

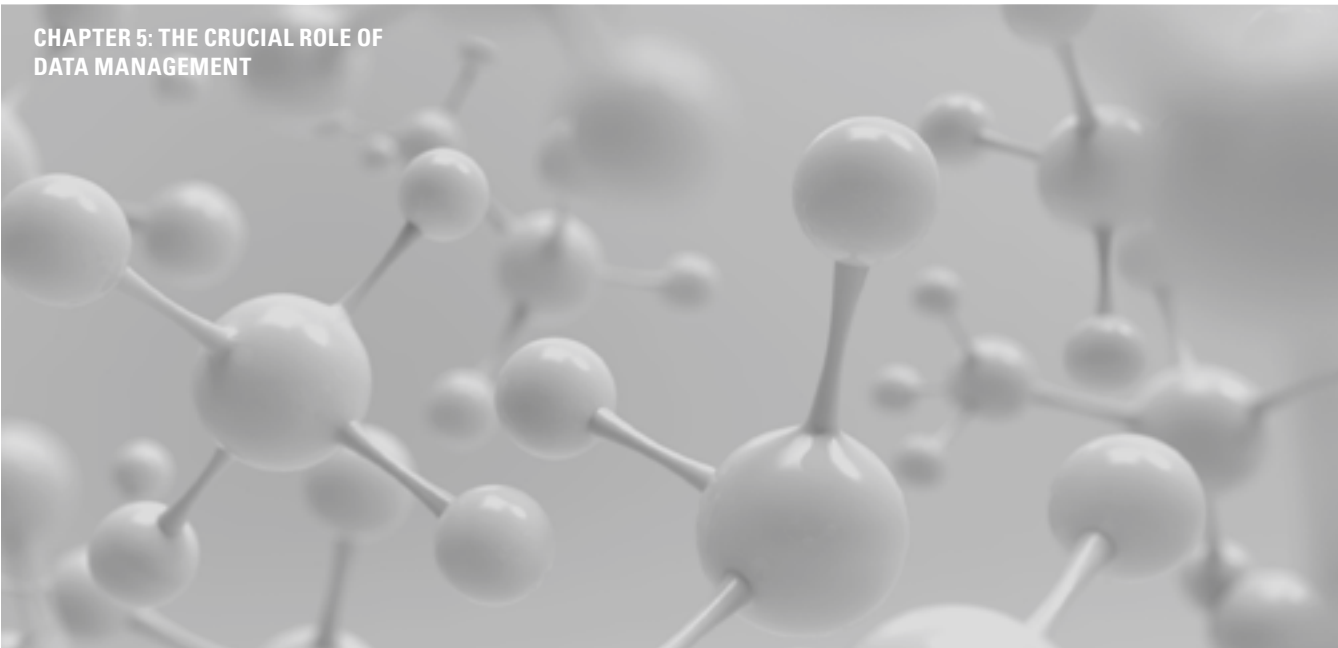
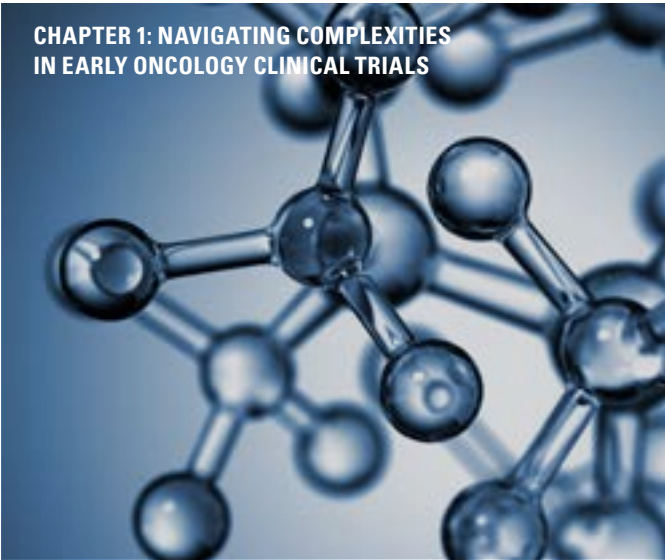


Optimizing oncology trials

E-BOOK

SGS

Contents



Chapter 1:
Navigating complexities in early oncology clinical trials

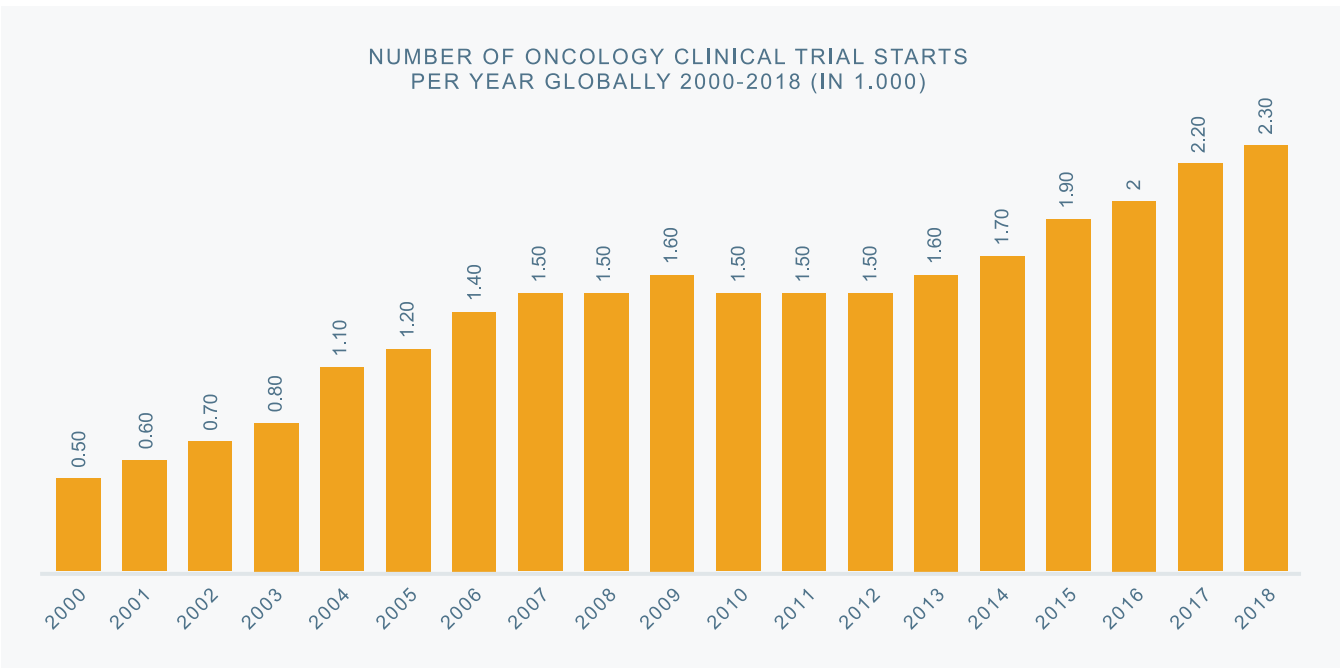


In the ever-evolving field of oncology, clinical trial play a pivotal role in advancing our understanding of cancer and developing novel treatments. Two prominent trends have emerged in recent years: the first, the increasing development of cancer-targeting drugs, leading to more early-phase clinical trials in oncology; and the second, the growing inclusion of biomarkers in oncology trials.

While these trends hold great promise for personalized cancer treatments, they also present unique challenges. In this article, we will dive into the complexities of early oncology clinical trials, with a specific focus on sample management. We will also explore strategies to effectively address these challenges.

TREND #1

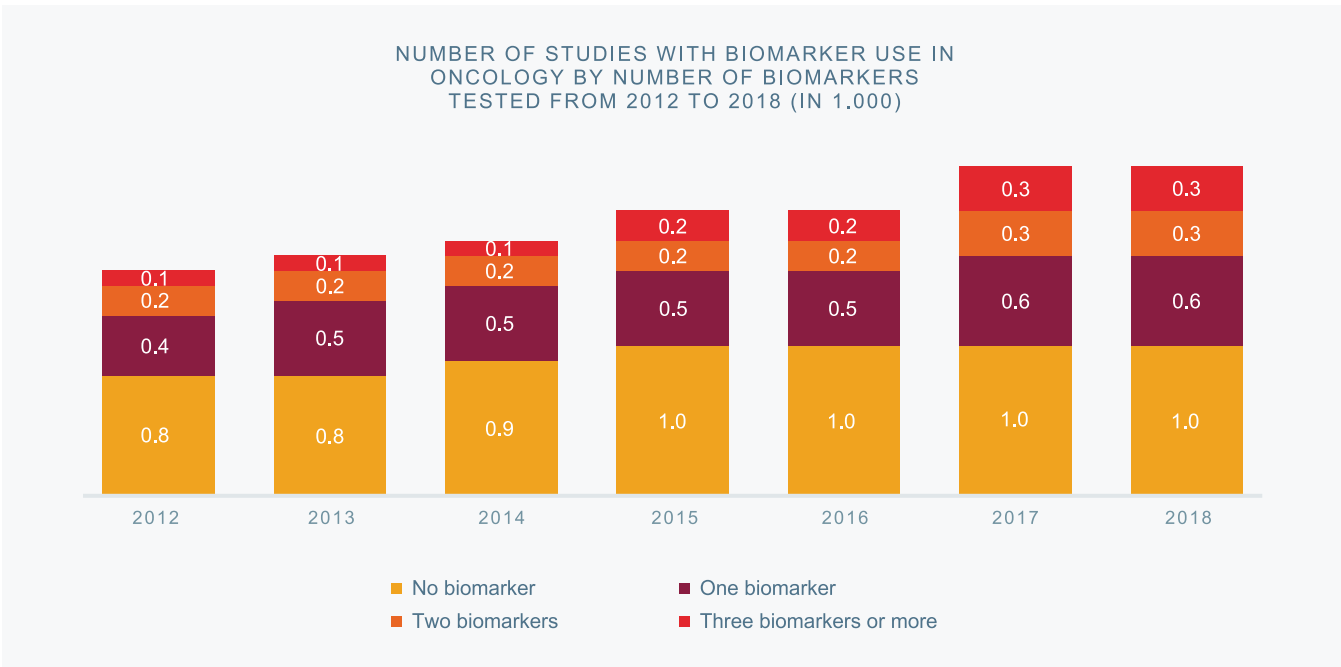
Rise in cancer-targeting drug development amplifies early-phase oncology trials



source: statista.com

TREND #2

The influx of biomarkers in oncology trials



source: statista.com

COMPLEX STUDY PROTOCOLS

Early-phase clinical trials in oncology are becoming increasingly complex. Study protocols encompass different cohorts and scenarios, combined phases, multiple elaborate assessments, extensive sampling and interim analyses. The challenge lies in the fact that study sites often lack the resources and expertise required to execute these complex protocols.

However, this challenge also presents an opportunity to improve the process. By providing intuitive instructions and meticulously designed visit kits, it's possible to simplify sample collection, handling and processing procedures at study sites. Additionally, thoroughly training study site personnel can empower them to navigate these multifaceted protocols more adeptly.

PROTOCOL ADAPTATIONS

Early oncology trials are known for their volatility, with protocols often adapting based on new outcomes or patient well-being considerations. Flexibility and adaptability are key. It's essential to establish clear processes for dealing with protocol amendments to ensure efficient adaptation. Moreover, maintaining transparency in cost structures is crucial to avoid unexpected financial burdens during protocol changes.

Early oncology trials are dynamic, often requiring protocol adaptations. Clear processes and cost transparency are essential for efficient and flexible trial management.



DIVERSE SAMPLE TYPES AND PARAMETERS

In early oncology trials, the extensive collection of diverse data, various sample types, and numerous parameters can complicate the need for multiple specialized labs and specific sample testing.

However, factoring a central laboratory into the process can streamline operations significantly. Central laboratories take charge of the entire sample workflow, ensuring that the right pre-processed samples are efficiently delivered to the specialty laboratories.

This eases the burden of the complex task of sample logistics on study sites, and lightens the load for CROs

or sponsors by entrusting laboratory management to the central laboratory. This optimized approach also benefits the specialty laboratories, allowing them to concentrate on sample testing as they receive cleaned, consolidated and inventory-proofed samples.

In addition, it optimizes data flow as the central laboratory can consolidate patient and visit data, eliminating the need for multiple databases and associated data cleaning tasks. This not only simplifies data management but also facilitates easier data analysis for CROs and sponsors.

WHAT TO CONSIDER DURING STUDY PLANNING

During the study planning phase, there are key considerations to keep in mind:

1. Scientific advice for parameter selection

In early study planning, seek scientific guidance for parameter selection. Identify valuable parameters, address pre-analytical considerations (such as sample handling and required tubes) and assess the ability to anticipate logistical challenges. Additionally, consult experts for recommendations on suitable laboratories for specific testing.

2. Site selection and collaboration

During site selection, connect with experienced research sites. Openly discuss the anticipated trial-related efforts – including lab sample complexities – and verify their operational capabilities, including infrastructure and skilled staff.

Gain insights into their standard processes, like sample fixation protocols, to avoid unnecessary work caused by protocol deviations.

3. A meticulously designed study protocol

Compile the gathered information to shape a thorough study protocol. Include alternative scenarios to address possible trial developments, such as assessing the benefits of an investigational medicinal product (IMP). Consider the implementation of a Secure Data Office (SDO) – an independent blinded group handling unblinded data transfers in support of IDMCs – if early-stage outcomes remain inconclusive.

CONCLUSION

Early oncology clinical trials are characterized by their complexity and the extensive collection of data and samples. While these trials present challenges, they are not unfeasible.

By carefully planning and considering the advice outlined in this article, and by working with a central laboratory, clinical trial stakeholders can navigate these challenges more effectively. This will lead to higher motivation among stakeholders, reduced errors, and ultimately, higher-quality trials.

Most importantly, these efforts will benefit the patients, who are at the heart of every oncology trial, bringing us closer to more effective and personalized cancer treatments.



Chapter 2: The crucial role of kit design in sample collection



Oncology clinical trials are a critical frontier in medical research, providing insights into potential treatments that can save lives. However, these trials are no straightforward endeavor.

They involve multiple blood-drawing time points and require multiple sample types – resulting in diverse

sample collection tubes and specific pre-analytical requisites – adding more layers of complexity. Amid these complexities, the minimal time given to site staff for collecting samples emphasizes the importance of being efficient and precise.

THE STRATEGIC APPROACH: CRAFTING USER-CENTRIC KITS

A pivotal strategy in mitigating the challenges of oncology clinical trials lies in the careful design of sample collection kits. The principle is simple: The kits should make the process as seamless as possible for the site staff. This means that each patient’s visit should be neatly encapsulated within a dedicated kit.

Whether the visit requires pre-dose blood drawing or multiple post-dose time points, the kit box should be organized so that the necessary materials are easily accessible.

EXAMPLE SCENARIO: STREAMLINED KIT FOR MULTI-TIME BLOOD DRAW

Imagine a patient visit that necessitates blood drawing prior to administration and then at 30 minutes, two hours, and four hours post-administration.

In this scenario, a well-structured kit is essential. Each patient’s visit should be encapsulated within a dedicated kit. This kit box should be meticulously packed so that upon opening, the materials (including gloves, butterfly pipettes and labels) required for each specific blood-drawing time point are readily accessible.

For instance, the pre-dose kit should be conveniently positioned on top of the others, containing all the essential items for pre-dose blood collection. As the layers unfold, the subsequent kits for the 30-minute, two-hour, and four-hour post-dose time points seamlessly reveal themselves. the kit box should be organized so that the necessary materials are easily accessible.



GUIDING WITH CLARITY: INSTRUCTIONS AND QUICK REFERENCES

Clear and concise sample collection instructions are central to this process. The laboratory manual should be designed to be easily understood and followed, acknowledging the time constraints faced by study nurses.

A quick-reference sheet offers helpful descriptions that guide study nurses just before sample collection.

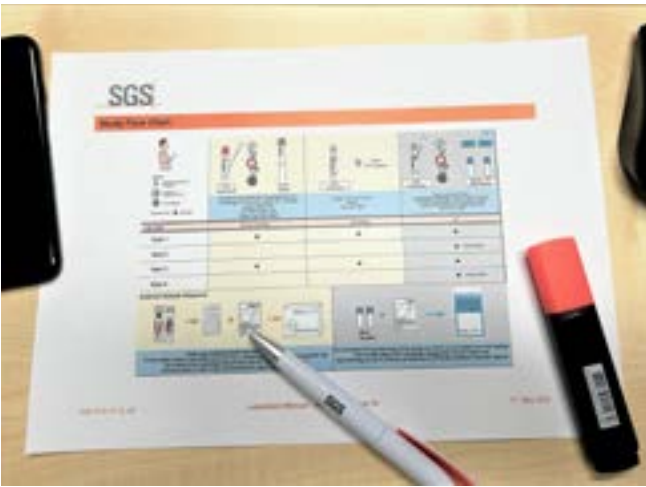
It helps them ensure the correct order of blood drawing for various primary tubes and follow essential pre-analytical sample handling steps.

This addition not only streamlines the process but also minimizes the chances of errors.

EXAMPLE SCENARIO: LAMINATED REFERENCE SHEET FOR QUICK GUIDANCE

To facilitate swift and accurate execution, a laminated reference sheet with helpful descriptions can be provided.

This allows study nurses to quickly verify the correct order of blood drawing for various primary tubes (such as serum tubes without coagulants, followed by EDTA tubes) and follow pre-analytical sample handling steps like mixing, incubation and centrifugation.



COLORS THAT SIMPLIFY COMPLEXITY

For trials that demand serum, EDTA plasma, and citrate plasma, complexity peaks. Enter color-coded cryovials – a brilliant yet simple solution. These cryovials, each adorned with a specific colored top, are paired with preprinted cryovial labels in corresponding colors.

This visual coding ensures that even in the midst of complexity, sample handling remains straightforward.

EXAMPLE SCENARIO: COLOR-CODED CRYOVIALS FOR COMPLEX TRIALS

For example, serum samples could be designated for cryovials with white tops, EDTA plasma with red tops, and citrate plasma with blue tops.

The cryovial labels, mirroring the colors, would come with essential information preprinted: details about the study, visit, time point, materials and analytes to be tested. The same color-coding would then be applied throughout the entire study.



CONCLUSION

The impact of thoughtful kit design

When navigating the complex landscape of sample collection, never underestimate the power of thoughtful kit design. The culmination of these strategic design elements results in meticulously crafted study-specific kits.

These kits encompass all necessary materials, organize time-point kits in a logical sequence, and are accompanied by user-friendly lab manuals,

laminated reference sheets and color-coded cryovials with corresponding labels.

The benefits ripple across the entire process, as accurate blood collection and pre-analytics becomes the norm. The results obtained from these samples are dependable, patient safety is enhanced and the value of the clinical trial is bolstered.

Chapter 3:

The central laboratory's crucial role in study site support



The intricate landscape of oncology clinical trials demands a strategic approach that goes beyond the norm. Amidst the complexity of diverse sample types, multiple trials, and limited time frames, a beacon of support emerges – the central laboratory.

This article delves into how central laboratories assume a key role in elevating early development in oncology trials, ensuring streamlined processes and impeccable sample quality.

CHALLENGES IN ELEVATING SITE EFFICIENCY

The journey of oncology clinical trials is marked by multifaceted challenges. These include managing the collection of a variety of sample types, handling the concurrent oversight of several trials, and navigating the logistics of sending different sample types to multiple laboratories for analysis. This operational complexity is a direct result of the intricate nature of oncology trials and the multifaceted tasks they entail.

Navigating these complexities within the tight constraints of clinical site schedules often paves the way for human errors. It is here that central laboratories rise to the occasion, poised to redefine trial dynamics.

CATALYSTS OF PRECISION

Central laboratories are key enablers of success. Their provision of study-specific kits and meticulously curated laboratory manuals marks a transformative shift. By ensuring that every patient visit is accompanied by a well-equipped visit kit, central laboratories harmonize processes and mitigate discrepancies.

With a central laboratory's involvement, consistency is guaranteed. All clinical sites receive identical materials and instructions,

resulting in uniform sample collection and pre-analytical handling across the board. This reduces variations in sample quality.

Moreover, central laboratories expertise in optimizing blood-drawing procedures through appropriate collection tubes can significantly reduce required blood volumes, enhancing patient comfort and trial efficiency.

USER-CENTRIC DESIGN AND INSTRUCTIONS

The true essence of central laboratory support is woven into the fabric of simplicity. User-centric design principles, through color-coded secondary tubes and preprinted cryovial labels, lay the foundation for precision. This streamlined approach not only

minimizes errors and leads to less workload at the clinical sites but also empowers study nurses to focus on what truly matters – patient care. With standardized practices across diverse sites, the reliability of samples increases.



LABORATORY MANUALS AS NAVIGATIONAL TOOLS

Laboratory manuals aren't just documents; they are roadmaps for success. A comprehensive laboratory manual serves as a guiding beacon for clinical sites. Beyond step-by-step sample collection instructions, it delves into the nuances of sample handling and shipping.

A central laboratory streamlines processes by routing all stored samples, facilitating query resolution before analysis. This proactive approach occurs after samples reach the central laboratory but before they're analyzed or sent to specialty laboratories. This is particularly beneficial for oncology trials, allowing clinical sites to focus on shipping specific samples at precise temperatures. This eliminates the need to navigate multiple laboratories with diverse instructions and sample requirements.

A central laboratory streamlines processes, resolves queries before analysis, and simplifies shipping requirements for clinical sites, especially in oncology trials.



EMPOWERING CLINICAL SITES: TRAINING AND EDUCATION

Empowering study nurses and investigators with the necessary skills is an investment that pays off manifold. Central laboratories can actively participate in investigator meetings, offering insights through engaging presentations.

Covering kit design, sample collection procedures, label completion and logistics, these presentations bridge potential knowledge gaps and provide clarity up front.

CONCLUSION

Impact of teamwork

Success in oncology trials hinges on collaborative synergy, with central laboratories at the heart of this partnership. Their steadfast dedication to accurate sample collection, strategic counsel and knowledge-sharing amplifies the experience.

As central laboratories and clinical sites walk together, a fresh era of empowered oncology trials emerges, underscoring the profound impact of teamwork.



Chapter 4:
The benefits of centralized sample management



Clinical trials in the field of oncology bring about unique challenges, especially in early-phase studies with a multicentric design involving multiple sites and key opinion leaders (KOLs) across different countries. The management of various sample types, including critical tissue samples, demands meticulous attention.

In this article, we delve into the complexities of sample management in oncological studies and explore how a centralized approach can provide numerous benefits for both sponsors and researchers.

THE COMPLEX NATURE OF ONCOLOGICAL STUDIES

Oncological clinical trials, especially in their initial phases, present a multifaceted challenge. They often span across various countries, involving multiple research centers, and are greatly influenced by key opinion leaders (KOLs) whose expertise contributes to the complexity of these studies.

At the core of these trials lies the critical task of collecting, preserving and analyzing a diverse range of samples, including valuable tissue and blood specimens. The meticulous handling, thorough documentation and precise transportation of these samples is vital to ensure the integrity and reliability of study data.

Moreover, maintaining data consistency is a significant challenge. Inconsistencies or missing information within sample data can hinder the research process. Establishing a robust system to identify and resolve such issues is crucial for data accuracy.

Efficient sample logistics during shipment, whether ambient, refrigerated, or frozen on dry ice, selecting appropriate courier services and ensuring proper packaging are key to preventing sample degradation. Furthermore, early-phase oncological studies often demand specialized testing, such as new exploratory tumor marker analysis and genetic profiling. Collaborating with specialized laboratories is essential but adds complexity to the research process.

SAMPLE MANAGEMENT WORKFLOW

Sample management in oncological studies involves a series of intricate steps:



Sample collection and preparation

Properly collecting and preparing samples, including instructions to ensure consistency.



Sample shipment

Coordinating the shipment of samples to the laboratory, considering temperature requirements (ambient, refrigerated, frozen).



Data entry and validation

Checking samples upon arrival, resolving missing or inconsistent data and ensuring data quality.



Chain of custody

Maintaining a secure chain of custody for samples during storage and analysis.



Analytical methods

Offering a wide range of analytical methods, including esoteric tests like tumor markers, pharmacokinetics (PK), biomarker analysis, genetic testing and immunogenicity testing. This will minimize the number of laboratories that have to be involved, resulting in a more efficient workflow.



Method validation

Ensuring that all analytical methods comply with regulatory guidelines and sponsor-specific requirements so that data can also be used at the later stages of development.



Specialty laboratories

Identifying and qualifying specialty laboratories for specific tests, if necessary, resulting in further relief and less oversight for sponsors.



Data reporting

Providing test results in standardized laboratory reports with consistent units and reference ranges helps CROs and MDs as they don't have to get acquainted with various laboratory report layouts.



Customized flags

Enabling the flagging of results that meet predefined criteria, such as inclusion/exclusion of potential study subjects during screening, serving also as gentle reminders for the investigators to keep in mind each study-specific criterion.



Sample storage

Providing storage solutions for various sample types at different temperatures, regardless of whether interim or long-term storage is required.



Inventory management

Generating comprehensive inventory lists for all stored study samples.



Temperature monitoring

Implementing advanced surveillance systems to monitor storage temperatures and trigger alarms during temperature excursions as well as establishing appropriate backup solutions.

THE ROLE OF CENTRALIZED SAMPLE MANAGEMENT

A centralized laboratory service provider can significantly optimize the sample handling process within clinical trials. This approach offers a range of advantages.

Firstly, it ensures an efficient workflow. With a central laboratory overseeing all aspects of sample handling and flow, the complexities associated with managing samples across different sites and laboratories are reduced. Researchers can focus on collecting high-quality samples while leaving the intricate logistics to the experts.

Moreover, study sites can concentrate on their core responsibilities – collecting samples and ensuring proper storage and shipment conditions – as the central laboratory takes charge of the rest.

Furthermore, specialty laboratories can dedicate their efforts solely to testing without being burdened by query management and logistical tasks. This enables them to deliver accurate and timely results.

Lastly, this centralized approach simplifies sponsor management. Sponsors benefit from having a single point of contact for the entire sample workflow. This reduces administrative complexities, allowing sponsors to consolidate workflows and streamline study management.

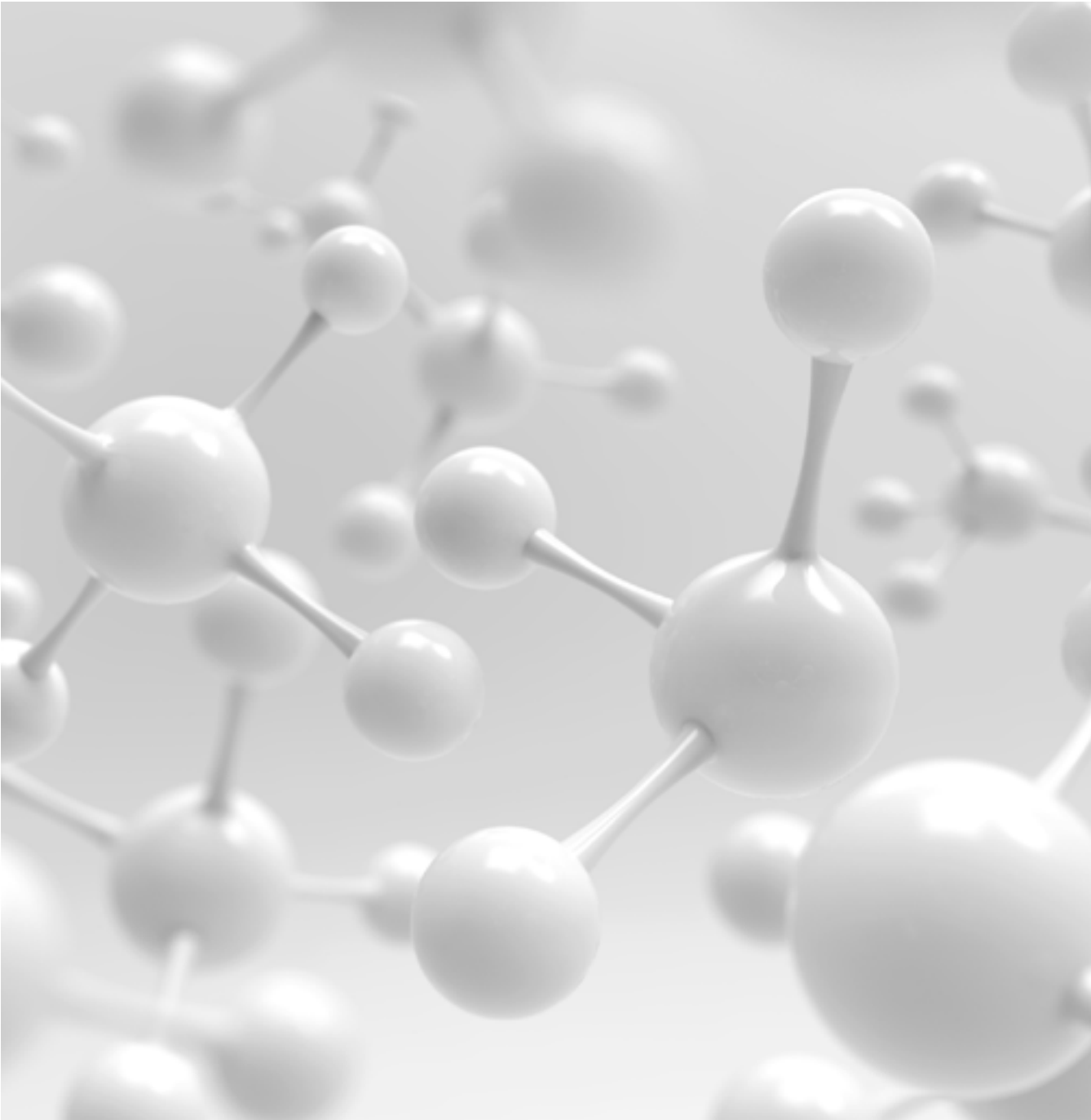
CONCLUSION

The complexities of managing samples in oncological studies, especially multicentric trials, can be daunting. However, a centralized approach to sample management can offer plenty of benefits. From streamlining workflows and reducing administrative burdens to enhancing the focus of



specialty laboratories, the advantages are far-reaching. By entrusting the intricate logistics of sample collection, storage, and analysis to a central lab, sponsors can optimize their clinical trials and contribute to the advancement of oncological research.

Chapter 5: The crucial role of data management



In the world of oncology clinical trials, data processing stands as the linchpin of success. Everything from designing study protocols and selecting research sites to executing analytical procedures is geared toward one ultimate goal: generating the data needed to evaluate the effectiveness of an investigational cancer treatment.

Ensuring the reliability, accuracy and integrity of this data is paramount, and central laboratories play an indispensable role in achieving these objectives. In this article, we shed light on how to prioritize data integrity and the invaluable contribution of central laboratories to this endeavor.

DATA CONSISTENCY IS KEY

Across the spectrum of clinical trials, the consistent handling of data is imperative. Every facet of the research process, spanning the development of study protocols, site selection, analytical procedures, and beyond, must align harmoniously. This entails a crucial need for consistency, whereby every phase, from data

generation to collection, storage, and transmission, must adhere to standardized procedures. This harmonization is essential not only for producing comparable and valid data but also for optimizing the efficiency of the entire trial process.

CENTRAL LABORATORIES: AN INDISPENSABLE ASSET

Central laboratories are instrumental in upholding data integrity. These facilities offer comprehensive services that extend well beyond traditional laboratory testing. These full-service facilities employ certified database systems equipped with validated interfaces to their analytical laboratories.

This technological advantage proves invaluable, particularly when dealing with extensive or intricate data sets. Furthermore, it allows for entirely electronic data processing, significantly reducing the potential for manual errors and ensuring precise data management.

EXPERT DATA MANAGEMENT

Central laboratories have dedicated data managers who excel in delivering study data in formats customized to meet the specific requirements of stakeholders. This professional approach to data delivery and uniformity simplifies subsequent tasks such as data cleaning, statistical analysis and regulatory submissions. The result is a seamless flow of data throughout the various stages of the clinical trial process.

By deploying a central lab the customer not only gets laboratory testing but a full range of complex services which make the goal of obtaining comparable and valid data much more economical and safer.



QUALITY ASSURANCE AT EVERY STEP

Ensuring data integrity requires a robust quality management system – a hallmark of central laboratories. Standard Operating Procedures (SOPs) meticulously describe every facet of data collection, storage and transmission. Rigorous quality checks are conducted at each stage, with detailed documentation and archiving of results.

This repository of information fosters transparency and accountability, especially during audits. On top of this, central laboratories implement robust data security measures in line with current industry standards. These safeguards, combined with audit trails within their databases, contribute to the overall data integrity and security of the clinical trial process.

KEY AREAS OF EXAMINATION

Data integrity is upheld through diligent examination, encompassing several critical areas:

1. Data exchange verification

Before each clinical trial, the interface between the laboratory's Laboratory Information Management System (LIMS) and the central database undergoes testing and validation.

2. Ongoing data verification

Throughout a clinical trial, collected data is subject to routine checks and comparisons with raw data to detect and address any discrepancies promptly.

3. Data file validation

Any data files sent to customers are meticulously verified to ensure accuracy and reliability.

4. Change management

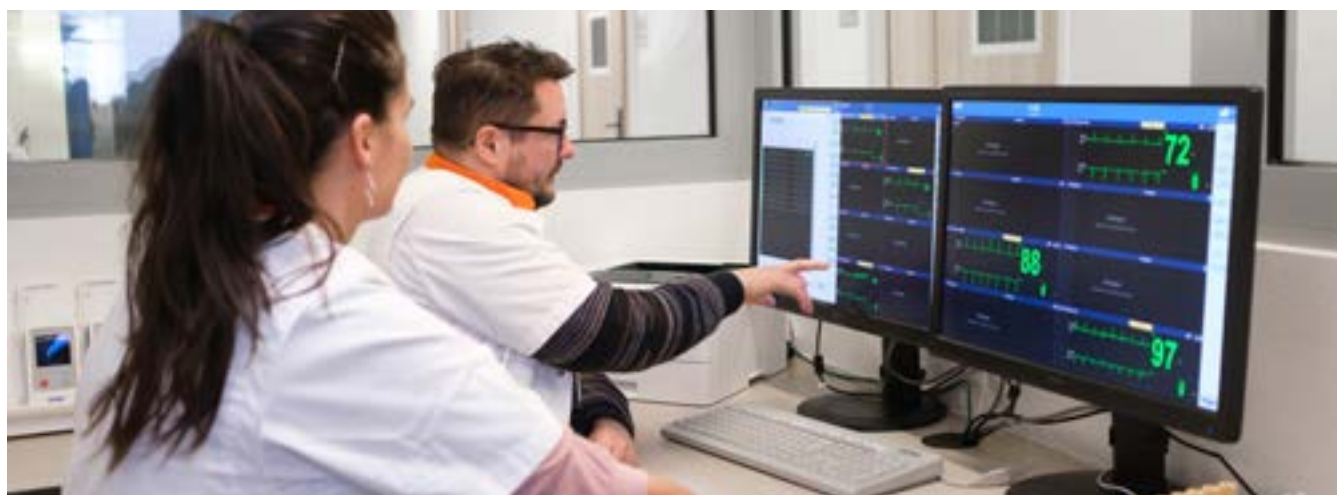
Any alterations to data, such as data cleaning, are meticulously documented to provide a clear and traceable record.



CONCLUSION

In conclusion, partnering with a central laboratory offers more than just lab testing. It provides a comprehensive suite of services that not only streamline the data management process enhancing data integrity and efficiency, but also make it more cost-effective and secure.

By entrusting data management to experts in the field, clinical trial sponsors can be confident in their pursuit of comparable and valid data, ultimately advancing the development of new medical treatments that benefit us all.



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When you need to be sure