

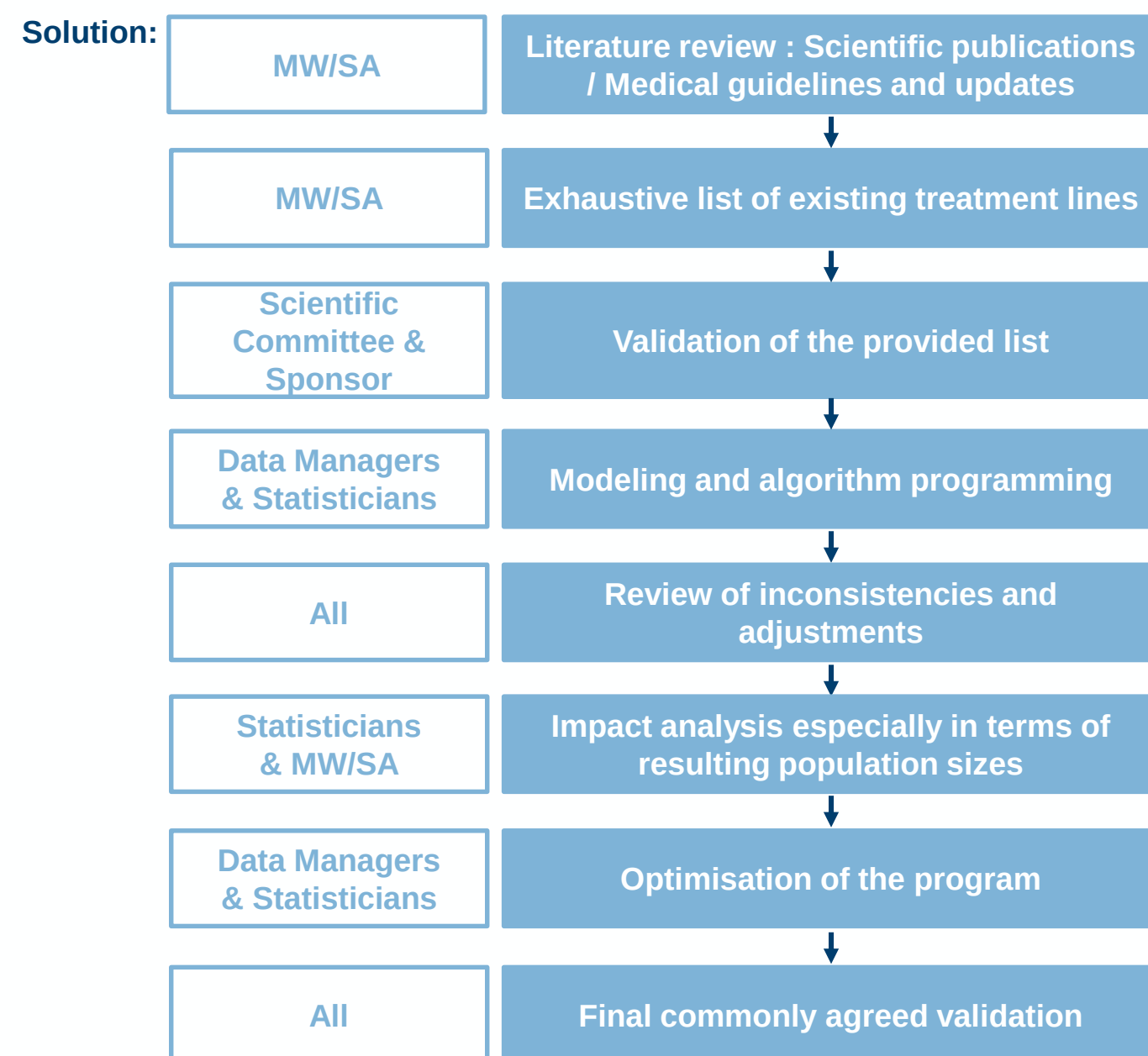
ABSTRACT

Confirmation of scientific findings is the hallmark of science. However, clinical trials are not or rarely repeated. Therefore, every single research result must be disseminated in consistency with a priori plans. However, the trial robustness and the resulting inconsistencies between initial plans and published results are regularly pointed out by methodologists and the scientific community (e.g. chloroquine's level of evidence to treat COVID-19 patients). As a mid-sized CRO specialized in phase I trials up to post-marketing studies, we choose to have internal staff (**Medical Writer/Scientific Advisor (MW/SA)**) with a combined high-level background in life sciences, medical writing and statistics. Such collaborators are strongly involved in all study steps: they ensure well designed documentation, provide ongoing support to project teams and actively participate to data reviews and analyses to facilitate data valorisation. The goal of this poster is to present examples also discussed in the light of the ICHE9(R1).

Case study #1: Cancer Database Analysis ► Identification of treatment lines

Objective: To develop the best algorithm identifying a specific ovarian cancer subpopulation using a French exhaustive Cancer database. This requested a preliminary identification of the various lines of treatments known to be complex in oncology.

Issue: Since there is lack of homogeneity and standardisation across sites regarding treatment characteristics (e.g. dates, names, surgeries) and due to the complexity of treatment lines in oncology, close interactions between the project MW/SA specialized in oncology, Biostatistician and Data Manager were required to propose solutions to the Sponsor.

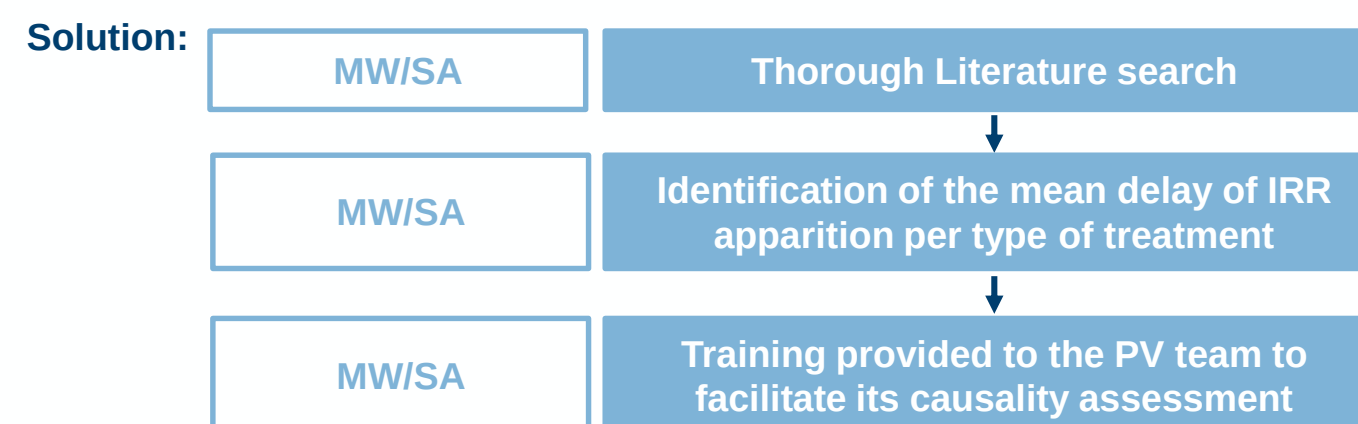


Result: Efficient algorithm to specifically identify the ovarian cancer subpopulation of interest.

Case study #2: First-in-Human (FIH) ► Assessment of Safety event's causality

Objective: Determining the causality of Infusion Related Reaction (IRR) in a cancer population treated with 3 different drugs including the new Investigational Medicinal Product (IMP) and 2 routine care treatments.

Issue: To help the pharmacovigilance department in managing serious adverse event/reactions during this first-in-human clinical trial in cancer patients and provide ongoing medical & scientific support throughout the trial.



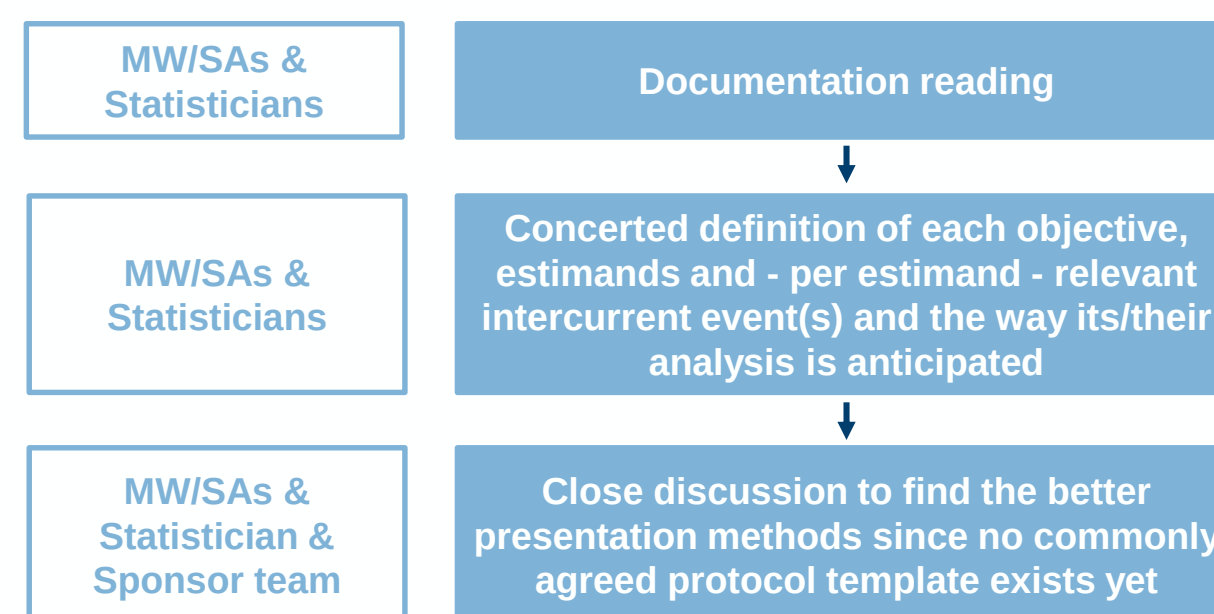
Result: the CRO and Sponsor's PV reached better assessment of IRR's causality, leading to more accurate PV reporting as the study drug was: i) a first in class and ii) studied for the first time in human in association with other systemic drugs.

Case study #3: Protocol development for a pivotal phase III study ► Compliance with ICH-E9 R1 guideline

Objective: To develop a pivotal phase III study protocol compliant with the new ICH-E9 Revision 1 guideline, which is applicable since July 30th 2020.

Issue: First protocol development in compliance with ICH-E9 R1, which requires to better define beforehand the trial methodology including objectives, estimands, intercurrent events and the way all these elements will be analyzed.

Solution: Internal working group composed of MW/SA and statisticians:



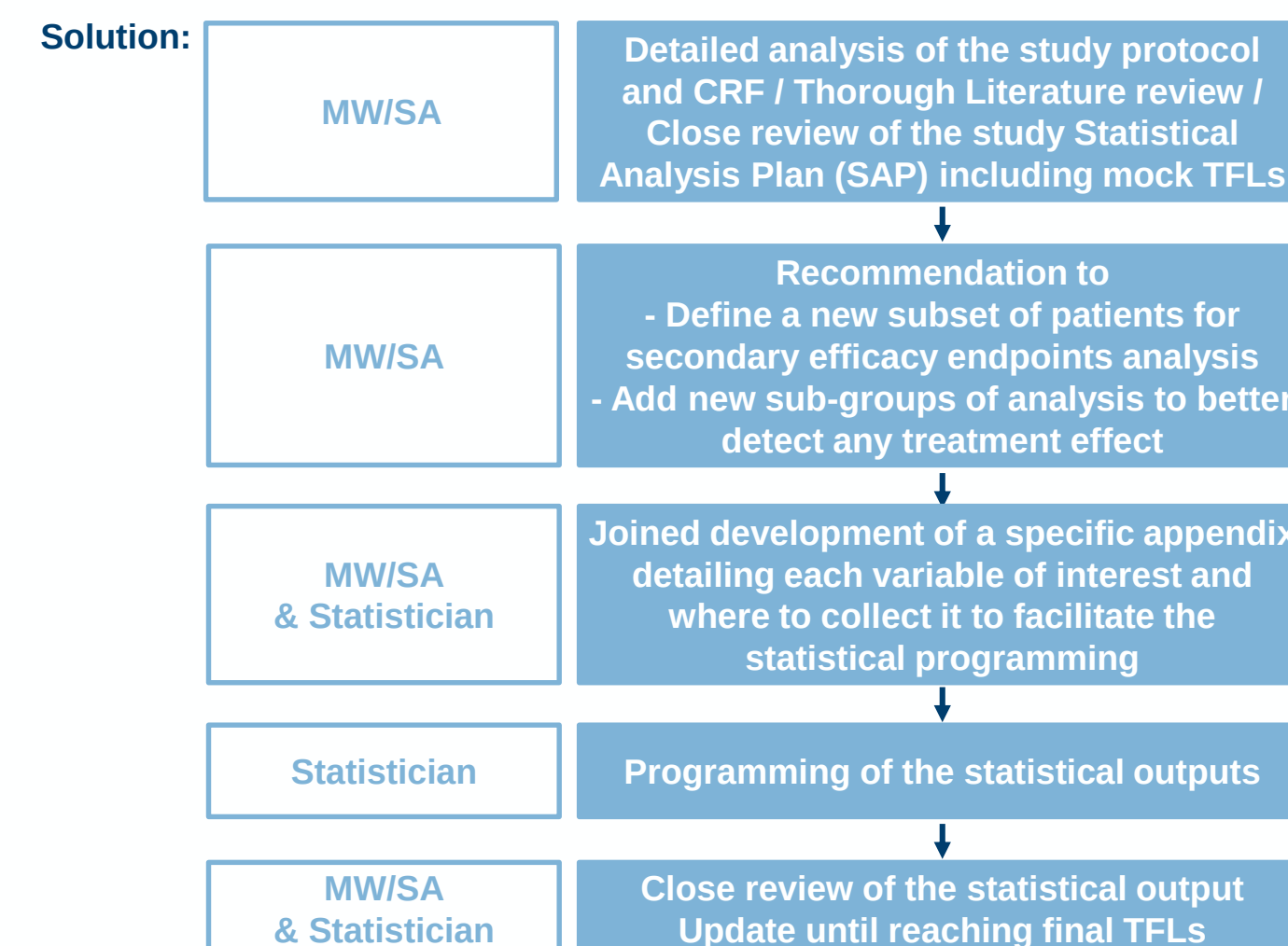
In parallel external training planned with an expert biostatistician to consolidate the team's new skill acquisition.

Result: As of today, the protocol is close to be finalized pending further feedback from the FDA to confirm the choices made.

Case study #4: NIS in In-vitro Fertilization ► Endpoints & variables selection

Objective: Initial study documents developed by Sponsor including a complex CRF and only few details on endpoints and planned statistical analyses.

Issue: Therapeutic area new to the biostatistician. Need to help the biostatistician to identify all variables of interest in the CRF to answer to all study objectives.



Result: The definition of new patient subsets enabled providing relevant analysis of secondary efficacy endpoints and allowed Sponsor to consider scientific communications in congress/scientific journals. The addition of new subgroups enabled the detection of specific treatment effect not anticipated by Sponsor.

CONCLUSIONS

