Comitato Scientifico

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IBIG FORUM

Milano, Viale Certosa 130 c/o Bayer

9-11 ottobre 2023

IBIG
Italian Biostatistics Group

SIMeF
Società Italiana di Medicina Farmaceutica
Italian Society of Pharmaceutical Medicine

Increasing success rate in drug development

The growing importance of statistics and statisticians

Topics

The rise of digital superpowers: new perspectives on artificial intelligence and machine learning in drug development

Historical data in support of drug approval: opportunities and challenges

The estimands journey: from theory to practice

RWE to drive clinical and regulatory decision-making: challenges and solutions

Better decision making in drug development through quantitative tools and innovative trial designs

Pre-Forum courses

R in Clinical Trial Reporting

A pragmatic approach to multiple endpoints resolution

Quote di partecipazione (IVA esclusa)		
	Entro il 31/7	Dopo il 31/7
Corso Pre Forum – Link Iscrizione		
Soci SIMeF	200€	300€
Non Soci SIMeF	300€	400€
IRCCS/No Profit/Enti Pubblici	200€	300€
Forum - Link iscrizione		
Soci SIMeF	400€	500€
Non Soci SIMeF	500€	600€
IRCCS/No Profit/Enti Pubblici	400€	500€
Studenti universitari e dottorandi	150€	250€
Iscrizione corso e Forum: 20% riduzione sul costo totale		

IBIG Forum
Milano, 9-11 ottobre 2023 (presso Bayer)

Increasing success rate in drug development:

The growing importance of statistics and statisticians

Pre-forum Courses

A pragmatic approach to multiple endpoints resolution: Stefano Vezzoli (Chiesi) e Luca Grassano (GSK)

Multiplicity is a crucial aspect in clinical trial design and analysis. This course will present the general multiplicity issue and how this impacts the interpretation of trial results. Several multiplicity adjustment methods will be described, ranging from simpler parametric approaches to non-parametric graphical procedures. A perspective on the methods will be provided in terms of operating characteristics and implementation in the analysis. In the practical session, case studies will offer the possibility to become familiar with the software implementation (e.g., R Mediana package or SAS) and to evaluate multiplicity adjustment options during the design phase of clinical trials.

"R in Clinical Trial Reporting": Federico Baratin (GSK)

More and more often R language is used in Pharmaceutical Companies. Alliances between different Companies have been established to create standards for Clinical Trials and Health Authorities started to give positive feedback on R implementation. The course will present initiatives and examples of R adoption, giving a chance to attendees to learning fundamentals and test themselves in practical applications.

Forum

The rise of digital superpowers: New Perspectives on Artificial Intelligence and Machine Learning in drug development

The success rate of new drug development is notoriously low, yet the potential financial rewards are enormous. Many strategies have been used by pharmaceutical companies to attempt to increase the success rate of drug development, but this goal is still difficult to achieve in many situations. The emergence of Artificial Intelligence (AI) and Machine Learning (ML), however, has opened up new possibilities for improving decision-making throughout the development path of pharmaceutical products, from very early discovery phases to clinical trials. Thanks to the exponential growth in biomedical data in recent years, these automated tools can identify patterns and extract useful information at scale. With the ability to accelerate the search for chemical or biological entities with desirable functional activity, AI & ML technologies could revolutionize drug discovery. In this session, we will discuss some case-studies to explore the future potential and the limitations of AI and ML in drug development.

Historical data in support of drug approval: opportunities and challenges

There is an increasing interest in utilizing historical data to supplement data from clinical trials. Potential applications of this approach include the replacement or augmentation of a control arm, extrapolation of evidence to other populations (e.g. pediatric) and borrowing from real-world data sources (such as electronic health records, claims data, and patient registries). This session will dig into key open questions related to the use of historical data for drug approval including:

- Health Authority's positions and regulatory requirements
- Effective strategies for incorporating historical data into a clinical development plan
- Statistical methodologies for integrating historical data with newly generated clinical data.

Real-world evidence to drive clinical and regulatory decision-making: challenges and solutions

Real-world evidence (RWE) provides information about risks and benefits of medical products derived from patients' health data that are routinely collected in clinical practice, often referred to as real-world data (RWD). Sources of RWD include administrative data, medical claims, electronic health records and regional or national registries. While modern advancements in technology make these data increasingly available, the possibility to use RWD to derive strong RWE is hampered by a variety of factors, including concerns about privacy protection, the lack of structured clinical information and of clinically relevant outcome measures in the available datasets, the need of advanced statistical methods to infer effects in observational designs and the lower trust often attributed to RWE findings as compared to RCT results. In this session, we discuss RWE challenges and the role of statisticians to leverage RWD.

The estimands journey: from theory to practice

The estimands framework has been introduced in 2019 by the Addendum to the ICH E9 guideline on statistical principles for clinical trials to improve alignment between clinical questions, objectives, design, and analysis of clinical trials. Since its release, the addendum has rapidly impacted the drug development world, triggering interest and discussions. Many efforts have been made to clarify the theory behind the framework to strengthen the interaction between relevant stakeholders and between sponsors and regulators. Now that the framework has started to be broadly adopted, several challenges have arisen during its implementation. The session will focus on experiences and case studies on practical issues encountered when adopting the framework in clinical trials.

Better decision making in drug development through quantitative tools and innovative trial designs

Drug development is a learning process where new evidence accrued in clinical studies must be integrated with previously available information. New tools today exist to explore a variety of opportunities in order to improve the decision-making process. The implementation of the "model-based drug development", with particular focus on the quantitative decision criteria, along with new adaptive designs aimed at making investment selections more efficient with an increased rate of treatment program success will be presented with practical examples and case-studies.