

# **Why should and how can trainees get involved in clinical trials?**

Indrani S Bhattacharya

ST7 Clinical Oncology/ CRUK Clinical Trials Fellow

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# Clinical Trials

- Why are clinical trials important?
- -enable us to identify optimal treatment options for patients
- -consultants expected to participate in trials
- -no formal training in trial-related activities

**....so how can trainees get involved in clinical trials?**

# Ways to get involved in clinical trials...

- Breast Trainees' Collaborative Group
- NCRI Breast Clinical Studies Groups (CSG) trainee reps

## Our NCRI Groups

The NCRI Groups have been in existence for more than ten years, and are a central part of the UK's cancer research infrastructure. The NCRI Groups:

- bring together clinicians, scientists, statisticians and lay representatives, amongst many others, to coordinate development of a strategic portfolio of trials within their field
- interact with clinical research networks, funders and researchers to develop studies aimed at improving outcomes for patients
- sit within the NCRI Clinical Research Groups (CRG) Team, providing the primary, but not sole, route through which new ideas for clinical trials are developed
- have two rounds of membership rotation annually (summer and winter) and NCRI Groups seeking applicants are advertised on the [NCRI website](#).
- are funded by a consortium of NCRI partners.



# NCRI Breast CSG Trainee Reps

- 2 trainee reps per tumour group
- Current – IB and AH (2018-2020)
- Role is for 24 months (approx. 2 meetings per year)
- Number of sub-groups and lead & participate in projects within the subgroups
- Linked projects to Breast Trainees' Collaborative Group
- Next advert will be Spring 2020, to start Autumn 2020

# Dedicated Trials Fellowships

- Clinical Trials Fellowships
- CRUK 'Clinical Trials Fellowship'
- Trainees apply jointly with a clinical trials unit (CTU)
- Network of CTUs across the UK (each have certain expertise)
- 1-3 years embedded within the CTU developing skills needed to run future trials
- Enables additional sub-studies to be conducted maximising data obtained
- Can obtain a higher degree (not compulsory)
- Alternative to traditional lab-based/ technical radiotherapy based research

# CRUK Clinical Trials Fellowship

- When to apply? (post-FRCR)
- Joint application with ICR-CTSU
- 50% funded by CRUK- match funded by host (ICR)
- 3-year full-time fellowship & PhD
- No clinical work
- Work across a range of trials
- Primarily breast radiotherapy trials: IMPORT & PRIMETIME (patient-reported outcomes)

# Work within studies in the CTSU

- PRIMETIME
  - - case report form development
  - - development of decision aids closely with **patient advocates**
  - - developed a study within a trial (SWAT)
- IMPORT
  - -data checking with data managers
  - Review of SAE for IDMC
  - Sub-studies of patient-reported outcomes
  - Sub-studies using RTTQA CT planning scan data
- Became member of PRIMETIME and IMPORT Trial Management Groups

# Trial Management Groups

*The TMG is a multidisciplinary committee responsible for overseeing the clinical, scientific and operational aspects of the trial*

- input into and critically review the **trial protocol**, risk assessment and case report forms
- oversee the **on-going conduct** of the trial
- **provide clinical or other expert guidance** to ICR-CTSU and participating sites
- provide **leadership to sub-studies** or projects associated with the main trial
- develop **strategies to optimise recruitment**
- input into the monitoring and classification of serious adverse events (SAEs)
- **promote the trial and maintain the profile of the trial** during its follow-up phase



# Trial Management Groups

- Who are the TMG members?
- *-CI, CCC, trials team from coordinating CTU, PI, collaborators, patient advocates*
- Trainees involved in sub-studies e.g. translational, patient-reported outcome can become TMG members
- Benefits for trainees
  - -understand how trials are being run and what are the issues
  - -learn from other sites
  - -importance of future-proofing

# Summary

- Clinical trials are needed to identify the optimal treatment approaches for patients
- In-training or out-of-training opportunities to get involved
- Next generation of consultants must be equipped to conduct trials