

The Biomarkers European Special Interest Group: Where are we now?



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...on behalf of the Biomarkers European Special Interest Group (ESIG)

“A biomarker is a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or biological responses to an exposure or intervention, including therapeutic interventions.”


Biomarkers, Endpoints, and other Tools, FDA – NIH, 2016


Biomarkers-based designs


 Methodology and experience sharing – enrichment, cut-off detection, decision making

 Hosted a webinar and gave a presentation at PSI in 2023!


Machine Learning for Biomarker Analysis

 **Goal**
Create a best practices guidance on the use of AI/ML with biomarkers in clinical development

 **Achievements**
Review and feedback to FDA’s discussion paper¹ on usage of AI/ML in drug development

 **Next steps**
Identify and choose topics with potential impact on drug development, e.g. Virtual Twin, GxP compliant AI/ML, use of image-based or digital biomarkers

Biomarker data catalogue

 Identification of publicly-available datasets to create a data repository

 20+ datasets in data repo!



Kick off
in March
2022

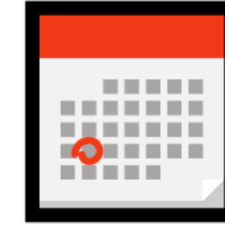
Webinar
in Jan.
2023

Webinar
in Nov.
2023

Poster @
PSI 2022

Session @
PSI 2023

Want to
join the
ESIG?

 Webinar on November 16th 2023!
Want to attend? Stay tuned on LinkedIn.



The Biomarkers ESIG is sponsored by PSI and the European Federation of Statisticians in Pharmaceutical Industry.
The Biomarkers ESIG was revived in 2022 by Nicole Krämer & Guillaume Desachy.

¹Using Artificial Intelligence & Machine Learning in the Development of Drug and Biological Products, FDA, 2023 ; <https://www.fda.gov/media/167973/download>