



Adjudication Services: Endpoint Adjudication Committee set-up and management

Fortrea possesses a depth of endpoint management expertise, which we leverage to achieve exceptional performance in the design and execution of adjudication projects. Our extensive knowledge base in this highly specialized area is widely recognized. Fortrea has established an Adjudication Services department with expert staff who serve in dedicated roles, and our team members are regularly sought out by clients for consultation and operational execution.

- Since its inception in 2012, our Adjudication Services department has set up, managed and executed adjudication processes on 100+ trials and processed about 50,000 endpoints across a variety of therapeutic areas and indications

The successful setting up and operationalizing of a project with adjudication involves a myriad of decisions and considerations. Our subject matter experts can provide you with strategic consultation throughout. We have developed best practices based on our expertise and experience, but can also present options and suggest which would be most conducive to meeting your needs and the trial's specific objectives for endpoint adjudication.

With our proven ability to significantly shorten endpoint adjudication cycle times, while maintaining the highest quality standards, our team drives powerful results with this model, ensuring:

- Accurate and complete endpoint capture
- Expedited endpoint data and document collection
- High-quality endpoint dossiers for committee review
- Rapid and robust adjudicated outcomes for critical decision-making

Services

The Adjudication Department has a full-service, end-to-end offering that includes:

Adjudication Process Design and Set-Up

Committee membership compilation and management; charter development; endpoint reporting and adjudication CRF design; endpoint detection and trigger program development; strategic partnership with industry leading technology vendor; electronic adjudication system specification and management; endpoint site manual development; process and system training for all process stakeholders

Adjudication Project Leadership

Functional project management of endpoint case processing and adjudication deliverables; participation in project communications and team meetings; status reporting; adjudicator payment coordination; project file maintenance

Endpoint Dossier Compilation

Case processing for investigator-reported endpoints and triggered events; endpoint data and document collection and preparation; endpoint dossier compilation and submission; committee adjudication workflow coordination; adjudication outcome data capture

Adjudication Committee Meeting Coordination

Meeting planning, logistics and conduct: agendas, meeting materials, hosting, minutes

Driving results—optimized critical decision-making

Fortrea Adjudication Services displays mastery in this highly-specialized core competency, delivering expertise that promotes process optimization. Our approach combines an unwavering commitment to seamless customer delivery with skilled leadership, best-in-class procedures and an efficient electronic endpoint management system. Our KPI data demonstrate maximal efficiency and high quality, with our exceptional performance translating into tangible benefits for our sponsors.

Fortrea adjudication services - KPI data (2023 calendar year)

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

* Industry benchmark utilized for baseline data



Benefits of Fortrea adjudication project delivery model

Decision empowerment—the ability to make timely, data-driven decisions with confidence.

For adjudication projects, our expert team drives the availability of outcome data, which are needed to optimize critical decision-making processes throughout the project lifecycle. As a result, the Fortrea adjudication project delivery model yields the following advantages:

- More complete endpoint datasets for periodic review by Data Monitoring Committees
- Higher volumes of adjudicated outcomes for increased sensitivity of interim analyses
- Rapid delivery of adjudicated endpoints for adaptive trial design decision-making
- Timely end of enrollment, without over-enrollment, for event-driven trials
- No delay to database lock milestone for adjudication projects

Learn more about how **Adjudication Services** can optimize critical decision-making on your projects.
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