



Clinical Trials in Metastatic Breast Cancer

Understanding Your Options

Dr Olubukola Ayodele

Consultant Medical Oncologist, University Hospitals Of Leicester NHS Trust
Medical Oncology Breast Tumour Lead, Leicester Cancer Research Centre
Honorary Senior Lecturer, University of Leicester

What today is about

- What clinical trials are (in simple terms)
- Why they matter in metastatic breast cancer
- What taking part actually involves
- Pros, cons, and common concerns
- Where to find and explore trials

This is about giving you information, not persuading you

What is a clinical trial?

- A research study involving people
- Designed to improve treatment and care
- Helps answer key questions:
 - Does this treatment work?
 - Is it safe?
 - Is it better than what we already use?

Every treatment we use today once came through a clinical trial

Why are clinical trials important?

- Drive progress in treatment
- Improve survival and quality of life
- Help personalise treatment
- Offer access to new therapies earlier

Without trials, cancer care would not improve

Types of clinical trials

- New drugs/targeted therapies
- New combinations of existing treatments
- Trials focused on side effects
- Quality of life and supportive care studies

Not all trials are about trying a brand-new drug

How clinical trials work

- Conducted in a structured, step-by-step way
- Treatments are tested gradually over time
- Carefully monitored throughout
- Strict ethical and safety regulations
- Reviewed regularly by independent experts

Your safety and wellbeing are always central

Phases of clinical trials

- **Phase 1**
 - First time a treatment is tested in people
 - Focus: **safety and dose**
 - Small number of participants
- **Phase 2**
 - Looks at how well the treatment works
 - Continues safety monitoring
 - More participants
- **Phase 3**
 - Compares new treatment with standard treatment
 - Larger groups of patients
 - Helps decide if it should become standard care
- **Phase 4 (after approval)**
 - Ongoing monitoring in real-world use

Randomisation & placebos

- Some trials use randomisation:
 - Like a computer-generated allocation
- Often compares:
 - Standard treatment vs standard + new treatment
- Placebos:
 - Combined with standard of care
 - You are not left without active treatment

Myths & misconceptions

- **Myth 1: “I’ll be treated like a guinea pig”**
 - Trials are highly regulated and closely monitored
 - Your safety and consent are always prioritised
- **Myth 2: “I might get no treatment”**
 - In metastatic breast cancer, you are **not left untreated**
 - Usually: standard treatment ± new treatment

Myths & misconceptions (2)

- **Myth 3: “Clinical trials are only a last resort”**
 - Trials can be offered at different stages
 - Sometimes earlier in the treatment pathway
- **Myth 4: “My doctor is experimenting on me”**
 - Trials follow strict scientific and ethical guidelines
 - Your team will explain all options before you decide
- **Myth 5: “People like me aren’t included in trials”**
 - Some groups have been underrepresented
 - There is increasing focus on improving inclusion and access

Who might be offered a trial?

- At different stages of your treatment
- Based on:
 - Subtype
 - Previous treatments
 - General health
 - If your current treatment is still working
- Availability varies by hospital/location

Not everyone will be eligible for every trial

Benefits and considerations

- **Potential benefits:**

- Access to new treatments
- Closer monitoring
- Contributing to future care

- **Things to consider:**

- More hospital visits/tests
- Side effects may be less well known
- Uncertainty about outcomes

It's always your choice

Lack of diversity in clinical trials

- Many trials do **not reflect real-world populations**
- Underrepresentation of:
 - Ethnic minority groups
 - Younger women
 - Certain socio-economic groups
- This can affect:
 - How well treatments work across populations
 - Trust in the system

How to explore clinical trials

- Speak with your oncology team
- Ask questions:
 - Why this trial?
 - What are my other options?
 - What does it involve day-to-day?
- You can also search for trials yourself using trusted websites:
 - **UK-focused support:**
 - Breast Cancer Now
 - Cancer Research UK (trial finder)
 - Make 2nds Count (clinical trials service)
 - **National research platform:**
 - National Institute for Health and Care Research – *Be Part of Research*
 - **Global database:**
 - ClinicalTrials.gov

Questions & discussion

- What are your thoughts or concerns?
- Has anyone been offered a trial before?
- What would help you feel more confident?

- **CONTACT INFORMATION**
- **Email:** olubukola.ayodele@nhs.net
- **LinkedIn:** Dr Olubukola Ayodele “DrBookiesNuggets”
- **Instagram:** @bookslala
- **TikTok:** DrBookiesNuggets