARD1 (previously only BRCA1/2 tumour pathology distributions were included) based on Dorling et al., NEJM 2021;
8. Changes to the default mutation search sensitivities for all genes, using more up-to-date data (these can be
CanRisk introductory videos are now available in the Quick Start Guide.

CanRisk

Updated version of BOADICEA
Personalised breast/ovarian cancer risk assessments
BRCA ‘mutation’ likelihood calculator
NHS approved

Can include:

- Family history of cancers
- Tumour details
- Genetic testing results
- Lifestyle risk modifiers including
- BMI
- Alcohol use
- OCP use

canrisk.org

LWH Favourites | EuroGentest: English | Video Call Manage... | CGG - Cancer Gene... | Research | Cancer | PGD | general genetics | Europe PMC | Cystic fibrosis | TP53 Testing – The... | Log in - G Number... | https://nhsgms-pan... | Other bookmark

en fr nl de es pt it

Home | Tool | Batch Tool | Guide | About | Logout [redacted]

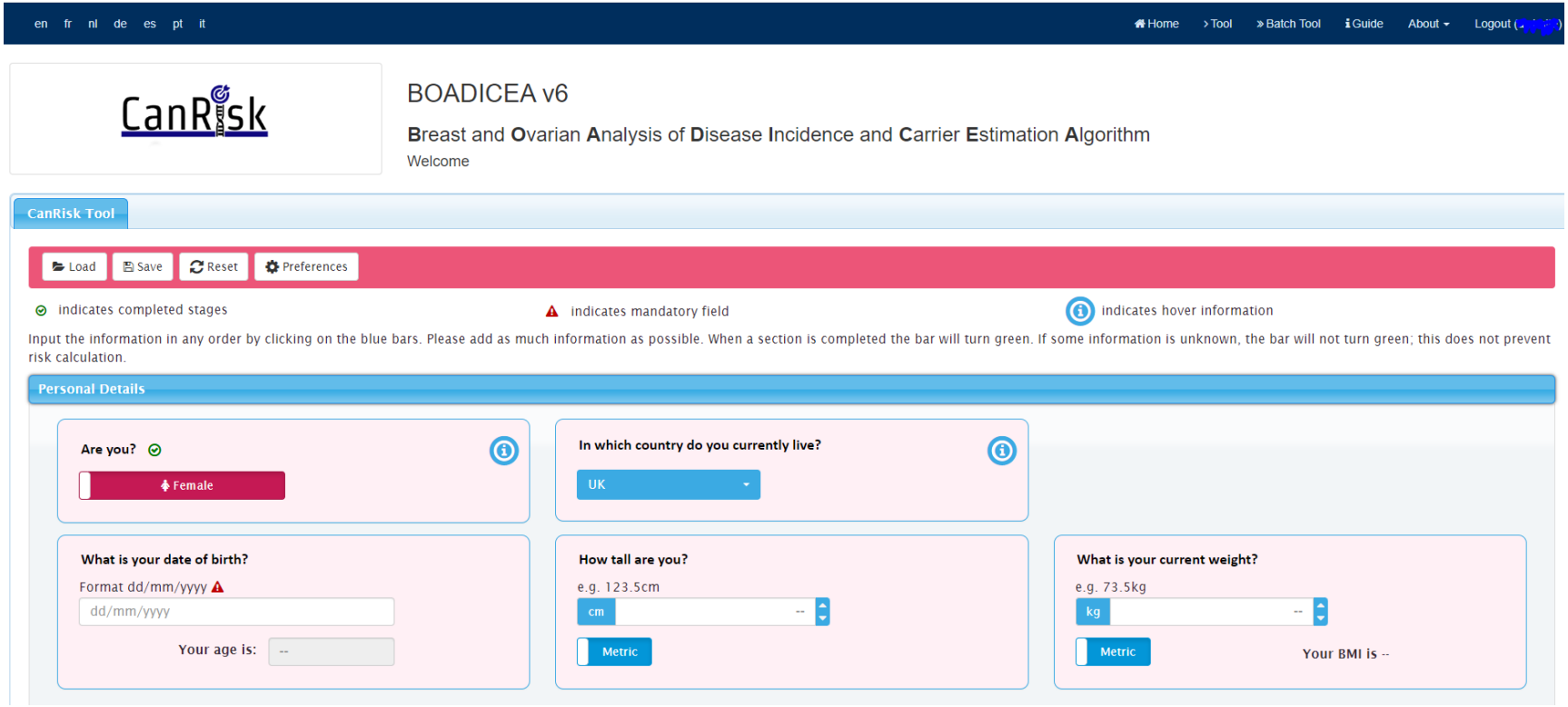
The **CanRisk Web Tool** incorporates the new version of **BOADICEA v6**, the **B**reast and **O**varian **A**nalysis of **D**isease **I**ncidence and **C**arrier **E**stimation **A**lgorithm.

CanRisk

Start CanRisk

BOADICEA is a comprehensive model that can be used to calculate the future risks of developing breast or ovarian cancer using information on family history, lifestyle/hormonal risk factors, rare pathogenic variants in moderate and high risk breast/ovarian cancer susceptibility genes, common breast/ovarian cancer genetic susceptibility variants (Polygenic Risk Scores) and mammographic density. It can also be used to calculate the likelihood of carrying mutations in the moderate to high risk genes BRCA1, BRCA2, PALB2, ATM, CHEK2, BARD1, RAD51C and RAD51D.

CanRisk introductory videos are now available in the Quick Start Guide.

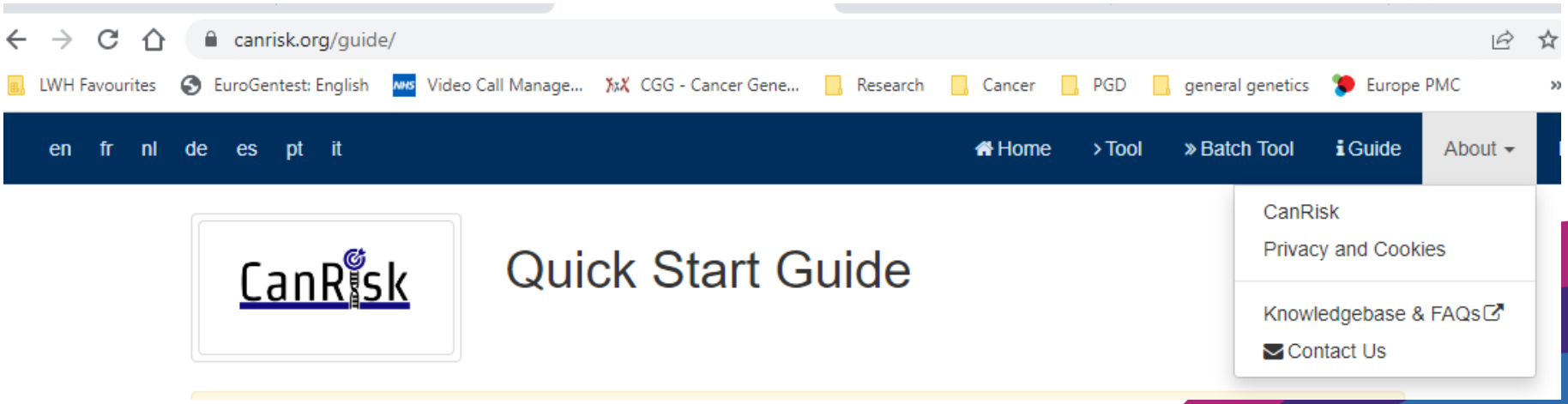

en fr nl de es pt it
Home
Tool
Batch Tool
Guide
About
Logout
CanRisk
BOADICEA v6
Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm
Welcome
CanRisk Tool
Load
Save
Reset
Preferences
indicates completed stages
indicates mandatory field
indicates hover information
Input the information in any order by clicking on the blue bars. Please add as much information as possible. When a section is completed the bar will turn green. If some information is unknown, the bar will not turn green; this does not prevent risk calculation.
Personal Details
Are you?
Female
In which country do you currently live?
UK
What is your date of birth?
Format dd/mm/yyyy
dd/mm/yyyy
Your age is:
How tall are you?
e.g. 123.5cm
cm
Metric
What is your current weight?
e.g. 73.5kg
kg
Metric
Your BMI is --

CanRisk

Video user guides available online

https://canrisk.org/guide/

Also guide with FAQs, via About tab



R208 eligibility via CanRisk

CanRisk score of 10%+ (chance of finding pathogenic variant)

R208 Inherited breast cancer and ovarian cancer

Testing Criteria

1. **Living affected individual (proband)** with breast or ovarian cancer where the individual +/- family history meets one of the criteria. The proband has:
   a. Breast cancer (age <40 years, excluding grade 1 breast cancers), OR
   b. Bilateral breast cancer (age < 50 years), OR
   c. Triple negative breast cancer (age < 60 years), OR
   d. Male breast cancer (any age), OR
   e. Breast cancer (age <45 years) and a first degree relative with breast cancer (age <45 years), OR
   f. Combined pathology-adjusted Manchester score ≥15 or single gene pathology adjusted score of ≥10 or BOADICEA/CanRisk score ≥10%
   g. Ashkenazi Jewish ancestry and breast cancer at any age

CanRisk

CanRisk Tool | Result 12:41:33 | Result 12:42:20 | Result 12:42:40 | Result 12:43:12 | Result 12:43:35 | Result 12:44:09

Print/Save Report | Save Input

Breast Cancer | Risk Category (NICE) | Ovarian Cancer | Mutations | Inputs | Extra Information

Mutation Carrier Probability

From the breast cancer model, based on the woman's information, the mutation carrier probability for a pathogenic variant in:

- BRCA1 is 19.02%
- BRCA2 is 2.98%
- BRCA1 or BRCA2 is 22.00%
- PALB2 is 2.15%
- CHEK2 is 1.94%
- ATM is 0.82%
- BARD1 is 0.19%

From the ovarian cancer model, based on the woman's information, the mutation carrier probability for a pathogenic variant in:

- RAD51D is 0.15%
- RAD51C is 0.20%
- BRIP1 is 0.10%

This results in the carrier probability for a pathogenic variant in:

- any of the genes; BRCA1, BRCA2, PALB2, CHEK2, ATM, BARD1, RAD51D, RAD51C or BRIP1 genes is 27.55%
- none of the genes; BRCA1, BRCA2, PALB2, CHEK2, ATM, BARD1, RAD51D, RAD51C or BRIP1 genes is 72.45%

R208 eligibility – small print

NOTES

- *Breast cancer definition includes high grade DCIS
- The proband's cancer and majority of reported cancers in the family should have been confirmed
- The pathology adjusted Manchester score involved incorporation of pathology data for the tested proband alone, i.e. pathology need not be sought for other family members.
- Ovarian cancer: Fallopian Tube and Primary Peritoneal cancers can be included
- BRCA1/BRCA2 testing should not typically have previously been performed. Exceptions may include, for example, patients who have been tested through the Jewish Community's NHS BRCA-Testing Programme for BRCA1/BRCA2 and not received a molecular diagnosis
- Testing of unaffected and deceased individuals can only be offered by Clinical Genetics

Refer to Genomic Medicine if
family history is unclear, complex or needs confirming
unusual cancers in the family
Genetic alteration already known in the family (include details)

Summary

Genetic test eligibility for patients with breast cancer

- Genomic Test Directory eligibility criteria
- Manchester Scoring
- CanRisk