IHI Call Days | Call 12

ISIS : Innovative Solutions to Inform Study Inclusion of Pregnant Women

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Link to the IHI Brokerage Platform:

- Wolfreys

Challenges and objectives

- IHI Objective SO2 : integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users
- Inclusion of WoCBA and pregnant women in clinical trials will increase in the coming years
  - Increasing interest in industry and with Health Authorities alike not to exclude WoCBA and pregnant women from clinical research
  - Finalisation and implementation of the ICH E21 guideline on inclusion of pregnant and lactating individuals in clinical trials by 2027 will contribute to changes in the landscape
  - However, the amount of data, the study types and the acceptability of data packages to enable inclusion of WoCBA / pregnant women in clinical trials are not harmonised across industry or with regulatory authorities
  - There is a lack of clarity on building evidence based risk assessments to support safe and inclusive clinical research in WOCBA and pregnant women
  - The increasing pressure on reducing the use of animals will also influence the future landscape, and novel approach methodologies will have increased prominence

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Your approach to solve the problem

Vision:

A public-private, cross-sectoral partnership enables development, validation, and implementation of innovative tools and processes that no single sector could achieve alone

Solution:

- Map the available and in-development novel and current in vivo Reprotox studies and NAMs (in vitro, ex vivo, in silico, AI/ML) and identify strengths and weaknesses and context of use
- Integrate and analyse available data from in vivo reprotox studies and NAMs to identify remaining gaps and improve risk/benefit assessment
- Foster collaboration between biotech/pharma, CROs, academia, and regulatory agencies to establish how these can be integrated into a weight of evidence approach to achieve regulatory alignment on inclusion of WOCBA in clinical trials
- Share data, expertise, and best practices across all stakeholders

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Is your project suitable for IHI?

Experience and expertise are found across industry and across different sectors, meaning that only a private-public partnership will enable Project ISIS to succeed.

Ultimately, success of this project will enable **safer access to novel therapies for pregnant women**.

Outcomes and Impact

- Increase knowledge on strengths/weaknesses and context of use of a toolbox of available assays to address specific questions on inclusion of pregnant women in clinical trials
- Enabling access to safer, more effective and equitable therapies for WOCBA including pregnant women by creation of a framework for improved benefit-risk assessments and regulatory authority acceptance

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Expertise and resources

- We have:
  - UCB will be a co-Lead
  - in-kind contribution
  - collaboration and commitment from EMA
- We are looking for:
  - industry co-lead
  - Industry partners with expertise in either reproductive toxicology data packages and/or NAMs for reproductive endpoints ((small molecule drugs or biologics)
  - Industry partners with experience in regulatory authority submissions regarding WOCBA
  - Academic partners with expertise in novel reproductive toxicology and/or NAMs technologies

* IKOP - in-kind contributions to operational activities

** IKAA - in-kind contribution to additional activities

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