

Project title: Online tool for guidance on designing biomarker-guided randomised controlled trials (www.bigted.org)

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Purpose of grant: The approved funding was to cover the costs of an IT specialist working within the University of Liverpool CTTC to develop a website using interactive visualisation to provide a user-friendly and easily accessible resource for informing those embarking on a biomarker-guided trial on the most optimal trial design. The intention was for the website to mirror the findings from two recent systematic reviews of biomarker-guided trial designs, as published by the project's group, but in a much more accessible format. The funding was also to attend conferences (1 UK and 1 European) to publicise the website, and to host the website.

The original objectives:

- Develop a freely and easily accessible website (www.bigted.org) for end-users to browse using interactive visualisation and to aid them in choosing the best biomarker-guided trial design for their needs.
- Promote use of the website by publicising it at conferences.

The key deliverables:

- A functioning and sustainable, freely accessible and user-friendly online tool to provide guidance on the various biomarker-guided trial designs, including information on each design's benefits and limitations, how patients flow through the trial, randomisation arms, interim analyses and (for adaptive designs) potential adaptations. To aid in providing this guidance, the graphical representations of each trial as presented in the systematic reviews would be replicated on the website, with 'hover and click' capability to aid explanation.
- Promotion of use of the website at meetings and conferences.

What was achieved:

- The online tool was developed as planned, and is now freely available and easily accessible at www.bigted.org
- The online tool was promoted via a short presentation as part of an invited session at ICTMC/SCT 2017, chaired by Dr Andrea Jorgensen
- The online tool was promoted as part of an oral presentation by Miranta Antoniou at ISCB 2017

- The online tool has been described (whilst in development) to the Stratified Medicine Strategy Group at CRUK during a visit by James Wason and Andrea Jorgensen on behalf of the MRC HTMR Stratified Medicine Working Group
- The online tool has been promoted via a tweet from the MRC HTMR Network

Plans for the next 12 months:

- We have secured further network funding for a 9 month postdoc position to investigate issues arising when including continuous biomarkers within a biomarker-guided trial. It is anticipated that BiGTed will be updated to reflect relevant findings from this project. The fourth objective of that network funded project states: “The fourth objective will be to consider, for the various biomarker guided trial designs identified in our previous work, and which feature on our BiGTed website, how information on continuous biomarkers should be incorporated into the different trial designs, including during the developmental phase of the biomarker when an optimal threshold has not yet been chosen, and also during later phases when the biomarker is dichotomised. This work, together with findings from our systematic reviews of the literature on choosing thresholds, will feed into guidance that we will publish to help those designing trials with continuous biomarkers in future. We will also update our online tool, BiGTed, with this guidance.”
- Continue promoting the website during presentations at conferences and meetings (promotion slide/weblink)