

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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Clinical Trials w/100% remote QA oversight



Leveraging analytics [1]



Real-time QA support



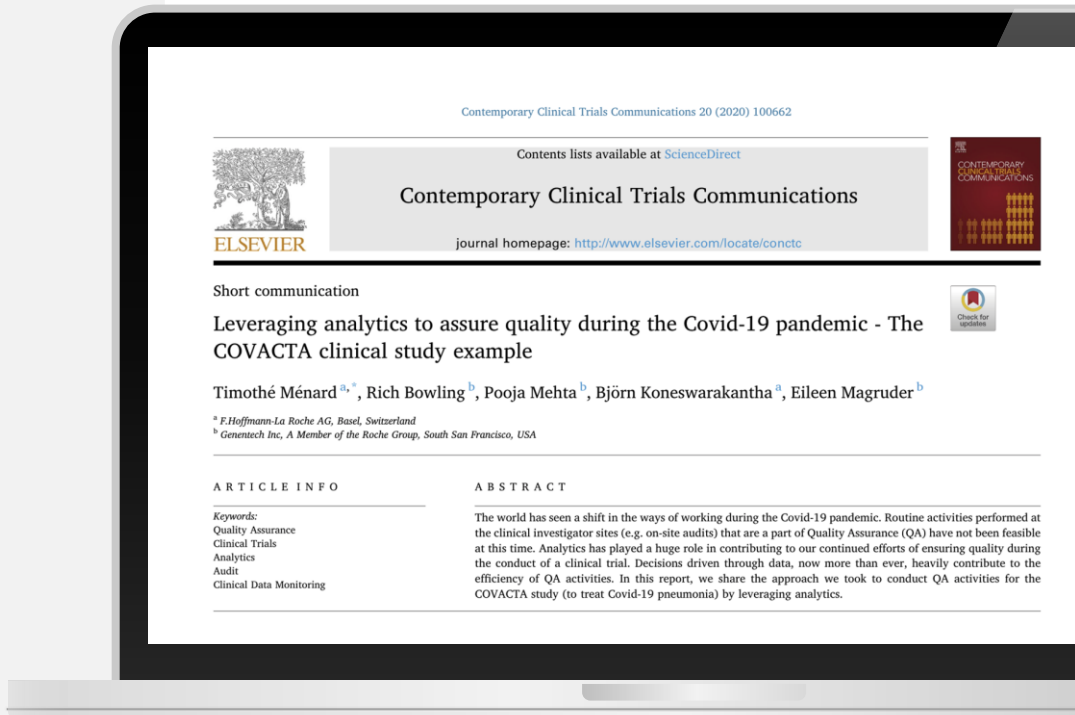
Accelerated timelines



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

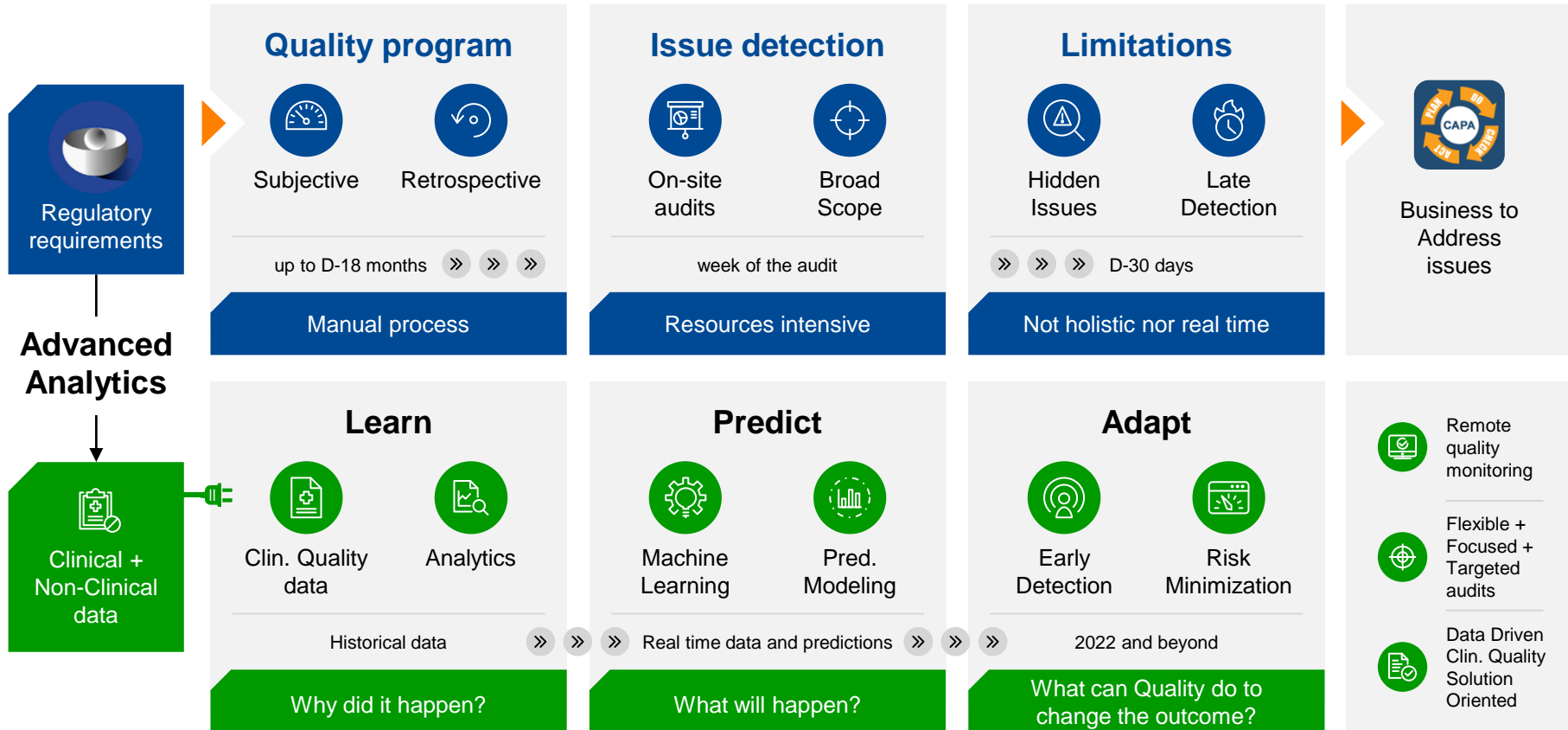
- ✓ Analyses conducted on a daily basis, required the equivalent of 2.5 FTEs for a period of several weeks
- ✓ Requirements: reliable IT infrastructure and access to the data
- ✓ Quality professionals with advanced data literacy plus data analysts/scientists with sufficient business/GxP knowledge



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?



Advanced Analytics use cases in clinical quality



Using various methods

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



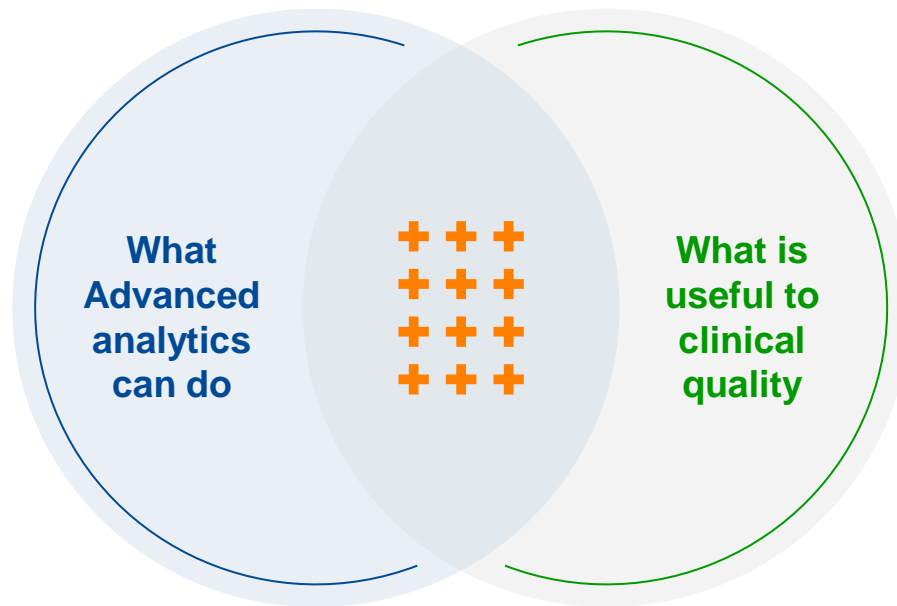
Anomaly detection

- ✓ 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?



CPT: Pharmacometrics & Systems Pharmacology

PERSPECTIVE | [Open Access](#) | 

Cross-company collaboration to leverage analytics for clinical quality and accelerate drug development: The IMPALA industry group

Timothé Ménard  Kyle Young, Laura Siegel, Jennifer Emerson, Robert Studt, Leslie Sidor, The IMPALA Industry Group

First published: 11 July 2021 | <https://doi.org/10.1002/psp4.12677>

Funding information:
No funding was received for this work.

SECTIONS PDF TOOLS SHARE

Abstract

Quality functions from pharmaceutical sponsor companies aim to increase the use of analytics in their oversight of Good Clinical Practices and Pharmacovigilance activities. To leverage and accelerate progress, several companies decided to establish a collaborative model. The goals of this collaboration span the sharing of knowledge and ideas, the sharing of analytics methods, discussion of talent upskilling and technology adoption strategies, and collaborative discussion on these potential changes with global Health Authorities.

Early View
Online Version of Record before inclusion in an issue

References Related Information

Recommended

A systems pharmacology model for gene therapy in sickle cell disease

Bo Zheng, Lucia Wille, Karsten Peppel, David Hagen, Andrew Matteson, Jeffrey Ahlers, James Schaff, Fei Hua, Theresa Yuraszcek, Enoch Cobbina, Joshua F. Apgar, John M. Burke, John Roberts, Raibatak Das

CPT: Pharmacometrics & Systems Pharmacology

Accelerating Drug Development Through Collaboration: The Hepatitis C Drug Development Advisory Group

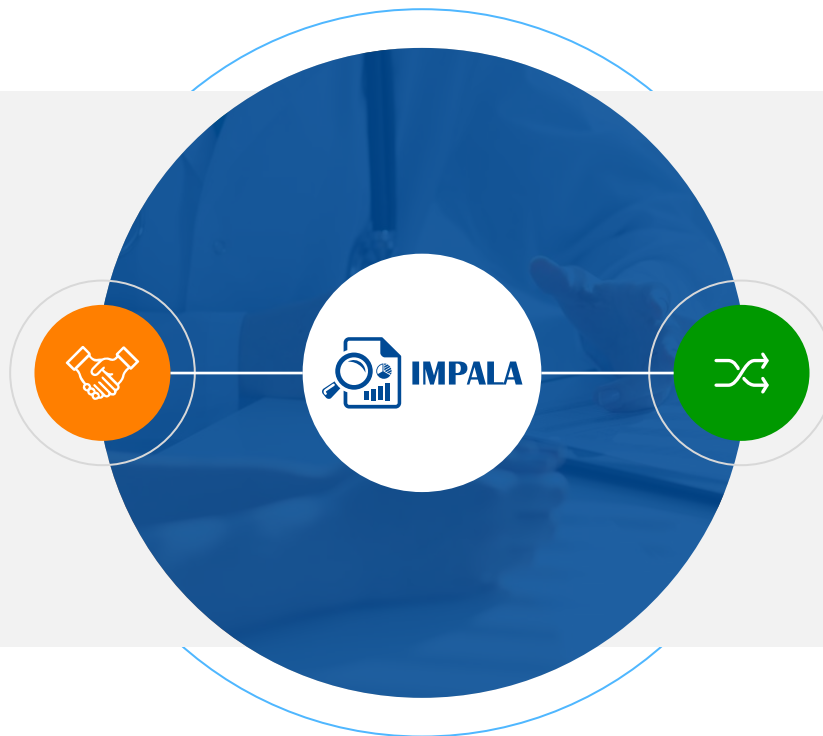
C Hutchison, A Kwong, S Ray, K Struble, T Swan, V Miller

Clinical Pharmacology & Therapeutics



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 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



IMPALA Work Products - example of open source analytics package



<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

- 1 Ménard, T., Bowling R., Mehta P. et al. Leveraging analytics to assure quality during the Covid-19 pandemic - The COVACTA clinical study example. Contemporary Clinical Trials Communications (2020). <https://doi.org/10.1016/j.conctc.2020.100662>
- 2 Ménard T, Young K, Siegel L, Emerson J, Studt R, Sidor L; The IMPALA Industry Group. Cross- company collaboration to leverage analytics for clinical quality and accelerate drug development: The IMPALA industry group. CPT Pharmacometrics Syst Pharmacol. 2021;10:799– 803. <https://doi.org/10.1002/psp4.12677>
- 3 Ménard T, Infographic - Advanced Analytics for Clinical Quality, value proposition. <http://dx.doi.org/10.13140/RG.2.2.22658.20164>
- 4 Koneswarakantha B, Barmaz Y, Ménard T, Rolo D. Follow-up on the Use of Advanced Analytics for Clinical Quality Assurance: Bootstrap Resampling to Enhance Detection of Adverse Event Under-Reporting. Drug Saf. 2021 Jan;44(1):121-123. doi: 10.1007/s40264-020-01011-5. <https://link.springer.com/article/10.1007%2Fs40264-020-01011-5>

