

### Introduction

If clinical events are used as study endpoints, central adjudication by a panel of independent experts is needed, to normalize endpoint outcomes of this type for statistical analysis.

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 adjudication roles, and our adjudication team members are regularly sought out by clients for consultation and for operational execution.

Expertise promotes process optimization, and our proprietary adjudication project delivery model yields KPIs which are un-matched by the competition, establishing Fortrea as the industry leader in adjudication project delivery.



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:

- 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**

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; 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 representation in team meetings; status reporting; adjudicator payment coordination; project file maintenance, archive and transfer	
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 of a highly specialized core competency. Our approach combines an unwavering commitment to seamless customer delivery with: skilled leadership, sophisticated modelling techniques, best-in-class procedures, and an efficient electronic endpoint management system. Our KPI data demonstrate maximal efficiency and high quality, and our exceptional performance translates 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	100 calendar days	≤ 50 calendar days	36 calendar days
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 to the EAC for ongoing studies	55%	80%	96%

<sup>(\*)</sup> 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

# Fortrea Together, exceptional is possible

For more information on how our Adjudication Services can optimize critical decision-making on your projects, contact:

Catherine Tyner

Executive Director, Adjudication Services
catherine.tyner@fortrea.com



