Faculty of Pharmaceutical Medicine publishes

Clinical Trials Resilience Survey Report

15/12/20

For immediate release

The Faculty of Pharmaceutical Medicine (FPM) today publishes the Clinical Trials Resilience Survey Report. The report is based on the results of a survey of FPM members and non-members. The survey was undertaken to understand the pressures on clinical trials brought about by the COVID-19 pandemic, and the resulting adaptations and innovations that those working in pharmaceutical medicine have made.

The results of the survey have been illuminating. We have learnt about a myriad of changes and adaptations that have been made by pharmaceutical physicians and their colleagues in big pharma, small biotechs, contract research organisations and regulators. Most of the respondents were involved in running trials, and the survey demonstrated that only one or two stopped the trials prematurely. Most paused recruitment and made creative changes to continue and adapt clinical research programmes and are re-starting trials.

Some of these adaptations are fundamental, like the shift towards variations on remote monitoring and an increasing use of adaptive trial designs and the amalgamation of development phases. Many are likely to become integrated into 'normal' practice and may bring about permanent changes to the specialty of pharmaceutical medicine and the wider industry.

The outputs and recommendations within the report will support the clinical trials infrastructure, both in the UK and globally, learn and develop as a result of the COVID-19 pandemic and be more resilient to such challenges in the future. They are relevant to the pharmaceutical industry and the service sector, regulators, governments, academic centres and clinical trial investigators.

- Over half the respondents stated that they personally, or their company, have been developing treatments or vaccines for COVID-19
- 79% of all respondents reported that other clinical research programme activities in their organisation had been impacted by the pandemic
- Almost all respondents reported the use of virtual and digital technologies to keep trials running and keep patients and investigators safe
- Respondents from both pharmaceutical and the service sector praised the speed and flexibility of regulatory agencies around the world
- Almost half of respondents reported that the pandemic had impacted their organisation's standard operating procedures (SOPs) for clinical programmes and trial design

Comment from Dr Flic Gabbay, Vice President of the Faculty of Pharmaceutical Medicine:

"Some really valuable information has been generated from this survey, uniquely from a mix of pharma, service sector, academia, investigators and regulators. It demonstrates how much increased collaboration and scientific ingenuity made rapid change to keep patients in trials. This was essential to protect innovative research programmes and kept patients safe during the pandemic. It must have involved a great deal additional resource and determination at all levels and in all sectors.

The report highlights a number of issues we have to address, in terms of future guidance to maintain standards and to adjust to reviewing evidence and quality of trials that have been hit during this period. Ultimately, we must benefit from these activities, to make the trials future-proof and develop standards for aspects such as remote working. These activities will continue to improve the efficiency and resilience of the pharmaceutical, regulatory and academic research and development community."

Comment from Dr Sheuli Porkess, Chair of the Policy and Communications Group of the Faculty of Pharmaceutical Medicine:

"The pandemic has forced us to think differently about many aspects of life. Pharmaceutical medicine is no different and the way we do clinical research has had to adapt. The Faculty of Pharmaceutical Medicine aims to advance pharmaceutical medicine and we have drawn on the expertise of our members in order to provide a report on what needs to be done to make sure clinical trials are resilient to any further disruption. This report contains key insights on what trial sponsors and others need to do to ensure their trials are fit for now and the future, whilst continuing to be scientifically robust and ethical. We look forward to working with all stakeholders to embed the learnings from the report as we rebuild clinical research across all areas."

Comment from Dr David Jefferys, Trustee and Board member of the Faculty of Pharmaceutical Medicine:

"The report released today clearly shows the impact of the pandemic and the challenges for recruiting patients into trials and for maintain patients in trials. It is impressive to see the response of all the stakeholders to establish studies for vaccines and for new treatments for COVID-19. There has been cooperation at pace with the regulators. New flexibilities and agilities have been introduced and new approaches adopted. The report highlights the role that pharmaceutical physicians have played.

It has been so critical that clinical research has been maintained. Had this not happened, future patients would have suffered too, through delayed or abandoned new medicines. What is especially pleasing is how individual physicians and companies of all sizes have been willing to share best practices in the interest of clinical research and ensuring patient safety."

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Notes for Editors

Please contact Ben Cottam, Head of Policy and Communications, for more information:
b.cottam@fpm.org.uk
020 3696 9034
07912 600 645
Website: www.fpm.org.uk

The FPM is a professional membership organisation and standard-setting body, with 1,500 members who are practising or retired pharmaceutical physicians or those with a professional interest in the speciality. FPM's mission is to advance the science and practice of pharmaceutical medicine by working to develop and maintain competence, ethics and integrity and the highest professional standards in the specialty for the benefit of the public.