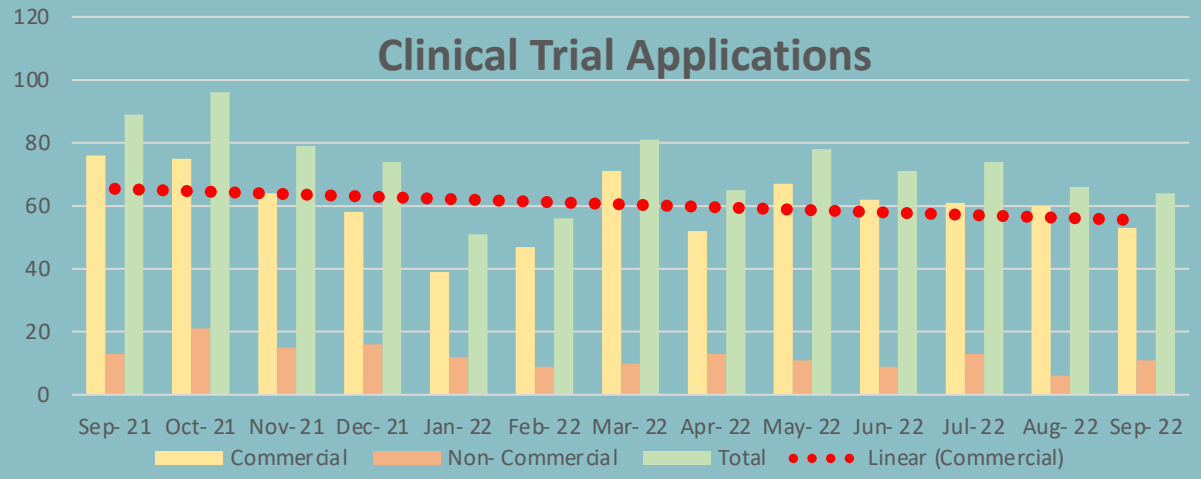
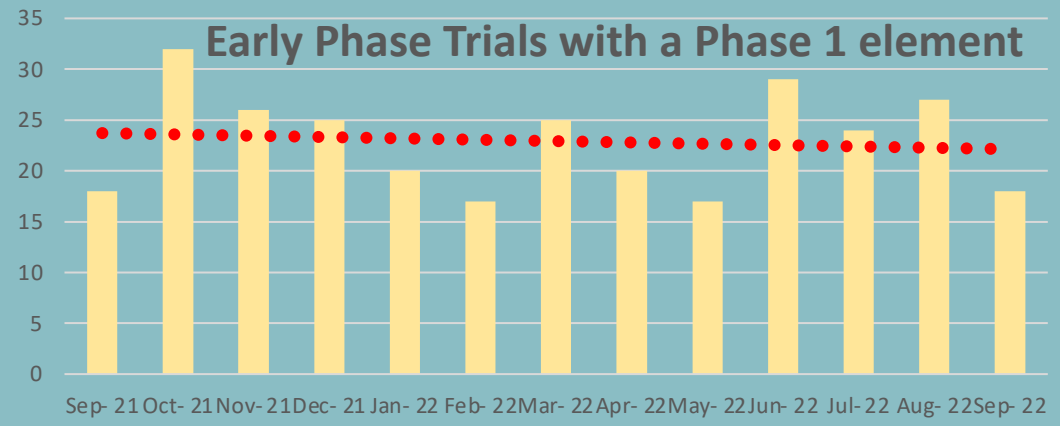
AHPPI
Association for Human Pharmacology in the Pharmaceutical Industry

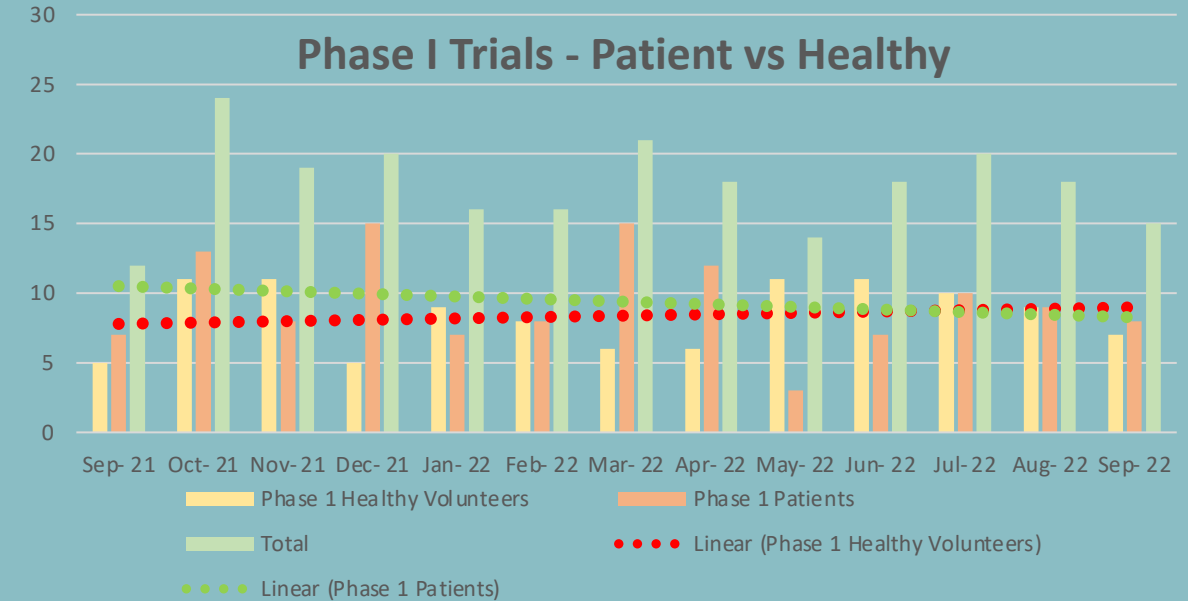
Discussion session: Conducting interactions with the MHRA

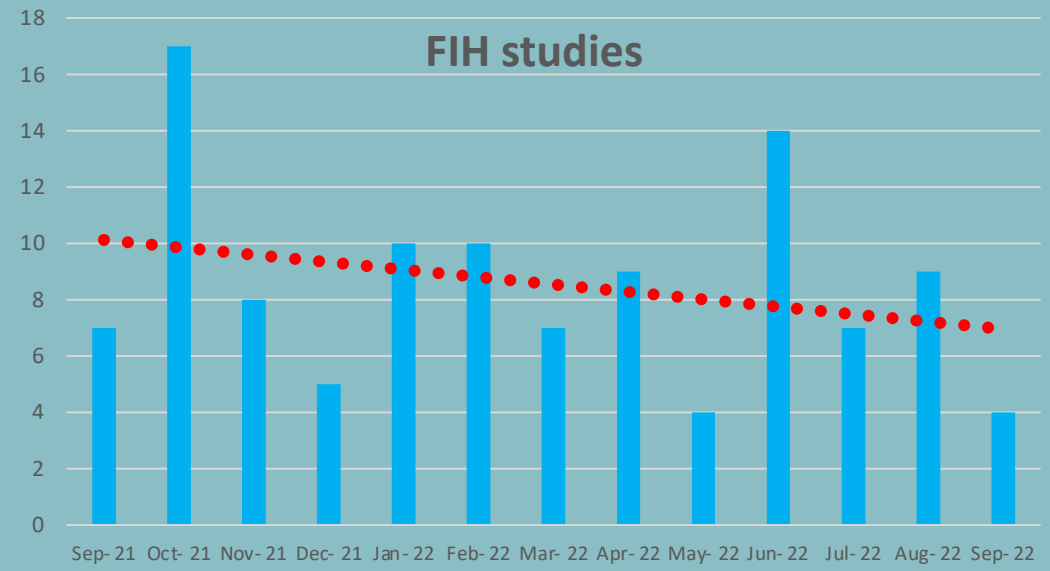
AHPPI meeting - 7th December 2022

Clinical trial applications Sep 21 – Sep 22









Why issue the survey

To explore ways the community (sites & regulators) can work together to improve the current landscape and ensure the accredited Phase I units continue to play a vital role in global research

Applications/Amendments and response times 2022

Of the applications made to date, (2022) what percentage have received an initial response within 30 days from submission?

4 /6 stated 50% or more of applications took longer than 30 days for an initial response.

On average, how long does it your organisation/sponsor to respond to points raised within Notices of Non-Acceptance?

7-10 days on average across the sites

Where a response to notices of Non-Acceptance have been made, what was the average time for approval (counting days from initial submission)?

1 site – on average <30 days

3 sites – 31 – 60 days

2 sites - >60 days

Where a response to an application of a substantial amendment was necessary, what was the total time to gain approval (counting days from initial submission to approval)?

Variable 10-60 days (66% <10days)

Discussion session
Improving the UK regulatory landscape

The why is clear!

- How
- What
- Who
- When

Can you provide suggestions on ways in which the Phase I community could aid the MHRA in improving its functionality and competitiveness

- **Communication**
  - Timelines
  - Between assessors and the applicants
- **Predictability**
  - Standards and previous Fast-track review if accepting all recommendations made by the MHRA.
- Support the development of **clear standards and guidance** around the accepted boundaries/parameters of adaptive design studies in healthy volunteers and the nuance of healthy volunteer research vs patient focused research
- A **dedicated Phase 1 CTA review** team solely focussed on review of Phase 1 studies
- Highlight clearly within initial submission processes as to which documentation within a CTA have been previously reviewed and approved by the MHRA
- Request the possibility of being able to submit **staggered responses to consolidated feedback** as and when this becomes available from each respective assessor
- CTIS – A great opportunity for UK PLC

Who Am I?

Director of Operations – Richmond Pharmacology

- ✓ Scientist by training yet commercially focused
- ✓ Oversight – Volunteer & Patient Recruitment
- ✓ Commercial Management of the Organisation

Engaged in >300 clinical trials FIH to PIII

- ✓ Currently 50:50 split – Patient v Healthy Volunteer
- ✓ Lead all recruitment feasibility studies
- ✓ Track record of delivering studies to schedule

Incoming Chair – Fulham Research Ethics Committee

RICHMOND Pharmacology