

Cystic

Fibrosis advancing care with clinical trials

Clinical Trials Accelerator Platform (CTAP) Commercial Involvement (Patient & Public Involvement)

'Patient & Public Involvement' (PPI) is a UK term used to describe engagement of Sponsors with patient advocacy groups. It is regarded as a highly important component of the UK regulatory process, with the UK Health Research Authority (HRA) strongly encouraging all Sponsors to **engage with PPI during trial design**. It is now widely acknowledged that the inclusion of PPI at all stages of the trials process **leads to better recruitment and retention rates**.

What is Commercial Involvement?

At the Trust, we prefer to refer to PPI as **Commercial Involvement**, recognising that people living with cystic fibrosis (CF) only identify as 'patients' in a hospital setting. This involvement should be an active and collaborative opportunity for Sponsors and the CF community, that allows CF representatives to act as advisers and partners.

How can Commercial Involvement benefit Sponsors?

- Access to an engaged and diverse representation of the CF community
- Focus group discussions via remote technology
- One-to-one interviews to access a specific knowledge base
- Protocol reviews by trained CF representatives
- Review of design and content of Patient Information Sheets and Consent Forms
- Support writing of lay trial summaries and lay result summaries

Maximum benefit can be achieved by initiating involvement at the earliest possible stage of a clinical trial concept or design, but involving CF representatives at any stage can enhance the progress or reporting of a trial.



Why involve the CF community?

Feedback from both Sponsors and CF representatives is overwhelmingly positive. Sponsors obtain an insight into living with CF that can enhance their clinical trial plans, making trials more attractive and feasible for people living with CF to take part in, alongside the existing burden of treatment associated with the condition. CF representatives feel valued, having the opportunity to help Sponsors and contributing to potential advances for future CF generations.

Feedback from sponsors and researchers

100% strongly agreed involving CF representatives improved their study.

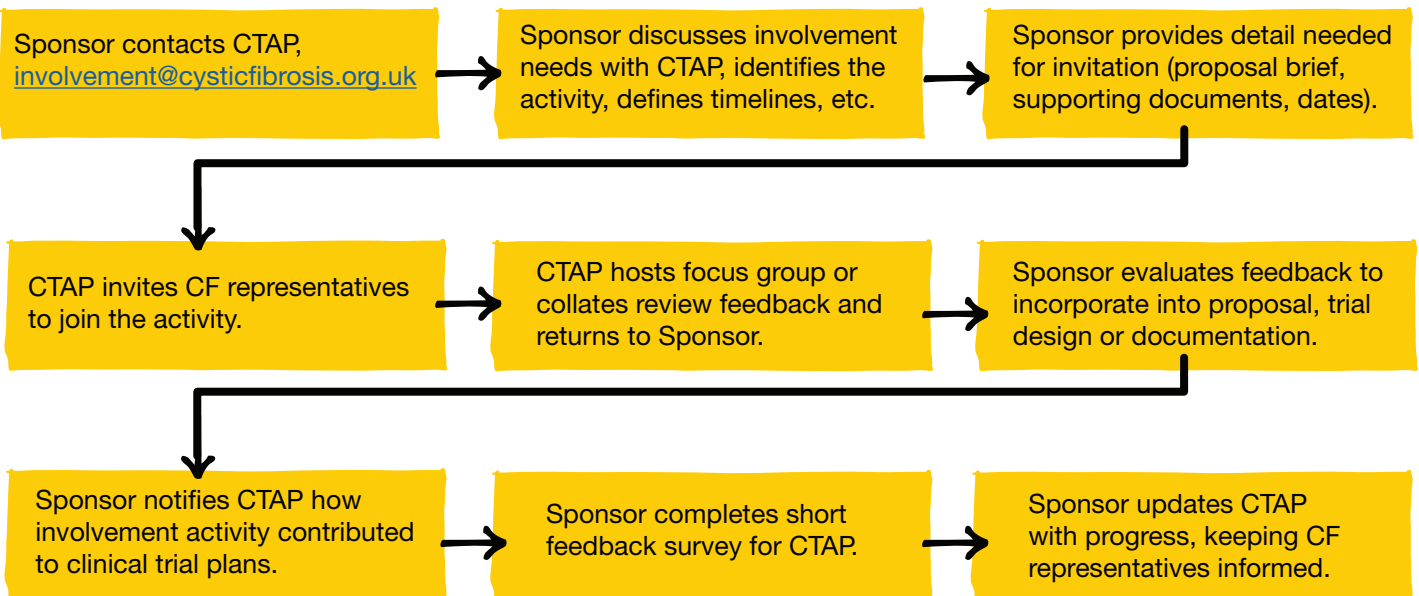
"We gained real lived experience from people with CF focused specifically around our questions. The people that attended the focus group were engaged, open and brought extremely relevant experience and knowledge to the table. The focus group was invaluable and will support the future of our project." – Project Lead, Drug Discovery Syndicate

"Extremely useful discussions via videoconference with the PPI group, which were instrumental in our plans for designing a clinical trial." – Lead Investigator, trial design working group

How to involve the CF community?

We have an established group of CF representatives (people with CF, and parents of children with CF) ready to share their lived experience to support Sponsors with trial design and delivery. We endeavour to provide an easy, straightforward process for Sponsors to engage with our community and collaborate on their proposals, getting maximum benefit from the engagement and any involvement activity.

Process for involving the CF community



To find out how we can help with your involvement requirements, please contact the CTAP Involvement Manager, Lorna Allen, involvement@cysticfibrosis.org.uk

cysticfibrosis.org.uk

© Cystic Fibrosis Trust 2020. Registered as a charity in England and Wales (1079049) and in Scotland (SC040196). A company limited by guarantee, registered in England and Wales number 3880213. Registered office: 2nd Floor, One Aldgate, London EC3N 1RE.

Fighting for a
Life Unlimited