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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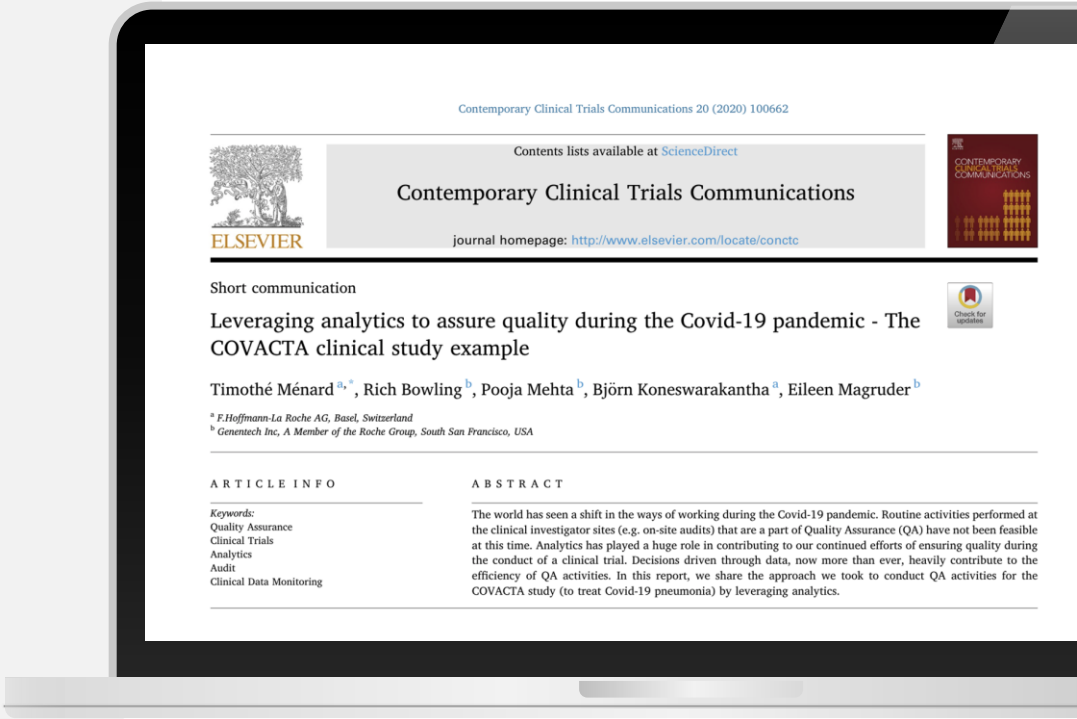
The Inter coMPany quALity Analytics (IMPALA)
Steering Committee Chair

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



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Short communication

Leveraging analytics to assure quality during the Covid-19 pandemic - The COVACTA clinical study example

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ABSTRACT

The world has seen a shift in the ways of working during the Covid-19 pandemic. Routine activities performed at the clinical investigator sites (e.g. on-site audits) that are a part of Quality Assurance (QA) have not been feasible at this time. Analytics has played a huge role in contributing to our continued efforts of ensuring quality during the conduct of a clinical trial. Decisions driven through data, now more than ever, heavily contribute to the efficiency of QA activities. In this report, we share the approach we took to conduct QA activities for the COVACTA study (to treat Covid-19 pneumonia) by leveraging analytics.

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?

Regulatory requirements

Advanced Analytics

Clinical + Non-Clinical data

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

Business to Address issues

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?

- Remote quality monitoring
- Flexible + Focused + Targeted audits
- Data Driven Clin. Quality Solution Oriented

Credit for infographic – Timothé Ménard, PharmD – Hoffmann-La Roche [2]

Advanced Analytics use cases in clinical quality

Using various methods

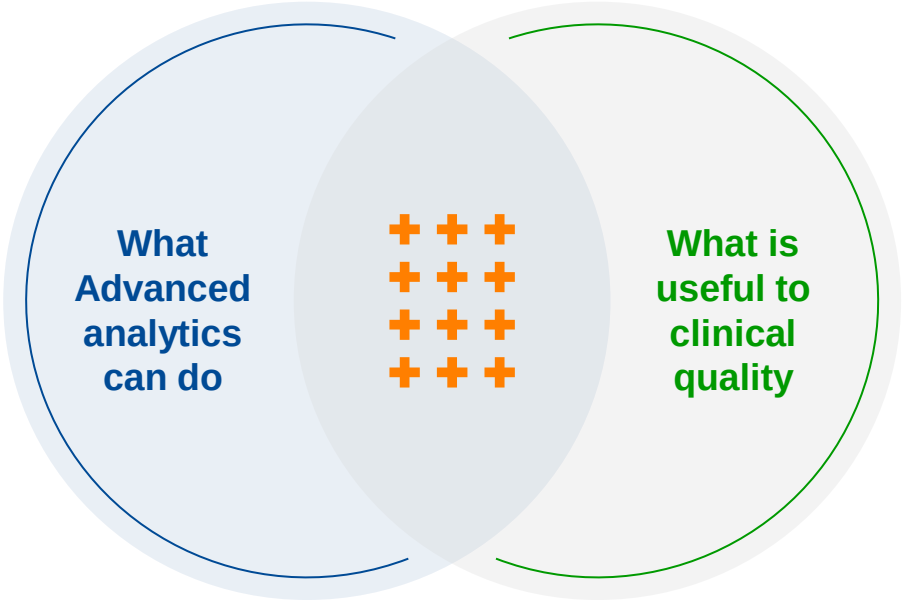
- Descriptive analytics (visualization)
- Statistical learning
- Bayesian statistics

Anomaly detection

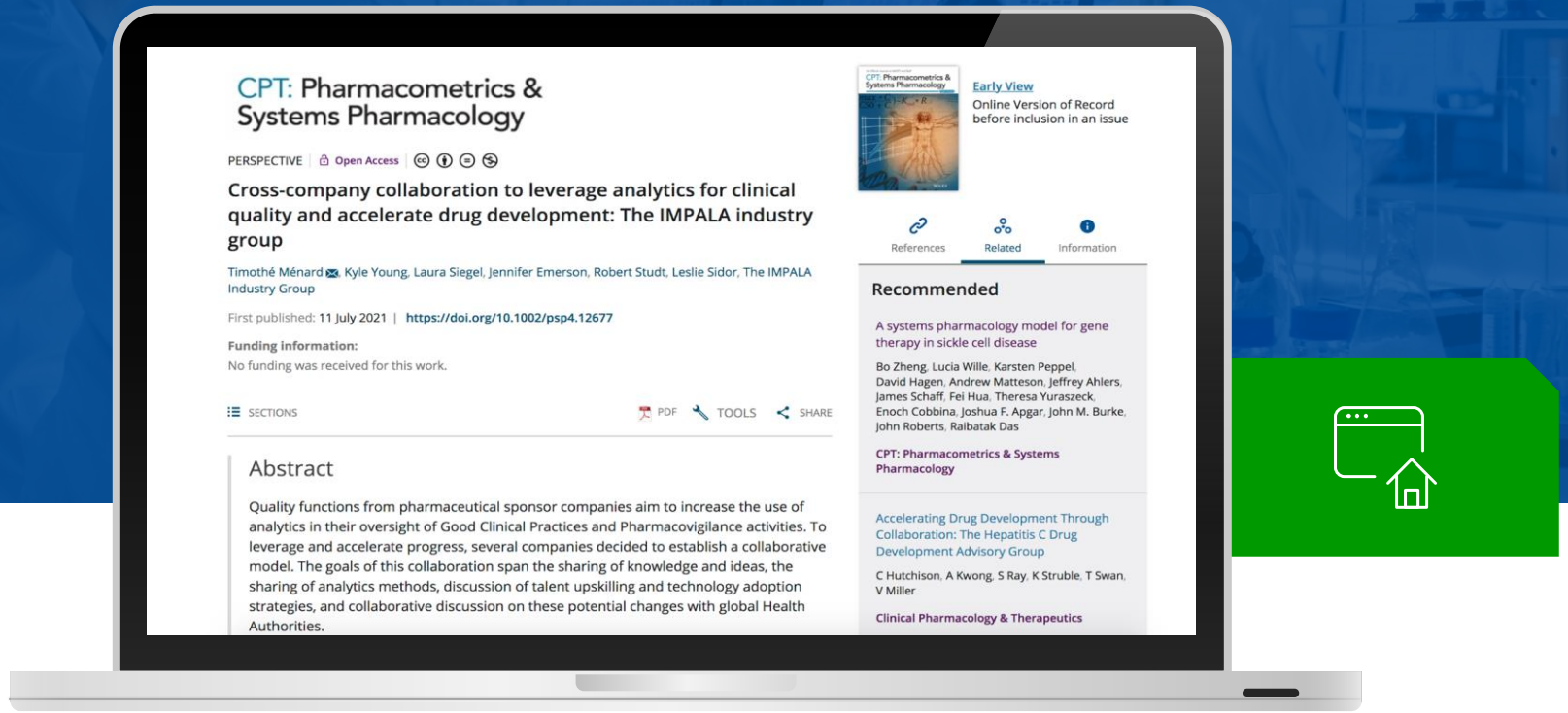
- Adverse Events
- Deviations
- Laboratory data

Risk Assessment

- Affiliate audits planning
- Quality Risk Indicators



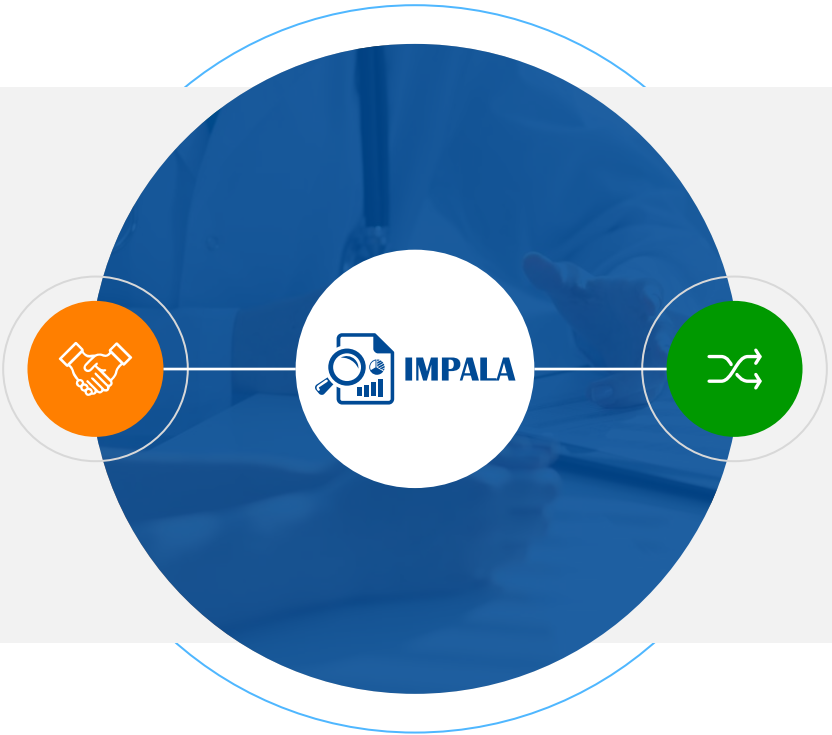
How can we shape the ecosystem to accelerate the adoption of advanced analytics for clinical quality?



The Inter coMPany quALity Analytics (IMPALA)

Vision

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 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

The IMPALA Alliance will provide the strategic focus for working across the Biopharmaceutical ecosystem to develop and gain industry-wide consensus for the adoption of improved QA using advanced analytics and best practices to be used across the industry; ultimately improving patient outcomes and quality care at greater efficiency and greater speed

The Inter coMPany quALity Analytics (IMPALA)

Members

Group established on Jul-2019

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

Roche
Biogen
J&J
MERCK
BAYER
Pfizer
MSD
Bristol Myers Squibb
Boehringer Ingelheim
astellas
NOVARTIS

IMPALA Work Products - example of open source analytics package

simaerep

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

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

References

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