Abstract

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Pandemic-future proofing clinical trials: lessons learnt from London

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Abstract

Statement of the Problem:
In 2020 non-COVID UK research was substantially reduced. The number of trials dropped 26% in Q1/Q2 of 2020 vs 2019 [1]and there were approx. 480,000 participants in non-covid research in 2020 vs 732,716 in 2019.
The pandemic in the UK had one of the highest infections per capita in Europe in three discrete 'waves' (March-May 2020, Nov 2020-Feb 2020, July 2021).[2]

Methodology and Theoretical Orientation:
We present the experience of a clinical research organization in London at the epicenter of the first wave. Richmond Pharmacology (RPL) conducts clinical research in both healthy and patient volunteers, including COVID vulnerable conditions such as cardiac amyloidosis, type II diabetes and Wilsons' disease. Early on a bespoke infection control guideline was established and adapted throughout the pandemic as required. This guideline has included on-site 30-minute turnaround PCR capability, strict entry protocol, HEPA filtration, mandatory N95 masks, social distancing, electronic contact tracing, vaccination and antibody testing. We also instituted an internal trial methodology collecting all data to constantly inform management decisions.

Findings:
RPL consistently reported positivity rates well below the national estimate (ONS data). Between March 2020 and Sept 2021 there were 69 community-acquired infections amongst volunteers and visitors, 90 PCR-positive infections amongst approx. 300 staff, significantly with zero documented cases of internal transmission.

Conclusion & Significance:
As a result, after the first wave we were able to continue normal clinical trial activity performing 29 early and late phase clinical trials enrolling 1225 volunteers (319 patients, 906 healthy volunteers) dosed between June 2020 and Oct 2021, with bed occupancy in the second wave comparable to pre-pandemic levels.
We present a gold-standard model of pandemic interventions to mitigate risk in an environment of high virus prevalence and a benchmark for continuing drug development in healthy and patient populations in anticipated future crises.

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Biography

Dr Jorg Taubel is medical practitioner and CEO of Richmond Pharmacology, a centre of excellence for experimental medicine studies, which he co-founded in 2001. A specialist in clinical pharmacology, Dr Taubel has extensive experience in cardiology, neurology, gastroenterology, and ethnic bridging studies. He was Principal Investigator in over 500 clinical trials in Phases 1 – 3. He is an MHRA recognised investigator for First in Human trials involving healthy and/or patient participants.

Most recently Dr Taubel has dosed the first patient in the pioneering global FIH study of NTLA-2001, the first CRISPR-Cas9 in vivo gene editing for transthyretin (TTR) amyloidosis. Working in close collaboration with Professor Julian Gillmore at Royal Free Hospital, Dr Taubel has enrolled the largest cohort of ATTR heart failure patients in five clinical studies. Dr Taubel also established the Richmond Research Institute, a not-for-profit organisation dedicated to academic research to clinical trial optimisation.

