Radiopharmaceuticals: Unique Challenges for Clinical Trials and Data Management

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What Are Radiopharmaceuticals

Radiopharmaceuticals = Radioactive Isotope + targeting molecule

Agents used for **diagnosis**, **therapy**, or **both** (**theranostics**) through targeted radiation delivery.

Key Characteristics

- **Targeted delivery**: molecule (ligand) binds to a tumor-specific receptor
- **Theranostic pair**: Same ligand, different isotopes for imaging versus therapy
- **Short-lived isotopes**: Required precise coordination of manufacturing, shipping, dosing, and imaging
- **Different dosing concept**: Activity (Bq) and absorbed dose (Gy), not mg

Every component on this slide (ligand, isotope, receptor, timing) produces data that must align for the science to work!

What Makes Radiopharmaceutical Trials Special

Dual Regulatory Framework

Radiopharmaceutical trials must comply with both pharmaceutical and radiation protection regulations, unlike conventional drug trials.

Unique Dosing Metrics

Dosing in radiopharmaceuticals is measured in Becquerels and Grays, focusing on radioactivity and absorbed dose instead of milligrams.

Theranostic Approach

These trials combine diagnostic imaging and therapy, making imaging data central to evaluating safety and efficacy.

Logistics and Dosimetry Challenges

Short isotope half-lives require precise scheduling and patient-specific delivery to optimize safety and maintain product viability.

Data sources and integration

In radiopharmaceutical development, the science can only work if data management can precisely synchronise biology, imaging, radioactivity, and time

Diverse Data Streams

Radiopharmaceutical trials use diverse data including nuclear logs, imaging data, and dosimetry outputs that increase complexity.

Data Linking Requirements

Linking datasets requires consistent identifiers, timestamps, and unit normalization to ensure data integrity across platforms.

Integration Architecture

Integration must support automated ETL, audit trails, and adhere to regulatory standards like 21 CFR Part 11 and GDPR.

Risks of Poor Integration

Without robust integration, data silos cause inconsistencies, analysis delays, and increase regulatory risks.

Dosimetry workflow and data capture

Dosimetry is where data quality becomes patient safety.

Data Collection and Modeling

Collect time-activity data from serial imaging and perform kinetic modeling for dosimetry calculations.

Dose Calculation and Documentation

Calculate absorbed doses using MIRD or voxel methods and document doses with uncertainties and software details.

Administered Activity Capture

Accurately capture administered activity including isotope, lot number, calibration time, and residual activity.

Quality Checks and Compliance

Perform edit checks for logical sequences and decay corrections ensuring patient safety and regulatory compliance.

In radiopharmaceutical development,

data management must move

from a support role to scientific foundation.

The science depends on it!