Fortrea Adjudication: Your Trusted Partner for Oversight Committee Management

Oversight Committees (OCs) play an important advisory and data standardization role in clinical trials. Fortrea can efficiently set up, manage and execute this important aspect of your clinical trial.

Founded in 2012, the Fortrea Adjudication Department is adept at navigating the complexities of OC management for Endpoint Adjudication Committees, Medical Decision Committees (Eligibility Committees, Dose Monitoring Committees, Treatment Algorithm Committees), Core Laboratories, Steering Committees, and Expert Panels/Scientific Advisory Boards. Fortrea differentiators include:

- **Oversight committee membership:** We have a vast network of past and present committee members we can assess for suitability for your trial. Alternatively, we can vet potential committee members you identify
- **Process expertise, collaboration and flexibility:** Our efficient, well-defined processes enable your oversight committees to operate optimally, promoting committee member satisfaction and facilitating quick data acquisition. Alternatively, we can adapt and discuss alternative workflows that cater to your needs, if desired. Averaging 10 years' individual experience, our staff have the expertise to consider benefits and risks and guide you to the best option for your trial
- **Coordination:** Oversight committee management is complex and dynamic. Output from one committee can provide important input for another; therefore, close coordination is required. We collaborate with stakeholders to identify, document and manage these interdependencies and timelines, ensuring you have the necessary results for swift decision-making

Fortrea

- **Technology:** Through strategic partnerships with industry-leading endpoint adjudication system partners, we have developed a "fit for purpose" system allowing for a paperless, end-to-end process that facilitates endpoint data collection and automates key processes, enhancing our work
- **Quality and speed:** Our unmatched Endpoint Adjudication Committee (EAC) metrics empower you to make swift, data-driven decisions with absolute confidence, reflecting our commitment to operational efficiency and responsiveness

Metric	Definition	Baseline data*	Fortrea target	Fortrea actual
Endpoint cycle time	Time from endpoint reported to endpoint dossier submitted (calendar days)	100	≤ 50	36
Endpoint dossier quality	% of endpoints with EAC requests for additional documentation	≤ 20%	≤ 2%	< 1%
Endpoint volume throughput	Average % of endpoints requiring adjudication for which dossiers have been submitted to the EAC for ongoing studies	55%	80%	96%

**** Industry benchmark utilized for baseline data.***

Evolving and unique requirements

Oversight group management is complicated and multifaceted. It requires careful analysis of numerous options since a diverse array of processes can be considered and implemented. A strategic approach must be followed to navigate the complexities inherent in this task. The absence of an industry-standard methodology presents both a challenge and an opportunity for innovation and customization in this niche area. Ultimately, effective management of oversight groups requires a nuanced understanding of the trial context, the interplay between different groups and the flexibility to adapt to evolving circumstances.

Five key oversight groups managed by the Fortrea Adjudication Department

- **Endpoint Adjudication Committees** review data and source documents when a potential clinical endpoint has been identified and provide consistent adjudicated outcomes for the trial's statistical analysis
- **Medical Decision Committees** examine data related to their committee focus and advise sites. For example:
  - *Eligibility Committees* review demographic and inclusion/exclusion data to verify subject enrollment criteria
  - *Dose Monitoring Committees* scrutinize dosing data and suggest alternative dosing if needed
  - *Treatment Algorithm Committees* provide independent medical guidance on complex treatment algorithms to promote protocol adherence
- **Core Laboratories** review specialty lab data and source documents to ensure consistency in assessments for endpoint identification and/or statistical analysis
- **Steering Committees** contribute scientific and thought leadership on protocol design, study start-up, study oversight and execution, publication strategy, study results analysis, clinical study report authorship and regulatory submission strategies
- **Expert Panels/Scientific Advisory Boards** advise on clinical development program strategy for an investigational product

The Fortrea Adjudication department offers a comprehensive solution that combines experience, flexibility and efficiency to navigate the complexities of oversight committee management. See what we can do for you!

Contact us today for additional information at:
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