INFO SHEET

A trusted MDD collaborator with complex global experience

Fortrea MDD: Advancing diagnostic imaging trials through global experience

Overview

Over the past five years, Fortrea's Medical Device and Diagnostics (MDD) team has supported a broad portfolio of diagnostic imaging studies, collaborating with multiple global sponsors across pharmaceutical, biotech and diagnostic imaging technology sectors.

This experience spans:

- More than 20 diagnostic imaging clinical studies across the globe over the past 10 years
- Magnetic resonance imaging (MRI), positron emission tomography/computed tomography (PET/CT), single photon emission computed tomography (SPECT) and contrast-enhanced diagnostic imaging modalities
- Exploratory through pivotal development programs

Fortrea's ability to deliver scalable, regulatory-compliant and operationally efficient diagnostic imaging trials has positioned the team as a trusted collaborator for complex, multi-regional studies.

Global scope and scale of experience

Fortrea has successfully supported diagnostic imaging studies across North America, Europe and Asia-Pacific.

This demonstrates:

- Proven multi-regional regulatory experience
- Established site networks for diagnostic imaging trials
- Capability to navigate diverse regulatory frameworks (FDA, EMA, NMPA, PMDA, etc.)

Americas

United States
Canada
Mexico

Europe

Austria
Bulgaria
Czech Republic
Denmark
France
Germany
Greece
Hungary
Italy
Netherlands
Norway
Poland
Portugal
Spain
Sweden
Ukraine
United Kingdom

Asia Pacific

China
Japan
South Korea

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Therapeutic and diagnostic imaging experience

Fortrea's portfolio reflects strong experience across key therapeutic areas:

Therapeutic area	Example diagnositic imaging applications
Oncology	PET/CT for tumor detection, receptor diagnostic imaging
Neurology	CNS lesion detection, Parkinsonian diagnostic imaging
Cardiovascular	Perfusion diagnostic imaging, contrast echocardiography
Musculoskeletal	Whole-body MRI diagnostic imaging
General diagnostics	Contrast-enhanced diagnostic imaging

Supported technologies include:

- MRI (contrast-enhanced and functional diagnostic imaging)
- PET/CT and PET diagnostic imaging agents
- SPECT diagnostic imaging
- Novel radiopharmaceuticals and contrast agents

End-to-end service delivery

Fortrea provides flexible delivery models, ranging from functional support to full-service outsourcing:

- Project and program management
- Regulatory strategy, submissions and maintenance
- Site selection and start-up (global)
- Clinical monitoring (including diagnostic imaging-specific oversight)
- Vendor management (e.g., central diagnostic imaging labs)
- Data management and biostatistics
- Safety and pharmacovigilance
- Medical monitoring and diagnostic imaging physician oversight
- CTMS and eTMF management

Across the portfolio, Fortrea has consistently delivered integrated services across multiple functions, supporting both full-service and strategic collaboration models.

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Breadth across study phases

Fortrea has supported diagnostic imaging studies across the full development lifecycle:

Study phase	Representative support
Early phase (I / Ia / Ib)	First-in-human diagnostic imaging agents, dose escalation
Phase II / Pilot	Exploratory efficacy and diagnostic imaging validation
Pivotal (Phase II/III)	Large-scale, multi-country diagnostic performance studies
Post-marketing	Whole-body MRI diagnostic imaging
General diagnostics	Safety and real-world diagnostic imaging evaluation

Operational complexity and differentiation

Fortrea MDD's diagnostic imaging portfolio includes:

- Large, multinational pivotal trials across more than 20 countries globally
- Highly specialized radiopharmaceutical studies (including dosimetry and PK endpoints)
- Pediatric and rare population studies
- Studies requiring complex vendor ecosystems (e.g., diagnostic imaging core labs, radiochemistry suppliers)

Key differentiators:

- Experience in diagnostic imaging-specific endpoints and standardization
- Strong coordination of cross-functional vendors and diagnostic imaging workflows
- Ability to support novel agents (e.g., PET tracers, contrast agents)
- Proven execution in highly regulated environments

Demonstrated delivery outcomes

Across the portfolio, Fortrea has demonstrated:

- Successful management of concurrent start-up, enrollment and close-out studies
- Delivery of both standalone services and fully outsourced programs
- Flexibility to adapt to:
    - Sponsor-driven timeline changes
    - Study expansions and extensions
    - Early terminations and lifecycle transitions

The data shows a balanced pipeline with studies across start-up, active enrollment, follow-up and close-out phases, reflecting sustained delivery capability and pipeline continuity.

Client-centric approach

Fortrea has collaborated with:

- Global diagnostic imaging leaders
- Mid-sized biotech innovators
- Emerging radiopharmaceutical companies

Across these collaborations, Fortrea consistently provides:

- Tailored delivery models aligned to sponsor needs
- Transparent communication and governance structures
- Proactive risk management and mitigation

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Depth of operational experience in diagnostic imaging pathways

A key differentiator for Fortrea MDD is the depth of hands-on experience in managing the inherent complexity of diagnostic imaging trials, particularly in navigating the full patient pathway.

Diagnostic imaging studies are highly multidisciplinary, requiring close coordination across multiple hospital departments, including oncology, surgery, pharmacy, radiology and laboratories. These interdependencies must be carefully aligned within strict protocol-defined timepoints, such as surgical procedures, investigational medicinal product (IMP) manufacturing and ordering, IMP administration and imaging visits.

Operational delivery is further challenged by site-specific constraints, including limited scanner availability, radio pharmacy manufacturing capacity and competing clinical priorities. These factors can vary significantly across sites and regions, introducing variability and risk if not proactively managed.

What distinguishes Fortrea is the experience of its teams in anticipating and navigating these complexities. This practical, site-level insight enables proactive risk identification, efficient cross-functional coordination and reliable study execution across diverse geographies and healthcare systems.

Fortrea brings:

- **Deep, hands-on experience managing complex, multidisciplinary patient pathways at site level**
- **Use of structured tools (e.g., patient pathway mapping) to de-risk study execution**

To support this, Fortrea has developed a structured **patient pathway mapping tool,** which captures the end-to-end patient journey at each site.

This tool is reviewed in conjunction with the study protocol to:

- Help all participating departments achieve a **clear, aligned understanding of the required workflow**
- Confirm that protocol-defined timelines are **operationally feasible at the site level**
- Establish **early cross-department communication pathways,** reducing the risk of downstream delays or deviations

This approach strengthens feasibility assessments, enhances site readiness and supports consistent, high-quality trial delivery across complex diagnostic imaging programs.

Conclusion

Fortrea MDD brings proven, global experience in diagnostic imaging trials, supported by:

- A strong track record of more than 20 diagnostic imaging studies in the past 10 years
- Deep experience across multiple diagnostic imaging modalities and therapeutic areas
- Ability to deliver complex, multi-regional programs with regulatory rigor

This positions Fortrea as a trusted collaborator for diagnostic imaging-focused clinical development, capable of accelerating timelines, supporting compliance and delivering high-quality data to support regulatory and commercialization goals.

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Key considerations, risks and mitigations when conducting diagnostic imaging trials

Diagnostic imaging trials require a unique combination of technical experience, operational precision and cross-functional integration. Fortrea MDD applies a structured, risk-based approach to support standardized imaging execution, high-quality data delivery and regulatory-ready outcomes across global studies.

Risk area	Key risk description	Potential impact	Mitigation strategy	Fortrea MDD value added
Imaging standardization	Variability in imaging acquisition, scanner types and protocols across sites	Inconsistent data quality Reduced endpoint reliability Regulatory challenges	Standardized imaging manuals and acquisition protocols Site qualification and scanner calibration Phantom testing and QC procedures	Established imaging SOPs Centralized protocol development Proven site qualification processes
Image quality and endpoint integrity	Poor image quality, missing scans or inconsistent interpretation	Invalid or non-evaluable endpoints Increased variability Regulatory risk	Real-time image QC checks Blinded Independent Central Review (BICR) Double reads and adjudication	Integrated imaging vendor oversight and central reading coordination
Site capability	Sites lack knowledge, infrastructure or experience with imaging modalities	Start-up delays Protocol deviations Poor data quality	Imaging-focused feasibility assessments Selection of experienced imaging sites Site training and certification	Global network of imaging-experienced sites Targeted training programs
Radiopharmaceutical supply chain	Short half-life tracers Logistics complexity Supply interruptions	Missed patient visits Protocol deviations Recruitment delays	Advance supply chain planning Backup suppliers and contingency strategies Alignment of dosing and imaging schedules	Vendor management experience and experience with radiopharma logistics

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Risk area	Key risk description	Potential impact	Mitigation strategy	Fortrea MDD value added
Regulatory and compliance	Misalignment with regional regulations (radiation, imaging and combination products)	Study delays Inspection findings Approval risks	Integrated regulatory strategy Compliance with GCP, ISO, radiation safety regulations Country-specific regulatory planning	Strong regulatory experience across FDA, EMA and global frameworks
Operational complexity	Coordination challenges between clinical teams, imaging vendors and sites	Delays, inefficiencies and communication gaps	Clear governance model and RACI Regular cross-functional meetings Integrated project plans	Proven cross-functional delivery model with strong PM oversight
Visit scheduling and timing	Imaging must occur in strict protocol-defined windows	Protocol deviations Missing critical endpoint data	Defined visit windows with operational flexibility Real-time tracking and escalation pathways Site scheduling optimisation	Experience aligning imaging and clinical workflows across global studies
Patient recruitment and selection	Imaging-specific eligibility criteria limit patient pool	Slow enrollment High screen failure rates	Site selection based on patient population and imaging capability Clear screening criteria and imaging eligibility guidance Targeted recruitment strategies	Proven enrollment strategies for imaging-driven studies

Risk area	Key risk description	Potential impact	Mitigation strategy	Fortrea MDD value added
Data management and integration	Complexity in imaging data transfer (DICOM), storage and integration with EDC	Data delays, loss or inconsistencies Audit risks	Validated imaging data transfer platforms Secure storage and integration workflows UAT and system validation	Integrated data management and imaging workflows Validated systems
Vendor management	Multiple vendors (core labs, radiochemistry and imaging providers)	Misalignment, delays and quality issues	Vendor qualification and oversight Defined SLAs and KPIs Centralized vendor governance	Strong vendor management model and established collaborator ecosystem
Cross-regional delivery	Variability in site practices, regulatory timelines and infrastructure	Delays in start-up and execution Inconsistent performance	Standardized global processes Regional experience and local regulatory support Harmonized training programs	Global footprint with local experience across more than 25 countries
Theranostic complexity	Integration of diagnostic imaging with therapeutic delivery pathways	Increased operational and regulatory complexity	Alignment of imaging and therapeutic protocols Integrated biomarker and patient selection strategies Cross-functional coordination	Combined experience in diagnostic imaging and complex clinical trials