

1st Announcement and Call for Abstracts

Towards Global Scientific Best Practices for Immunogenicity Assessment

Moving Beyond Regional Guidelines Towards Science-Driven Global Alignment

June 17-18, 2027 - NH Málaga, Spain

INTRODUCTION & AIM OF THE WORKSHOP

Immunogenicity assessment has become a critical component of the development and regulatory evaluation of therapeutic proteins, biosimilars and emerging modalities. Over the past decade, regulatory guidance has evolved considerably, with dedicated recommendations now available from the FDA, EMA, NMPA (China) and other health authorities.

Although these guidelines share many common scientific principles, important differences remain in expectations regarding assay strategies, data interpretation and the clinical application of immunogenicity results. For companies conducting global development programmes, these differences often lead to additional complexity without necessarily improving scientific understanding or patient benefit.

This Focus Workshop aims to move beyond a comparison of regional regulations and instead identify the scientific principles that should underpin immunogenicity assessment worldwide and support the development of globally harmonised, science-driven best practices.

CALL FOR ABSTRACTS

We invite abstracts for presentations that align with the workshop's key themes:

1. **Global Regulatory Perspectives – Where Do We Align and Where Do We Differ?**
   - Experiences with FDA, EMA, NMPA, PMDA/MHLW or other regional expectations.
   - Scientific rationale behind differing regulatory approaches.
   - Impact of regional differences on global development programmes.
2. **Clinical Relevance of Immunogenicity**
   - Interpreting ADA data beyond assay performance.
   - Clinically meaningful immunogenicity assessment: integration of ADA with PK, PD, efficacy and safety.
   - Case studies demonstrating science-based decision making.
3. **Towards Science-Driven Best Practices**
   - Risk-based immunogenicity assessment strategies.
   - Experiences supporting globally applicable scientific approaches.
4. **Future Directions**
   - Opportunities for greater global scientific alignment.
   - Lessons learned from regulatory interactions.
   - Proposals for future international best practices.

Abstract Submission Deadline: 21-MAR-2027
Submit your abstract at to focus@e-b-f.eu . Abstracts will be evaluated for their scientific quality, relevance and their ability to stimulate discussion. Acceptance notifications will be sent by 05-APR-2027.

MEETING AGENDA & FORMAT

The agenda will feature a combination of invited keynote presentations, scientific contributions selected through this call for abstracts, interactive roundtable discussions and case studies from the EBF community.

Consistent with the philosophy of EBF Focus Workshops, presentations should stimulate discussion rather than provide comprehensive reviews. Speakers are encouraged to present scientific challenges, practical experiences and unresolved questions that will contribute to the development of future best practices.
The meeting will start at **09:00 CET on 17-JUN-2027** and end at **16:30 CET on 18-JUN-2027**.

WHO SHOULD ATTEND?

This workshop is intended for scientists involved in immunogenicity assessment, bioanalysis, translational sciences, clinical pharmacology and regulatory sciences from pharmaceutical and biotechnology companies, CROs, academia and health authorities. It will be of particular interest to scientists involved in global development programmes and those seeking science-driven approaches to immunogenicity assessment.

HOW TO REGISTER (Registration will open 31st October 2026)

- Registration (registration fee: 680 Euro). There will be no early bird rate nor 1-day passes.
- To register: https://springfocus.e-b-f.eu/registration/ (tab: Registration). Link will become active 31st áOctober 2026.
- For maximum interaction, the meeting attendance is capped at 90 delegates and 3 delegates/company (excluding presenters, for which the registration fee will be waived)
- The meeting will be at NH, Málaga (Spain). Hotel reservations are independent from the EBF and not included in the meeting registration. More info in travel and lodging: https://springfocus.e-b-f.eu/travel-lodging/ (tab: Travel and Lodging).

MEETING ORGANISATION, ON BEHALF OF THE EBF
Kyra Cowan, Rob Wheller, Cecilia Arfvidsson, Lee Goodwin, Michaela Golob, Robert Nelson and Matthew Barfield.
Meeting management: Philip Timmerman, EBF
EBF Focus workshops are organised by the EBF vzw as non-sponsored non-profit events and are independent from EBF member companies.