

Your ADC programs deserve a collaborator who understands science, safety and the operational demands of this modality



A KEY QUESTION

What does it take to move an ADC program from first-in-human to registration with greater speed and predictability?

KEYWORDS

First-in-Human and Dose Escalation, EPON Partner-Site Network, Biomarker and NGS-Enabled Recruitment, Integrated Safety and Medical Monitoring, Global Regulatory (FDA/EMA/PMDA)

Antibody-drug conjugates are one of oncology's largest growth segments, combining the precision of a monoclonal antibody with the potent anti-tumor activity of a cytotoxic payload. With ~20 ADCs approved globally, 1,600+ trials and a market past \$10B, realizing their potential takes a provider fluent in the biology, toxicity management and operational execution. Fortrea brings deep, proven ADC experience, from first-in-human through registration and commercialization

Core capabilities

Early-phase and first-in-human oncology execution

Proven ADC development experience from first-in-human dose escalation to expansion cohorts and registration-enabling studies, with deep capabilities in dose optimization, recommended Phase II dose (RP2D) selection, clinical pharmacology, PK/PD and global oncology execution.

FIH and dose escalation, MTD/RP2D/dose optimization, dual-payload experience, PK/clinical pharmacology

EPON: Accelerating early oncology development

Fortrea's Early Phase Oncology Network (EPON) provides direct access to more than 80 leading oncology centers worldwide, leveraging trusted investigator relationships, pre-established

Five-year overview

Proven delivery at global scale

40+ ADC trials 2021 (Q3) – 2026 (Q2)

9,300+ Patients enrolled globally

2,500+ Sites

43 Countries

agreements and proven recruitment capabilities. Together with strategic collaborators including START, Exigent and Pangaea, we reduce activation timelines, improve enrollment predictability and help sponsors reach critical development milestones faster.

80+ curated sites, +22% enrollment vs. non-network sites, non-enrolling risk cut to 26.7%, faster start-up

Biomarker-driven patient identification

Fortrea's oncology network integrates routine molecular prescreening, companion diagnostic capabilities and precision-oncology workflows, including but not limited to NGS, to identify eligible patients before study activation. This enables faster enrollment of biomarker-selected populations across established and emerging ADC targets, such as HER2 (including HER2-low), TROP2, HER3, Nectin-4, c-Met and RAS, while reducing screening inefficiencies and increasing enrollment predictability.

Molecular prescreening, HER2/HER2-low, TROP2, HER3, Nectin-4, c-Met, RAS, CDx capabilities, predictable enrollment

Specialized logistics and endpoint management

Specialized logistics for API and biological sample handling and processing, pharmacy capabilities for ADC storage and preparation, acute toxicity management and diverse endpoint delivery, from PK in blood and tissue to early-efficacy imaging of antibody targeting.

ADC pharmacy, storage and prep, API and sample management, acute toxicity management, PK (blood/tissue) and imaging endpoints

Integrated safety and medical monitoring

Real-time safety data review and 24/7 medical monitoring throughout dose escalation with safety-committee (SRC/DSMB) support, integrated pharmacokinetic (PK), exposure-response and safety assessment and a rigorous focus on eligibility and safety through targeted source-data verification, so early signals are identified and managed proactively.

Real-time safety review, dose-escalation and DLT oversight, SRC/DSMB support, PK-safety integration

Global regulatory and integrated delivery

Global regulatory experience across FDA, EMA and PMDA, managing the three lenses regulators apply to ADCs: Quality, clinical pharmacology and patient safety with CMC/payload handling and integrated multi-vendor oversight.

FDA/EMA/PMDA, CMC and payload handling, multi-vendor and CDx oversight

Our process – from strategy to submission

01

Protocol and feasibility

Design, dose strategy, feasibility

02

Site selection and activation

EPON network, fast start-up

03

Enrollment and monitoring

Safely-focused, risk-based

04

Data lock and analysis

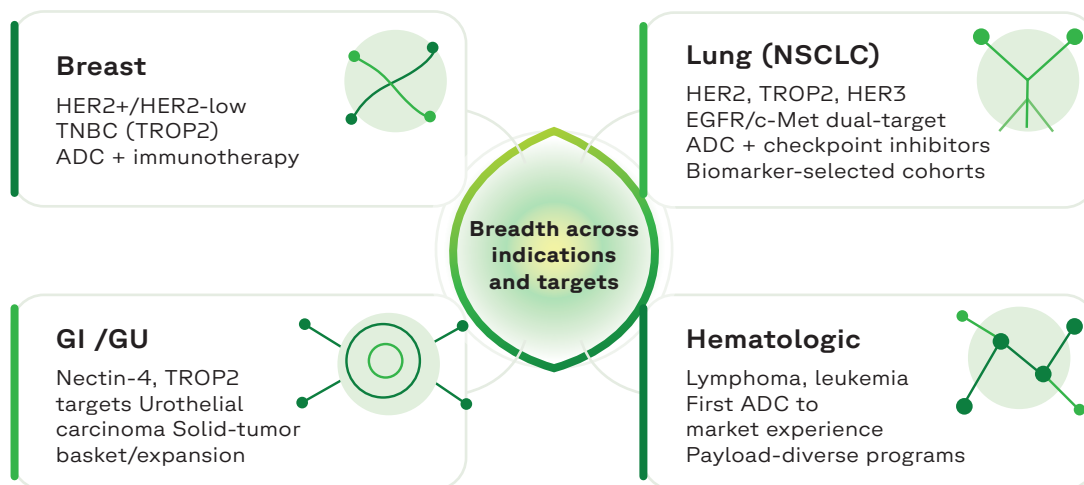
PK/biomarker integration

05

Regulatory submission

FDA/EMA/PMDA

ADC study depth



Why sponsors choose Fortrea for ADCs'

Combining scientific depth. Operational excellence. Proven ADC delivery

- ✓ Modality experience: Proven ADC experience from first-in-human through to registration and commercialization milestones
- ✓ Early-phase execution designed for dose optimization, including DLT monitoring, cohort management, exposure-response assessment and comprehensive PK support to de-risk development decisions early
- ✓ EPON site network that accelerates start-up and boosts enrollment, with existing peer-to-peer investigator relationships and master agreements
- ✓ Integrated, real-time safety and medical monitoring across dose escalation and expansion with SRC/DSMB support and PK-safety integration
- ✓ Single-CRO global regulatory experience across FDA, EMA, PMDA and NMPA
- ✓ Biomarker-driven patient identification through established NGS pathways and companion-diagnostic integration across global oncology networks

Fortrea – Combining scientific leadership with delivery excellence

50+

Oncology physicians
and scientists
supporting ADC
development

50+

Peer-reviewed
oncology articles
since 2020

40+

ADC studies
delivered globally
2021 (Q3) - 2026 (Q2)

Our oncologists co-author in high-impact journals and collaborate with industry and academic leaders, reflecting hands-on therapeutic depth in ADCs across breast, lung and other indications.

Featured ADC publications by Fortrea oncologists:

- Salifu I, et al. Antibody-drug conjugates, immune-checkpoint inhibitors and their combination in advanced non-small cell lung cancer. *Cancer Treatment and Research Communications*, 2023
- Ko H, et al. Is HER2-low a new clinical entity or merely a biomarker for an antibody-drug conjugate? *Oncology & Therapy*, 2023
- Saini KS, et al. Antibody-drug conjugates, immune-checkpoint inhibitors and their combination in breast cancer therapeutics. *Expert Opinion in Biological Therapy*, 2021

Global regulatory experience

- Single-CRO global submission support across FDA, EMA, PMDA and NMPA
- Payload and linker CMC handling with specialized manufacturing logistics
- Experience supporting accelerated and registrational development pathways
- Multi-vendor oversight integrating imaging, companion diagnostics and central labs

Explore our marketing-approved ADC content**Guide**

[Antibody Drug Conjugates \(ADCs\):
A guide to Regulatory Clinical Development](#)

Publication

[Peer-reviewed oncology
articles since 2020](#)

Want to learn more?

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