Joint BIA-FPM workshop

'The Patient is Waiting': workshop on strategic options for expediting clinical research

Thursday 27th April 2017

Hosted by the Faculty of Pharmaceutical Medicine, Angel Gate, London

Summary document

The BIA's Science & Innovation Advisory Committee and Faculty of Pharmaceutical Medicine (FPM) brought together representatives from Biotech, Pharma, the MHRA, Academia and Medical Charities, to discuss strategic options for expediting clinical research. The combined experience of the workshop attendees from across the biotech/healthcare community, reinforces the fact that the United Kingdom remains an extremely attractive region in which to conduct the clinical development of new treatments modalities; both early and late phase. The intention of both the BIA and FPM was to address some of the points highlighted, such as the good science base supporting pre-clinical to clinical translational science and the many opportunities for patient recruitment via specialized networks, by bringing together all the relevant parties, and encouraging open dialogue; these points being cited as features making the UK extremely attractive as a region for conducting clinical trials.

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The workshop was hosted by the Faculty of Pharmaceutical Medicine (FPM), in their new offices in Angel Gate, London; it was opened by joint chairs, Professor Alan Boyd, President of the FPM, and Dr Will West, Vice-Chair of the UK BioIndustry Association (BIA) Science and Innovation Advisory Committee (SIAC). Representatives from Large Pharma, Biotech, and the MHRA gave short talks, which were then followed by discussion sessions.

Professor Simon Hollingsworth, Executive Director and Global Project Leader at AstraZeneca, gave the first talk; discussing the challenges of precision oncology drug development, and providing some examples of best practise and potential pitfalls from large Pharma.

The workshop then went on to discuss opportunities for removing barriers to the expedition of clinical research.

Dr Penelope Ward, Chief Medical Officer at Karus Therapeutics, gave the next talk; discussing Innovations to expedite clinical development: a SMART approach.

The workshop then discussed the application of science in expediting clinical studies.

Dr Kirsty Wydenbach, Deputy Unit Manager and Senior Medical Assessor at the MHRA Clinical Trials Unit, gave the final talk; providing a Regulatory Authority Perspective on options for expediting clinical research.

The workshop then discussed what additional regulatory initiatives could be considered to enable/expedite early studies in humans.

Overall, the following features, that could enhance modern trial approaches, were highlighted and discussed; these are being increasingly adopted by the pharma industry:

1. **Support for translational medicine collaborations and stratified medicine approaches**

a) Increasing the number of networks participating in multi stage translational activities, with the objective of enhancing stratified medicine approaches to increase early patient access to novel therapies. Exemplars of such networks include PRECISION-Panc and the National Lung Matrix Trial, which can stand as models for the development of other similar networks in multiple disease arenas beyond oncology
b) To enable the extended use of stratified medicine approaches, a national databank of patient samples linked to clinical data would enable an improved understanding of the frequency of patients with specific mutations or molecular aberrations, amenable to targeted therapies, within the population; increasing the chance of technical success for therapies designed to target these disease sub-types. This would enable, for example, researchers to identify specific gene frequencies in patients following first, second, third, etc. line of prior therapy

2. **Enhancing disease understanding and improving trial efficiency by design**

a) Encourage a 'systems biology' approach to understanding disease pathogenesis, e.g. by creating an open source data sharing environment and facilitating the formation of 'expert networks' to facilitate access to, and increased use of, systems biology approaches to disease research
b) Support for an expert network dedicated to 'modelling and simulation' approaches to enhance trial designs and improve use of novel statistical methods enabling greater trial designs, particularly for studies in diseases with small patient populations
c) Support for development of unified lifelong collection of all patient data to permit development of models of disease progression/regression enabling use of real world evidence to enhance (b)

3. **Facilitating access to clinical trials across the nation**; consider 'cross regional' funding to enable patients to access trials being conducted at clinical sites outside of their NHS region

4. **Reducing points of delay in trial start up processes**

a) Reinforcement for/mandating use of the ABPI model clinical trial contract for sponsored trials at local level across all NHS sites and administrations within the UK
b) Enhanced, user friendly access to the NRES/HRA on line application tools
c) Support for training of ethics committee members on trial methods and risk benefit assessment

5. **Increasing, and earlier, interaction with the MHRA Clinical Trials Unit and Innovation Office**

a) This provides access to world-class knowledge, expertise and experience from specialists across MHRA, CPRD (Clinical Practice Research Datalink) and NIBSC (National Institute for Biological Standards and Controls), helping to ensure that queries and discussion points have been reviewed and answered by the most relevant experts in the field
b) This includes UK and EU regulatory advice; information, advice and guidance that clarifies UK and EU regulatory requirements and helps ensure confidence in the development of innovation for either regulatory environment