

Source A

Adapted from Cancer Research UK [1]

What is personalised medicine?

Personalised medicine involves using information about a person's own genes to help with the diagnosis and treatment of disease, such as cancer. It is an area that researchers are still working on. Cancer treatment usually depends on:

- the type of cancer you have
- how big it is
- whether it has spread (the stage)

In the past, everyone with the same type of cancer used to get the same treatment, but we know that this "one size fits all" approach does not work for everyone.

As doctors learn more about cancer, they also learn about the differences between cancer types. For example, doctors know that there is not just one type of breast cancer, there are many different subtypes of breast cancer.

Clinical trials

Our clinical trials aim to find out if a new treatment or procedure is safe, is better than the current treatment or helps you feel better. For example:

A study of a genetic test to identify people who have an increased risk of developing prostate cancer (BARCODE 1 Study)

Please note – this clinical trial is no longer recruiting patients. We hope to add results when they are available. This study is for white Caucasian men aged 55 to 69 years old who:

- have not had prostate cancer
- have not had a sample of tissue taken (biopsy) from their prostate in the last year

Researchers hope that around 5000 people from the UK will agree to take part.

Your GP practice may send you a letter asking you to join this study, along with a participant information sheet, a consent form and a questionnaire. If you would like to take part, you need to:

- read the information sheet
- sign the consent form
- complete the questionnaire

You then send the consent form and questionnaire back to the study team using a freepost envelope. You can also contact the study team directly.

The research team looks at the questionnaire and may call you if they have any questions. They then send you a kit in the post, for you to give a saliva sample. You send the sample back to the study team using the envelope provided.

The study team looks at the sample and works out your genetic risk score.

A low genetic risk score: The study team sends you a letter with your score and you stop this study. You can call them if you have any questions about your genetic score.

You can talk to your GP if you are worried about developing prostate cancer. It is important to remember that this study does not consider other prostate cancer risks factors such as having a family history of prostate cancer.

A high genetic risk score: You receive a letter explaining these results. The study team asks you to see a doctor at the Royal Marsden Hospital in London and have some tests. The tests you might have include:

- a blood test to measure the level of a protein called prostate specific antigen (PSA)
- urine sample
- an MRI scan
- a prostate biopsy

Your doctor will tell you what happens during a prostate biopsy. You have a biopsy with a local or general anaesthetic. If your test results are normal and do not show any cancer, you have regular PSA blood tests. You have them every year, for up to 10 years. You can have the blood tests at your local GP or at the Royal Marsden Hospital. If your tests show that you have prostate cancer, your doctor will explain the different treatment options and side effects of these treatments.

Medical records: The study team will ask to look at your medical records for up to 5 years after you joined this study. They will contact your GP to find out more about you and your medical history. Only people involved in this research look at your records. Your details will be kept confidential.

[1] https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-of-a-genetic-test-to-identify-people-who-have-an-increased-risk-of-developing-prostate?_gl=1*1lwj6ps*_gcl_au*MjA0MTY2NzEwLjE3MTEwMjc5MzI.

Source B

Adapted from: Science Direct article [2]

Choosing between the EORTC QLQ-C30 and FACT-G methods for measuring health-related quality of life in cancer clinical research.

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Annals of Oncology. Volume 22, Issue 10, October 2011, Pages 2179-2190

Abstract: This review aims to assist cancer clinical researchers in choosing between the two most widely used methods for measuring cancer-specific health-related quality of life:

- the European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) and
- Functional Assessment of Cancer Therapy—General (FACT-G).

Methods: A systematic literature review was undertaken to identify all English language articles, published since 1993, which assessed the quality of the two questionnaires, focusing on the properties of reliability, validity, and responsiveness. Each property was further subdivided into several psychometric properties. (for details of psychometric properties, see below at *)

Table 4. Summary of assessments of evidence for the reliability, validity, and responsiveness of the EORTC QLQ-C30 and FACT-G.

Properties		Assessment					
		Strongly supportive		Limited or mixed		Unfavourable	
		QLQ-C30	FACT-G	QLQ-C30	FACT-G	QLQ-C30	FACT-G
Reliability	IC	1 (3%)	13 (41%)	27 (90%)	15 (47%)	2 (7%)	4 (12%)
	TR	1 (33%)	9 (75%)	2 (67%)	3 (25%)		
	IR			4 (80%)		1 (20%)	
Validity	CV		1 (33%)	1 (100%)	2 (67%)		
	IS	9 (43%)		11 (52%)	8 (100%)	1 (5%)	
	Con V	12 (64%)	16 (73%)	7 (36%)	6 (27%)		
	DV	14 (48%)	17 (63%)	15 (52%)	10 (37%)		
	PV	1 (33%)		2 (67%)			
Responsiveness	FCE				1 (100%)	5 (100%)	
	Resp	4 (20%)	3 (37%)	12 (75%)	5 (63%)		

Numbers indicate the quantity of articles rated as reporting each level of evidence for each psychometric property.

Numbers in brackets () are the percentage of the total number of articles reporting on that psychometric property.

*Psychometric properties:

IC, internal consistency; TR, test-retest reliability; IR, interrater reliability; CV, content validity; IS, internal structure; Con V, convergent or divergent validity; DV, discriminant validity; PV, predictive validity; FCE, floor and ceiling effects; Resp, responsiveness.

[2] <https://www.sciencedirect.com/science/article/pii/S092375341937735X>

