Medicines & Healthcare products Regulatory Agency

Collaboration in clinical trials

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CPRD NIBSC MHRA

Agenda

MHRA portfolio of Vaccine Trials

G7 and Pandemic Preparedness Partnership

Potential areas for increased international harmonisation and collaboration

Proposals to take forward

Breadth of MHRA Vaccine Studies: Products

Approved in trials:

- Oxford/AstraZeneca (viral vector)
- Pfizer/BioNTech (mRNA)
- Janssen (viral vector)
- Moderna (mRNA)
- Novovax (recombinant spike protein)
- Valneva (inactivated whole virus)
- Imperial College London (saRNA)
- Medicago (Coronavirus-Like-Particle (CoVLP))
- Codagenix (ive-attenuated vaccine)

All reviewed with input from independent Commission on Human Medicines expert group(s)

Breadth of MHRA Vaccine Studies

- Adults
- Children
- Pregnant women
- Immunocompromised
- “Mix and Match”
- Third dose boost (homo/heterologous)
- Concomitant with Influenza vaccine
- Variant vaccine (against the South Africa B.1.351 strain)
- Intranasal /aerosol dosage forms
- Adjuvanted

Why is international collaboration important?

- Global healthcare emergencies need a global response.
- During the COVID-19 pandemic, rapid, robust and randomised trials have played a critical role in informing public health and clinical decisions.
- However, while vaccine development has been faster in this pandemic than ever before, improvements can be made
  - For example, there was no overall coordination of trial testing methodology
  - More effective international collaboration on trials would have made better use of scarce resources and may have saved lives
  - Generally, clinical trials have often been too small, duplicative, fragmented and poor quality.

There are clear outcomes for regulators from G7 and the pandemic preparedness partnership

- “…work with regulators, ethics institutions and committees to achieve greater harmonisation and to streamline regulatory process to act more proportionately to risk.” (G7 Charter)
- “…we will accelerate the sharing of data and results so that therapeutics proven to be effective and safe can be approved by regulatory bodies, incorporated into clinical practice guidelines and recommended for use in routine practice.” (G7 Charter)
- “…we should expect safe vaccines, regulated by a Stringent Regulatory Authority (SRA) and ready to be produced at a global scale, to build immunity and prevent infection” (100 Day Mission)
- “SRAs, working with WHO and other relevant organisations, should streamline, harmonise and simplify regulatory processes in business as usual, and agree a faster and joined-up approach in pandemics.” (100 Day Mission)

Where might we increase collaboration?

- Joint scientific advice
- Harmonisation of protocol design
- Harmonisation of submission requirements
- Sharing of assessment reports and decisions
- Timely sharing views/decisions on results
- Question: How do we bring ethics along with us?

Proposal

- To explore more collaborative ways of working to harmonise and streamline the design and approval of international vaccine trials taking into account pre-clinical, manufacturing/quality and clinical aspects

- To further collaborate with, and provide international thought leadership to help drive forward G7 (and subsequent G20) priorities.

- An ICMRA Clinical Trials Working Group?