

Importance of Adjudication Committees in Retrospective Chart Review Studies for Outcomes Event Data Collection

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Background

- Retrospective chart reviews analyze existing patient data to gain insights into health outcomes; however, a key limitation is incomplete or missing data.
- Safety event and outcomes data are essential for understanding the safety profile and effectiveness of medical interventions, supporting regulatory submissions and informing on practice guidelines.
- Standardized assessments are necessary to ensure consistency and reliability, enabling meaningful comparisons both within and across global studies.
- We demonstrate how an adjudication committee enhances accuracy of outcomes data using evidence from a chart review study.

Methods

- The goal of adjudication is to classify outcomes/endpoints/events in a measurable, accurate, consistent, objective, and bias-free manner (**Figure 1** and **Figure 2**).
- An adjudication committee of expert healthcare practitioners (HCPs) was established to independently review and determine hemostatic effectiveness for bleeding events, ensuring a bias-free assessment separate from sites.
- A safety charter was created to guide the review of data extracted from patient medical charts, following standard definitions of hemostatic effectiveness; this was outlined in the protocol to support the primary endpoint, classified via a binary assessment of “effective” or “not effective.”
- Adjudication is a structured, unbiased review of events of interest. A group of expert HCPs, known as an adjudication committee, independent from sites and sponsor, reviewed data extracted from patient medical records to arrive at consistent conclusions regarding whether a patient achieved hemostatic effectiveness.
- The adjudication committee reviewed data extracted from patient medical records into the study electronic data capture (EDC) system, which contained the clinical information required to assess hemostatic effectiveness based on an efficacy scale.

Figure 1. Adjunction Model

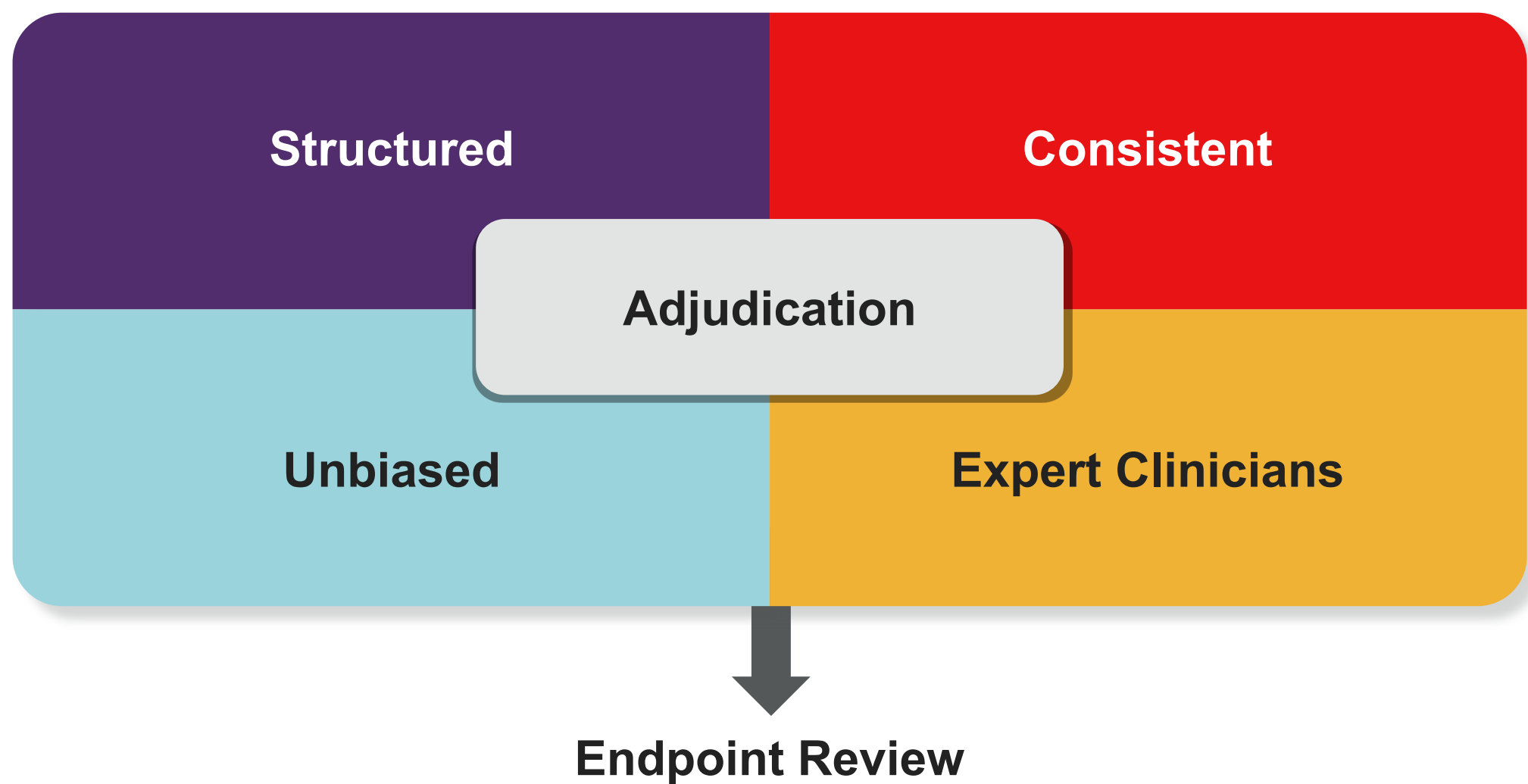
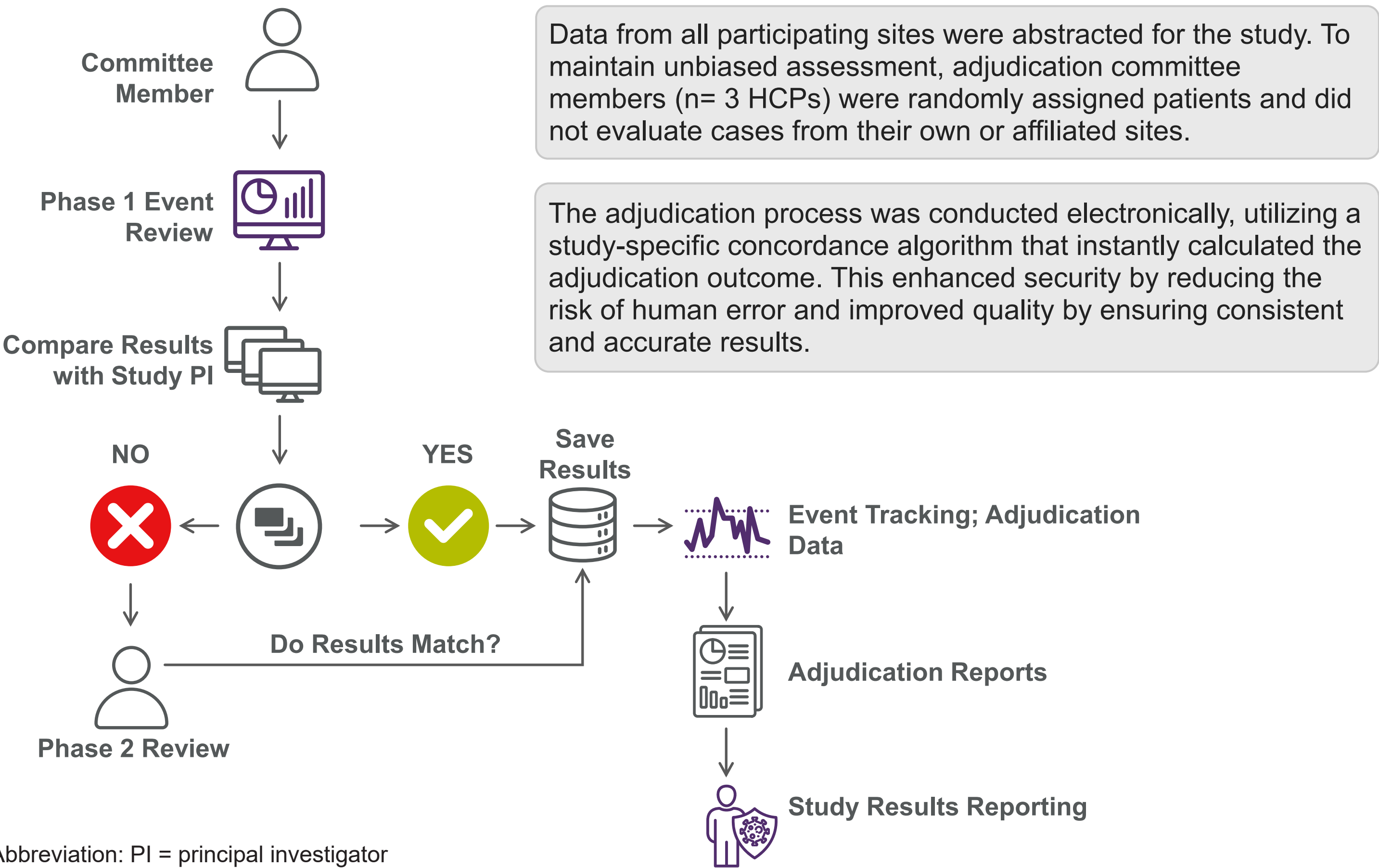


Figure 2. Adjudication Process Flow



Results

- A total of 328 bleeding events were adjudicated by three HCPs across six countries in Europe, the Middle East and Africa (EMEA). Of these, 85% were adjudicated with a definite hemostatic effectiveness rating of “effective” or “not effective”; this high rate was attributable to the standardized definition used, as well as committee guidance on data collection (**Figure 3**).
- A sub-cohort with a higher proportion of missing data showed an increased rate of definitive, standardized outcomes from 40% to 61%, significantly reducing the number of events where hemostatic effectiveness could not previously be determined and increasing the number of analyzable events for the primary outcome (**Figure 4**). The committee’s expert guidance and a collaborative approach to developing the charter were streamlined, contributing to the reduction of undetermined events (**Table 1**).

Results (cont.)

Figure 3. Cohort 1 Confirmed Hemostatic Effectiveness Outcome Percentage

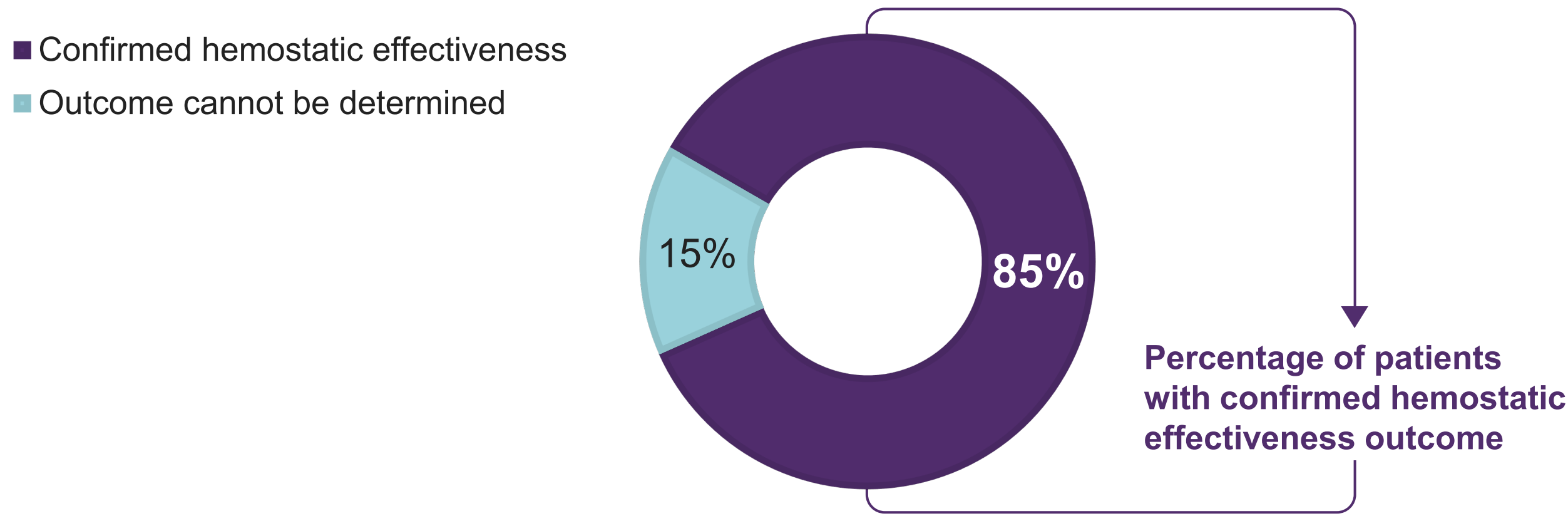


Figure 4. Cohort 2 Confirmed Hemostatic Effectiveness Outcome Percentage

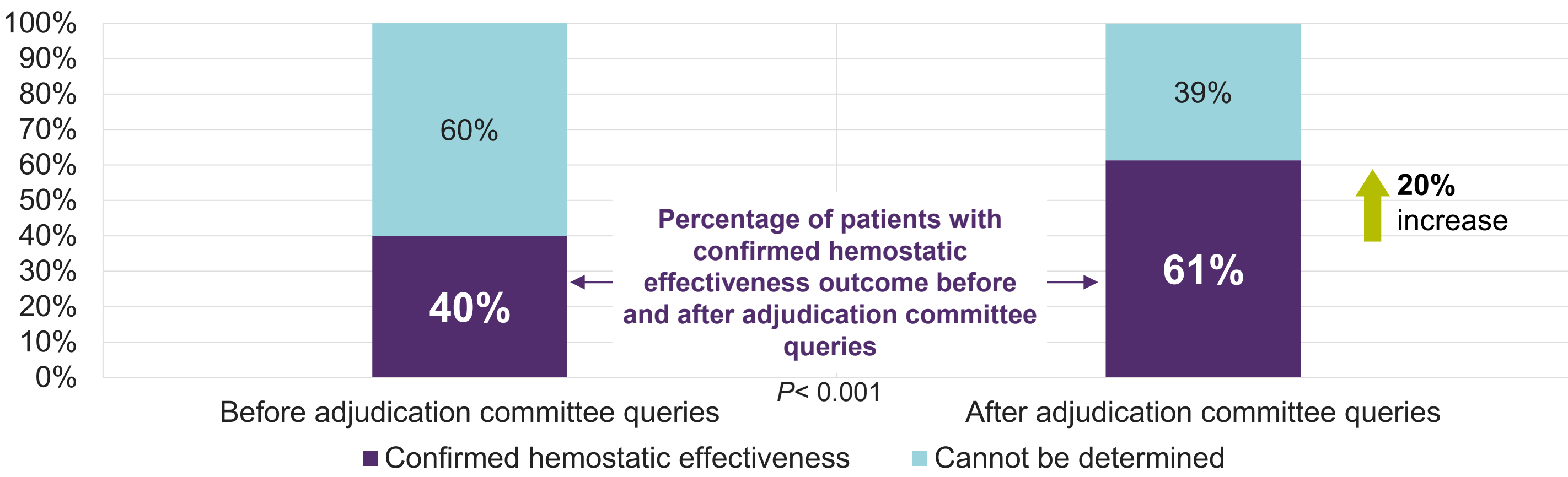


Table 1. Patients with Confirmed Hemostatic Effectiveness Pre- and Post-Adjudication Queries

	Before collection of additional details		After collection of additional details	
	Confirmed effective or not	Cannot be determined	Confirmed effective or not	Cannot be determined
Cohort 1	115	19	N/A	N/A
Cohort 2	78	116	119	75

- In implementing an adjudication committee for this study, several challenges were encountered, necessitating strategic solutions to effectively mitigate these issues (**Figure 5**).

Figure 5. Endpoint Challenges and Adjudication Solutions

Challenges	Solutions
The need for adjudication was identified later in the study, requiring establishment of the adjudication process during the study maintenance phase	<ul style="list-style-type: none">While optimal to engage an adjudication committee early in the study design, active committee involvement was requested in discussing adjudication requirements with the sponsor and providing expert guidance on study considerations and developing the adjudication charter.Committee training was provided on endpoint definitions and use of the adjudication platform.
There was a limited availability of therapeutic area/indication-specific experts	<ul style="list-style-type: none">In studies focusing on rare diseases or rare indications, the pool of available experts is often limited, posing a challenge for assembling a sufficiently knowledgeable adjudication committee therefore this study utilized practitioners who were already participating in the study.A randomized case assignment system was used to ensure that each expert reviewed cases from sites other than their own.
The quality of site data entry varied and posed challenges to ensuring adjudication success	<ul style="list-style-type: none">Site training focused on data entry and data-collection processes that affected adjudication requirements.A collaborative approach was implemented in adjudication set-up and implementation involving the adjudication committee, sponsor, data management, adjudication system, clinical database vendor, and clinical monitoring to optimize the process
There was insufficient documentation to paint the whole clinical picture for the adjudicators to objectively assess an endpoint	<ul style="list-style-type: none">Minimum-required documentation was identified (e.g., operative reports, CT scans) and was requested from sites, thereby supplementing data collected in the EDC system.

Abbreviations: CT = computed tomography; EDC = electronic data capture

Conclusions

- Adjudication committees allow for structured, unbiased expert reviews, enhancing the reliability of retrospective outcomes data.**
- When faced with complex or incomplete real-world data, the involvement of adjudication committees can ensure data integrity and accuracy, which is essential for regulatory or other decision-making processes, ultimately improving patient safety and informing healthcare guidance.**

Disclosures

All authors are employees of PPD™ Observational Studies, Thermo Fisher Scientific. Funding for this poster was provided by Thermo Fisher Scientific. Editorial and graphic design support were provided by Caroline Cole and Kawthar Nakayima of Thermo Fisher Scientific.