2nd APEC Roundtable Dialogue on Post-Pandemic Regulatory Innovation & Convergence for Vaccines and Therapeutics

Case study - Leveraging analytics for remote clinical quality oversight

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The Inter coMPany quALity Analytics (IMPALA)
Steering Committee Chair
Clinical Trials w/100% remote QA oversight

- Leveraging analytics [1]
- Real-time QA support
- Accelerated timelines
- Many examples during the pandemic: Covid-19 vaccines, Covid-19 treatments
- QA as an enabler - accelerating trials while assuring high quality
## Learning from COVACTA Trial

### Data
- **Data sources:** eCRF and the Clinical Trial Management System.
- The infrastructure used to collect, store and analyze data was based on a file distributed system (implemented for Roche A&I in 2018).

### Analytics Tools
- Descriptive analysis had been performed using Microsoft Excel and R
- For statistical analysis, we used R and Python
- For visualization, we used Tableau

### Challenges
- Analyses conducted on a daily basis, required the equivalent of 2.5 FTEs for a period of several weeks
- Requirements: reliable IT infrastructure and access to the data
- Quality professionals with advanced data literacy plus data analysts/scientists with sufficient business/GxP knowledge

### Looking forward
- Overall process we described should be streamlined and, where possible, automated. The frequency of the analysis can likely be decreased, especially when trials are conducted outside of urgent circumstances, such as the Covid-19 pandemic.
How advanced analytics enable clinical quality 2.0?

**Quality program**
- Subjective
- Retrospective
  - up to D-18 months
  - Manual process

**Issue detection**
- On-site audits
- Broad Scope
  - week of the audit
  - Resources intensive

**Limitations**
- Hidden Issues
- Late Detection
  - D-30 days
  - Not holistic nor real time

**Learn**
- Clin. Quality data
- Analytics
  - Historical data
  - Why did it happen?

**Predict**
- Machine Learning
- Pred. Modeling
  - Real time data and predictions
  - What will happen?

**Adapt**
- Early Detection
- Risk Minimization
  - 2022 and beyond
  - What can Quality do to change the outcome?

Advanced Analytics

Clinical + Non-Clinical data

Regulatory requirements

Credit for infographic – Timothé Ménard, PharmD – Hoffmann-La Roche
Advanced Analytics use cases in clinical quality

- Using various methods
  - Descriptive analytics (visualization)
  - Statistical learning
  - Bayesian statistics

- Anomaly detection
  - Adverse Events
  - Deviations
  - Laboratory data

- Risk Assessment
  - Affiliate audits planning
  - Quality Risk Indicators

What Advanced analytics can do

- What is useful to clinical quality
How can we shape the ecosystem to accelerate the adoption of advanced analytics for clinical quality?
The Inter coMPany quALity Analytics (IMPALA)

Vision

The IMPALA ecosystem (industry, regulators, patients) will contribute to a change in paradigm for QA, i.e., where co-developed advanced analytics and best practices can help detect and mitigate issues faster, reduce the burden of retrospective, time-consuming traditional QA activities and ultimately accelerate approval and patient access to innovative drugs.

IMPALA aims to engage with Health Authorities inspectors on defining guiding principles for the use of advanced analytics to complement, enhance and accelerate current QA practices.
The Inter company quALity Analytics (IMPALA)

Members

In scope

- Knowledge sharing and best practices for QA analytics
- Joint Health Authorities engagement on the topic of QA analytics
- Co-development of statistical models for QA
- QA / operational data sharing

Group established on Jul-2019

Roche
Biogen
J&J
MERCK
Pfizer
MSD
Bristol Myers Squibb
Boehringer Ingelheim
astellas
Novartis
IMPALA Work Products - example of open source analytics package

- **Statistical Software Package**
  - Standardized Structure
  - Reusable
  - Testable
  - Documentation Framework

- **Public Code Hosting Platform**
  - Version Control
  - Documentation Hosting
  - Automated Testing

- **Open Pharma Organisation**
  - Sandbox for Cross-Industry Open Source Development

[https://openpharma.github.io/simaerep/][4]
References


