



Anti-Biopharmaceutical Immunization: prediction and analysis of clinical relevance to minimize the RISK (ABIRISK)

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Research Areas



Biomarker Research



Basic Research

At a Glance

- Status: **Active Consortium**
- Year Launched: **2012**
- Initiating Organization: **Innovative Medicines Initiative**
- Initiator Type: **Government**
- **Rare disease**
- Location: **Europe**

Abstract

Anti-Biopharmaceutical Immunization: prediction and analysis of clinical relevance to minimize the RISK (ABIRISK) is a consortium managed by the Innovative Medicines Initiative (IMI). ABIRISK seeks to provide an integrated approach to anti-drug immunization by evaluating immunogenicity in hemophilia A, multiple sclerosis, and inflammatory diseases, and by exploring new tools for protein drug immunogenicity. By examining the correlation between patient and clinical factors and the incidence of immunogenicity, ABIRISK hopes to reduce the regulatory and resource burdens of immunogenicity testing.

Mission

ABIRISK aims to develop an integrated approach to anti-drug immunization through examination of immunogenicity in three other conditions: hemophilia A, multiple sclerosis, and inflammatory diseases. The data collected will be pooled in a single immunogenicity databank and will be standardized and used to develop models of anti-drug antibodies.



The objectives of the consortium are as follows:

Consortium History

2012: ABIRISK was started as a 60-month project.

Structure & Governance

ABIRISK is grouped into five working projects, which communicate with one another and provide each other with results and data for analysis. The five working projects are ADA assay development and validation and cohort management; cellular characterization and mechanisms of the AD immune response; evaluation and development of technologies for predicting immunogenicity; establishment of database, data analyses and integration; and project management and communication. Each working project has three to four team leaders.

As with other IMI-managed consortia, ABRISK project teams are managed by an IMI project manager, who reports to the IMI executive director.

Financing

ABIRISK received total funding of £34.9 million, which was broken down into IMI funding (£18.2 million), in-kind funding contributions from the European Federation of Pharmaceutical Industries and Associations (EFPIA; £11.2 million), and £5.5 million from other sources.

Intellectual Property

All IMI projects, such as ABIRISK, operate under the same intellectual property (IP) umbrella. Any IP discovered as a result of work in the collaboration is owned by the participating institution that made the discovery (or if the discovery was made jointly, by both institutions). Other participants have access



rights to the generated IP during and after the project for research use, and participant owners have the right to license their IP and associated obligations to other parties, including to affiliated entities. Third parties may request access rights, which do not involve the ability to sublicense without receiving authorization from the IP-owning participant.

Patent Engagement

ABIRISK recruits both retrospective study patients (after patients suffering from the three disease groups have undergone immunotherapy treatment) and prospective patients into dedicated studies. Uniform protocols were established to facilitate standardized data collection from both sets of patients.

Data Sharing

Uniform protocols were established to facilitate standardized data collection from both sets of patients. The intent of ABIRISK is to share its data as quickly as possible through its immunogenicity databank. In keeping with IMI policy, the project has up to one year after completion to disseminate IP or data created by the project.

Impact/Accomplishment

To date, nine publications have been released from groups associated with the ABIRISK project.

Links/Social Media Feed

Twitter	https://twitter.com/IMI_JU
LinkedIn	https://www.linkedin.com/groups/Innovative-Medicines-Initiative-1126077
Other social media	https://www.youtube.com/user/imichannel
Homepage	http://www.abirisk.eu/index.html
Other website	http://www.imi.europa.eu/content/abirisk

Points of Contact

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Alternatives

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