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192 · Conducting observational multi-country studies for regulatory decision making during COVID-19 pandemic: the strategic role of the scientific study manager [523]

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BACKGROUND

COVID-19 global health emergency revealed the need for pharmacovigilance projects to proceed rapidly while guaranteeing high-quality standards. Post-authorisation safety studies (PASS) are complex and mandatory pharmacovigilance activities that require the participation of specialised scientific study managers at every stage, from scientific and regulatory affairs consultancy to change management readiness.

During the COVID-19 pandemic, the undeniable contribution of scientific study managers in pharmacovigilance activities enhanced the ability of study consortia to adapt to rapidly evolving regulatory requirements on top of the existing challenges.

OBJECTIVES

To identify and describe coordination and management challenges in the design and execution of PASS that emerged during the COVID-19 pandemic. To develop and promptly implement methodological procedures for agile management whilst addressing regulatory requirements.

METHODS

We retrospectively reviewed executed and ongoing PASS workflows and tasks from the initial request stage to the final reporting and archiving. We analysed the impact of COVID-19 pandemics in the different aspects of study management including study governance, protocol development, data management and protection, reporting, quality, and risk management **(Figure 1)**.

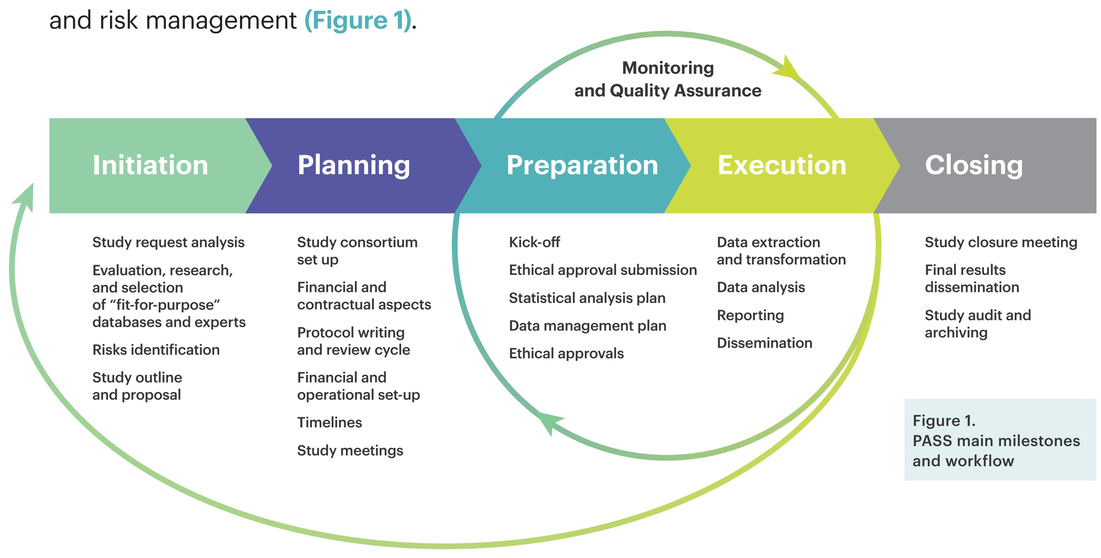


Figure 1.
PASS main milestones and workflow

RESULTS

COVID-19 pandemic affected all the steps of the implementation and execution of PASS due to the need to respond quickly to the requests of the regulators. As a result, we observed an increase in both the time dedication provided by scientific study managers and the tasks they are involved in to ensure the successful coordination and oversight of the studies according to their time and quality constraints **(Figure 2)**. Moreover, we identified several challenges that the scientific study manager had to face during the study lifecycle that contributed to the creation of a unique management expertise that is extremely important to performing PASS **(Figure 3)**. We established, adopted and validated high-reliability organisational principles and methodologies, such as good management practices, effective communication systems, actions as a learning partnership to optimise scientific study management processes of PASS and addressed the issues with the availability of updated data, data harmonisation and integration, Institutional Review Board (IRB) approvals during pandemics, rapidly changing regulatory requirements, fast-track reporting methodology, and accurate validation process of Adverse Events of Special Interest (AESIs).

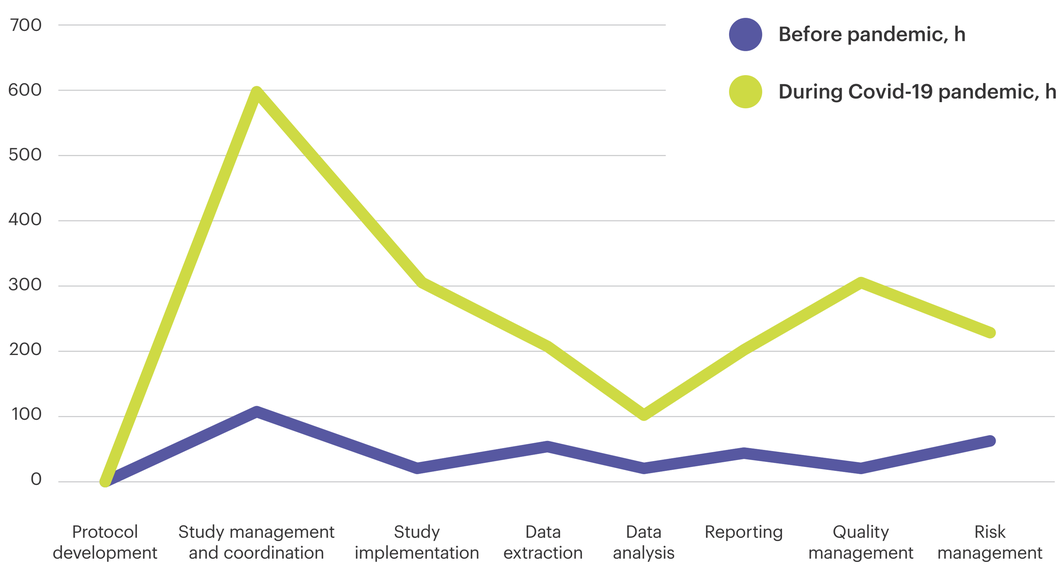
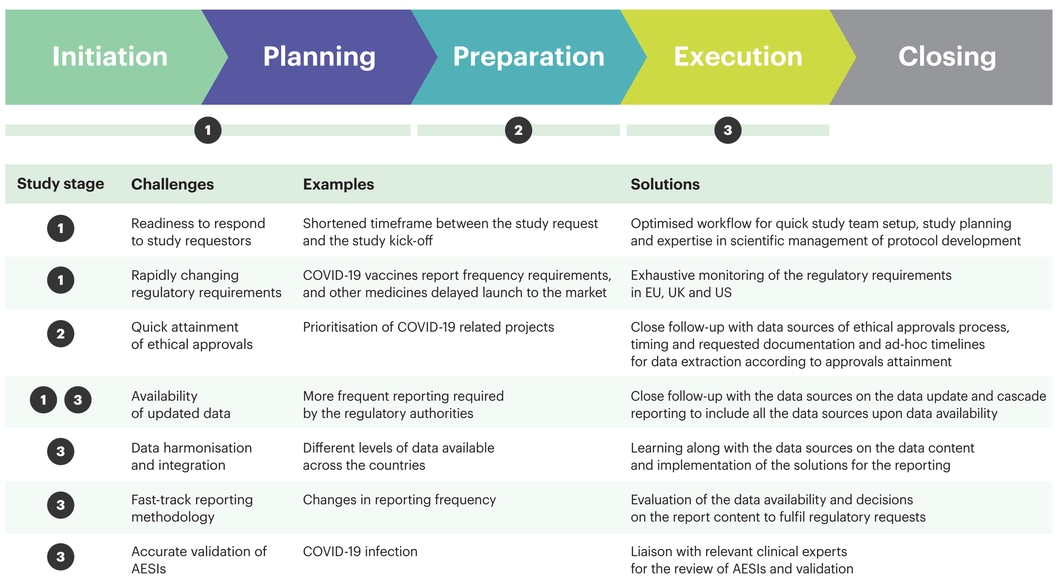


Figure 2. Scientific study manager contributions before and during COVID-19 pandemic



Study stage	Challenges	Examples	Solutions
1	Readiness to respond to study requestors	Shortened timeframe between the study request and the study kick-off	Optimised workflow for quick study team setup, study planning and expertise in scientific management of protocol development
1	Rapidly changing regulatory requirements	COVID-19 vaccines report frequency requirements, and other medicines delayed launch to the market	Exhaustive monitoring of the regulatory requirements in EU, UK and US
2	Quick attainment of ethical approvals	Prioritisation of COVID-19 related projects	Close follow-up with data sources of ethical approvals process, timing and requested documentation and ad-hoc timelines for data extraction according to approvals attainment
1 3	Availability of updated data	More frequent reporting required by the regulatory authorities	Close follow-up with the data sources on the data update and cascade reporting to include all the data sources upon data availability
3	Data harmonisation and integration	Different levels of data available across the countries	Learning along with the data sources on the data content and implementation of the solutions for the reporting
3	Fast-track reporting methodology	Changes in reporting frequency	Evaluation of the data availability and decisions on the report content to fulfil regulatory requests
3	Accurate validation of AESIs	COVID-19 infection	Liaison with relevant clinical experts for the review of AESIs and validation

Figure 3. PASS challenges during the COVID-19 pandemic

CONCLUSIONS

The role of scientific project management is crucial for successfully conducting PASS. Management of uncertainty, rapidly changing regulatory environment, stakeholders' collaboration, change management, continuous improvement through the creation of effective tools, flexibility, and prioritisation were identified as key factors for the successful coordination of PASS during the pandemic. Soft skills, such as change management, creative problem solving and others, are crucial for scientific study managers **(Figure 4)**. Beyond this, scientific study managers also contribute to shaping and improving the studies technical aspects, such as study implementation, data collection and reporting throughout the continuous support and monitoring alongside the study scientific coordinator or principal investigator **(Figure 5)**.

HARD SKILLS

Data management
Technical language and medical writing
Coordination
Organisation
Prioritisation
Project planning and goal setting
Risk management
Quality management
Delegating
Negotiation
Financial management

SOFT SKILLS

Communication
Leadership
Motivation
Conflict management
Change management
Adaptability
Resourcefulness
Teamwork
Influence
Strategic
Creative problem solving
Committed

Figure 4. Scientific study managers' crucial skills

Figure 5. Main interactions within the study group

CONFLICT OF INTEREST

Teamit experts conduct research for regulators and vaccine manufacturers according to ENCePP code of conduct.

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