



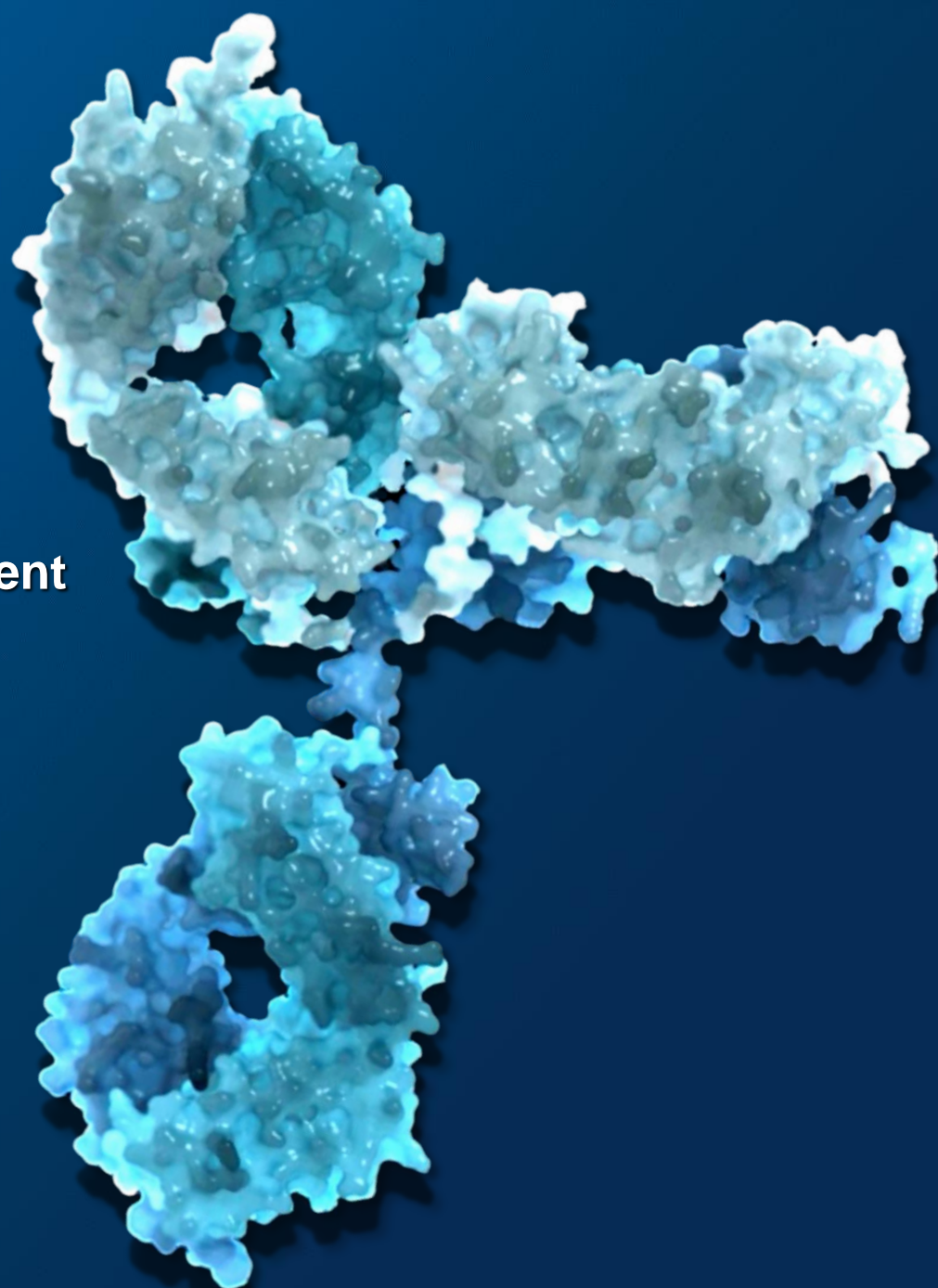
Cross-Functional Team Collaboration and Alignment In Meeting '*On Time*' Clinical Supply Needs

17th Annual Outsourcing in Clinical Trials West
Coast 2025

San Francisco, California

February 11, 2025

Anthony L. Colenburg, Sr
Sr. Director & Site Head of Quality



Forward Looking Statements

This presentation and the accompanying oral presentation contain “forward-looking” statements that are based on our management’s beliefs and assumptions and on information currently available to management. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our future financial performance, business plans and objectives, current and future clinical activities, timing, design and success of our ongoing and planned clinical trials and related data, updates and results of our clinical trials and related data, timing and success of our planned development activities, our ability to obtain and maintain regulatory approval, the potential opportunities and benefits of Luvelta and the Company's other product candidates and platform, financing plans, potential future milestone and royalty payments, competitive position, industry environment and potential market opportunities for Luvelta and the Company's other product candidates.

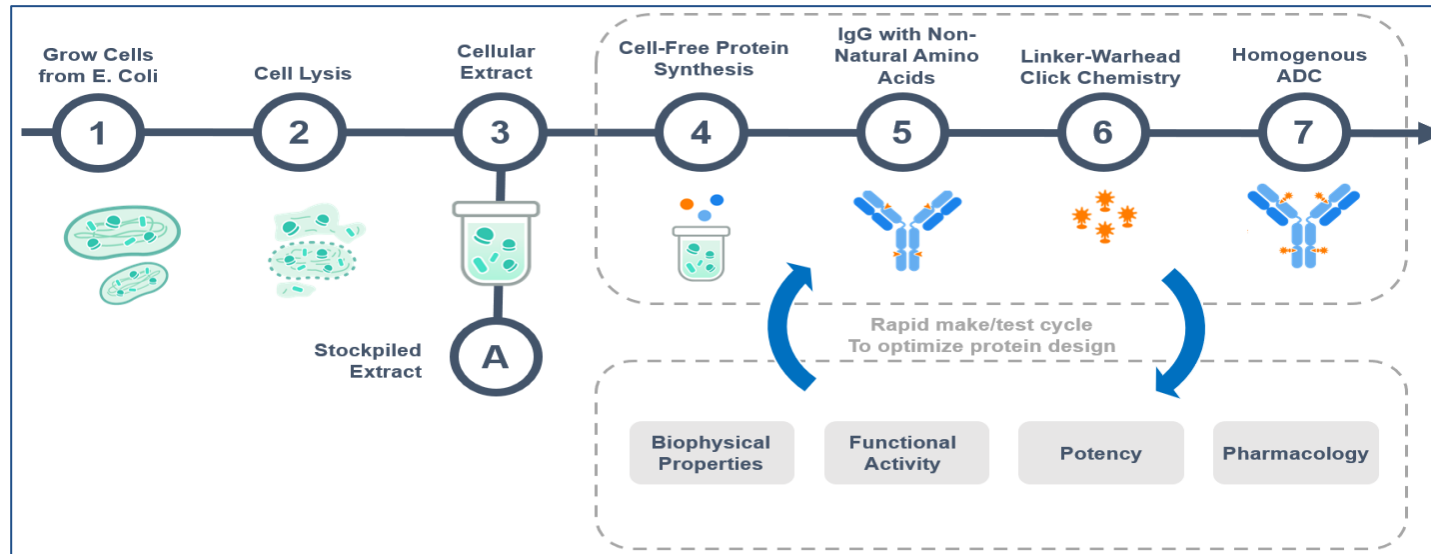
Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors, including risks and uncertainties related to our cash forecasts, our and our collaborators’ ability to advance our product candidates, the receipt, feedback and timing of potential regulatory submissions, designations, approvals and commercialization of product candidates, the design, and timing and results of preclinical and clinical trials. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. These factors, together with those that may be described in greater detail under the heading “Risk Factors” contained in our most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and other reports the company files from time to time with the Securities and Exchange Commission, may cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied by our forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although our management believes that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. Moreover, neither we nor our management assume responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to publicly update any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations, except as required by law.

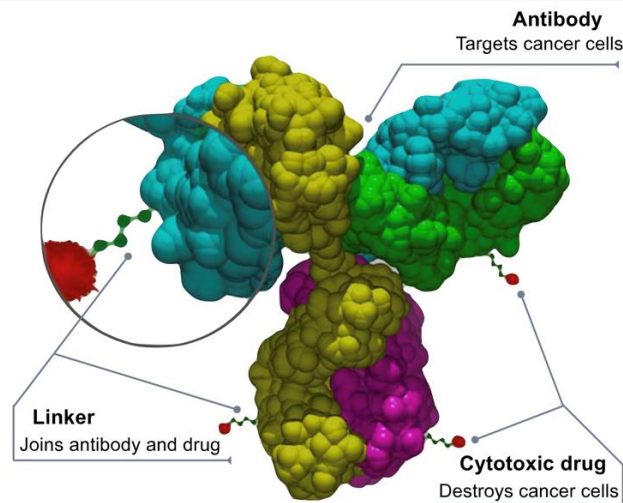
This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions, and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

Who Is Sutro Biopharma?

Industry Leading Cell-Free Protein Synthesis Platform



Sutro Biopharma is a clinical stage company pioneering a compelling and unique way of discovering, developing and manufacturing therapeutics. Our focus is aimed primarily on next-generation cancer therapeutics – antibody drug conjugates, bispecific antibodies and cytokine derivatives. Unconstrained by traditional methods of cell-based discovery, we can design and develop targeted medicines by innovating outside the constraints of the cell.








Our Technology Not Only Kills The Tumor But Also Elicits Immunogenic Cell Death

Sutro and our partners are dedicated to transforming the lives of cancer patients by creating medicines with improved therapeutic profiles for areas of unmet need.

Robust Pipeline of Candidates in Clinical Development are Enabled by Sutro's Platform

Unique engineering prowess in the field of precisely conjugated biologics, including next-gen ADCs

PROGRAM	MODALITY/TARGET	INDICATION	DISCOVERY	PRECLINICAL	PHASE 1/1B	PHASE 2	PHASE 3/ REGISTRATIONAL	WORLDWIDE OR GEOGRAPHIC PARTNER
SUTRO-LED PROGRAMS								
Luveltamab tazevibulin (Luvelta, STRO-002)	FR α Antibody-Drug Conjugate (ADC)	Ovarian Cancer						 (Greater China Rights)
		Ovarian Cancer (bevacizumab combo)						
		Endometrial Cancer						
		CBF/GLIS2 Pediatric AML						
		NSCLC						
STRO-004	Tissue Factor ADC	Solid Tumors						
PARTNER PROGRAMS								
VAX-24	24-Valent Conjugate Vaccine	Invasive Pneumococcal Disease						 VAXCYTE
VAX-31	31-Valent Conjugate Vaccine	Invasive Pneumococcal Disease						
MK-1484	Selective IL-2 Agonist	Advanced or Metastatic Solid Tumors						 MERCK
STRO-003	ROR1 ADC	Solid Tumors & Hematological Cancers						 IPSEN
Undisclosed Programs	Immunostimulatory ADCs (IADCs)	Cancers						 astellas

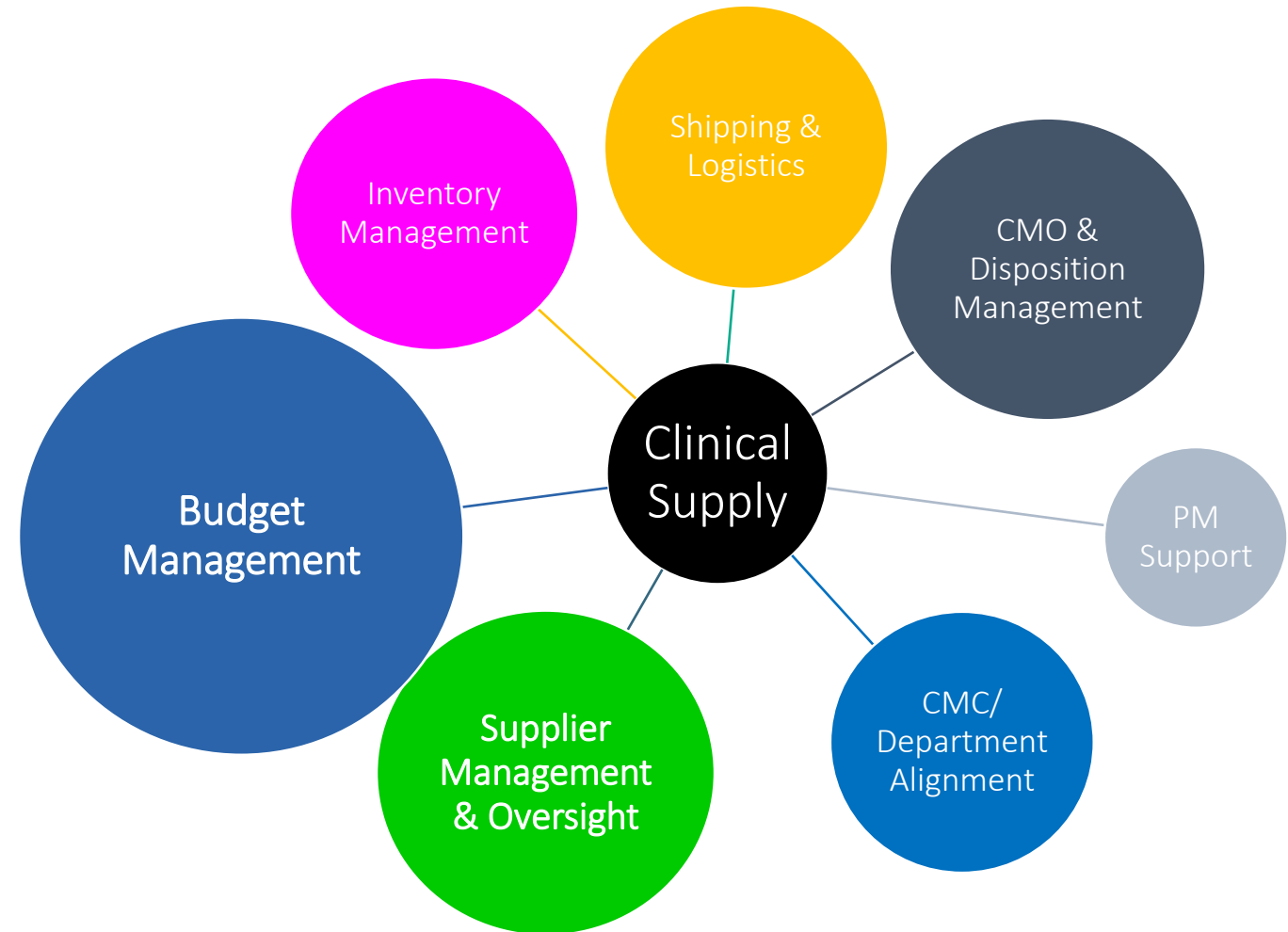
Aligning *Designing (QbD)* the Clinical Trial Ecosystem to be Operationally Efficient To Reduce Delays In Supply Deliverables

Quality-by-Design principles incorporate identifying factors critical to the quality of the study and then working to reduce risk associated with those factors.

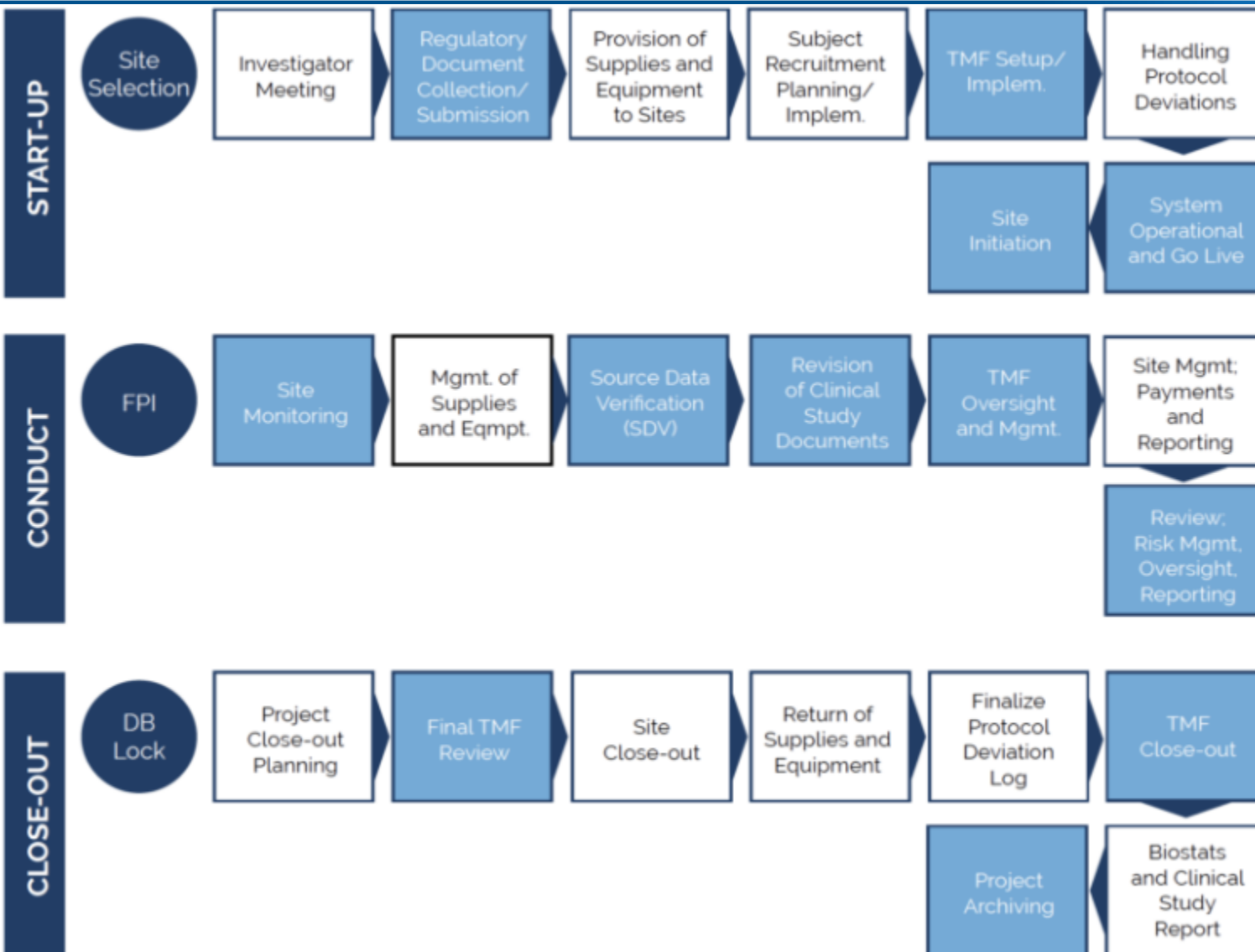
The Quality-by-Design approach has been around for quite some time. *Do you use this approach?*

NUGGET: In 2023, the top 2 most common FDA 483 Clinical Investigator observations involved:

1. General Responsibilities of Investigators Conducting Study
2. Investigator Recordkeeping and Record Retention



Fine-tuning the Clinical Supply Vendor Partnerships: How Can Sponsors & Service Providers Start Using Guidance in Totality Instead Of In Silos?



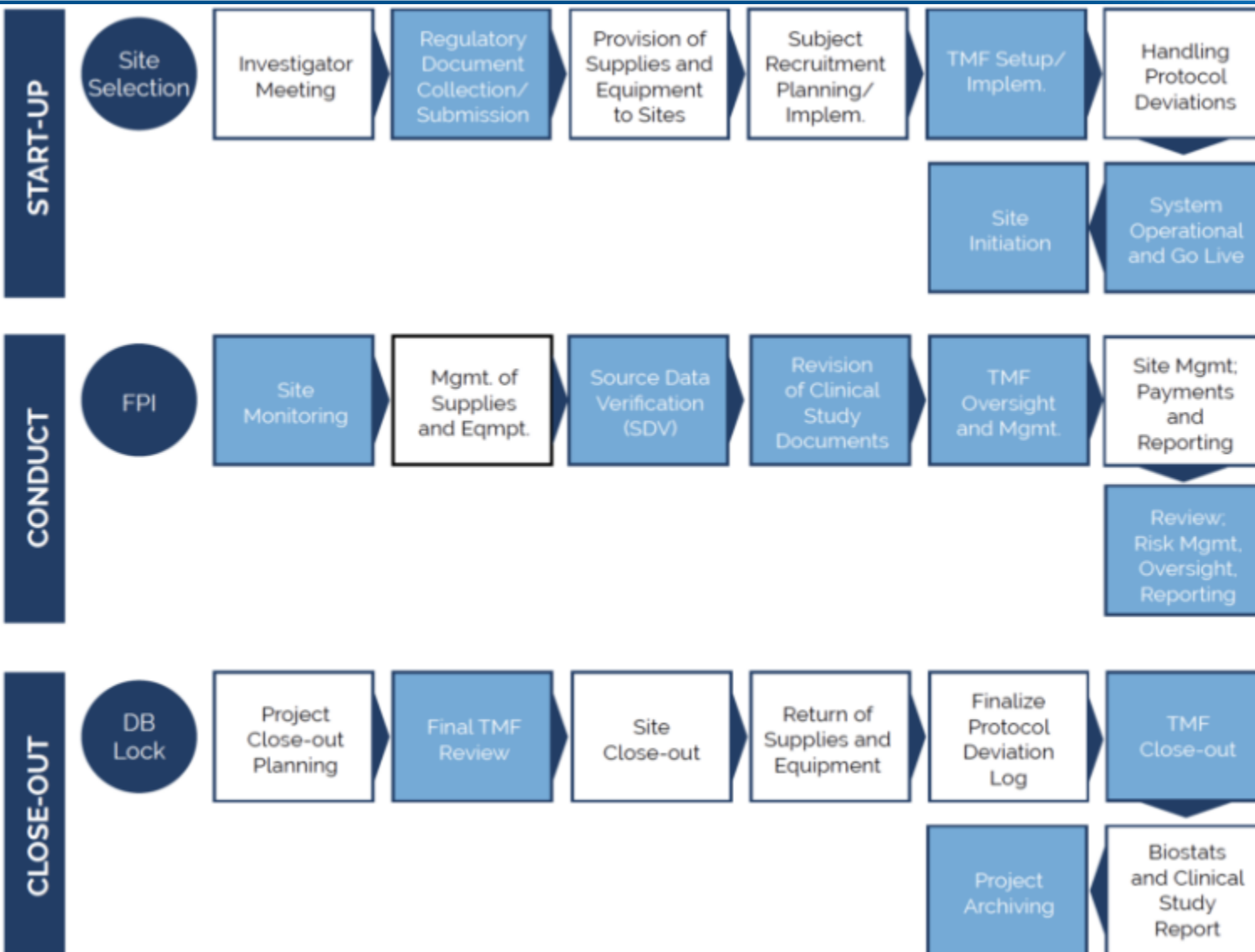
Sites, Sponsors, and CROs now perform the bulk of their clinical trial operations by logging into **cloud-based systems**.

Creating seamless integration across Sponsor, CRO and Site digital platforms starts with examining the Clinical Trial processes that utilize each platform and identifying challenges within the current system.

Clinical studies typically follow three distinct phases: Start-up, Conduct & Closeout. Within each of these phases are essential processes to ensure the study is on track and progressing.

Highlighted are the most impactful clinical study process challenges in this diagram.

Fine-tuning the Clinical Supply Vendor Partnerships: How Can Sponsors & Service Providers Start Using Guidance in Totality Instead Of In Silos?



Sponsors and CROs can rapidly accelerate clinical trial timelines and reduce the overall cost by creating a digitally connected ecosystem.

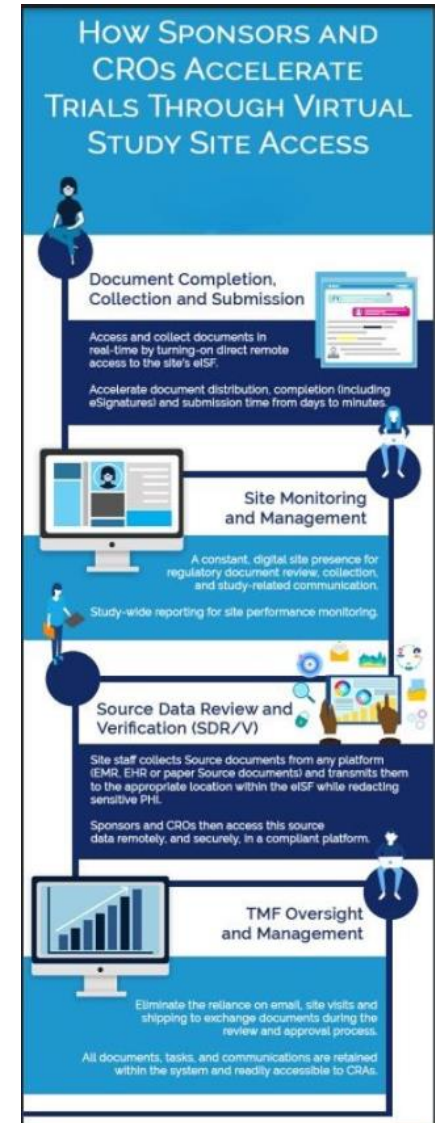
Key Takeaways:

1. Convergence of electronic Investigator Site File (eISF) solutions enables remote connectivity.
2. Remote eISF connectivity transforms core study processes.
3. Sponsor and CROs accelerate timelines and reduce costs.
4. Sponsors and CROs gain real-time site oversight and management.

Fine-tuning the Clinical Supply Vendor Partnerships: How Can Sponsors & Service Providers Start Using Guidance in Totality Instead Of In Silos?

Virtual Study Site Access:

1. Document Completion, Collection and Submission
 1. Access and collect documents in real-time by turning on direct remote access to the site's eISF.
2. Site Monitoring and Management
 1. A constant, digital site presence for regulatory document review, collection, and study-related communication.
3. Source Data Review and Verification (SDR/V)
 1. Site staff collects Source documents from any platform (EMR, EHR or paper Source documents) and transmits them to the appropriate location within the eISF while redacting sensitive PHI.
4. TMF Oversight and Management
 1. Eliminate reliance on email, site visits and shipping to exchange documents during the review and approval process.
 2. All documents, tasks and communications are retained within the system and readily accessible to CRAs.



Fine-tuning the Clinical Supply Vendor Partnerships: How Can Sponsors & Service Providers Start Using Guidance in Totality Instead Of In Silos?



NUGGET:

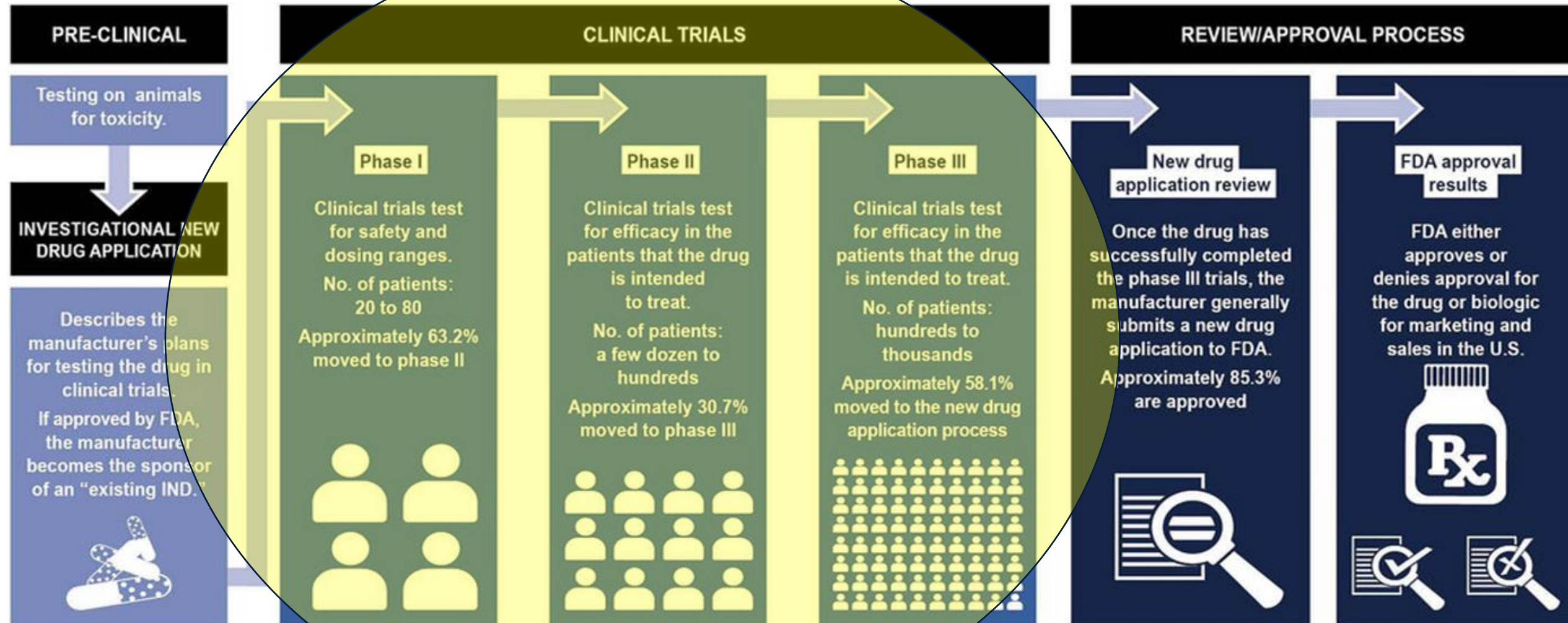
2022 75th World Health Assembly a Resolution (WHA75.8) recognizes:

*"...that **well designed** and well-implemented clinical trials are indispensable for assessing the safety and efficacy of health interventions."*

WHO is soliciting inputs on possible recommendations "on best practices and other measures to improve the global clinical trials ecosystem." – *opportunity for any current initiatives and clinical trials stakeholders to summarize lessons learned from COVID-19 for improvements to the clinical trial ecosystem.*

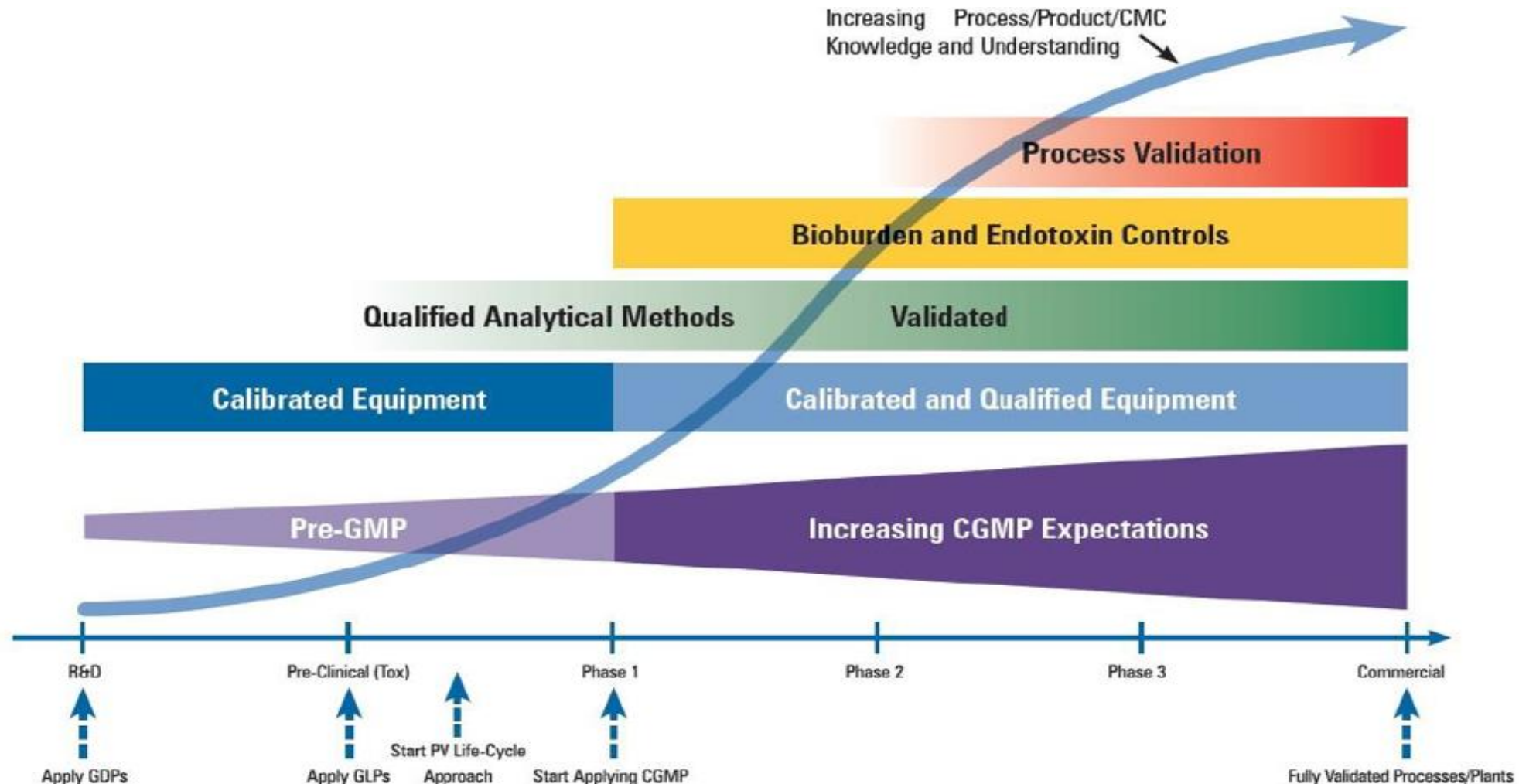
Clinical Trials Quality Management System?

Are There Different QMS Requirements Specifically For Clinical Trials?



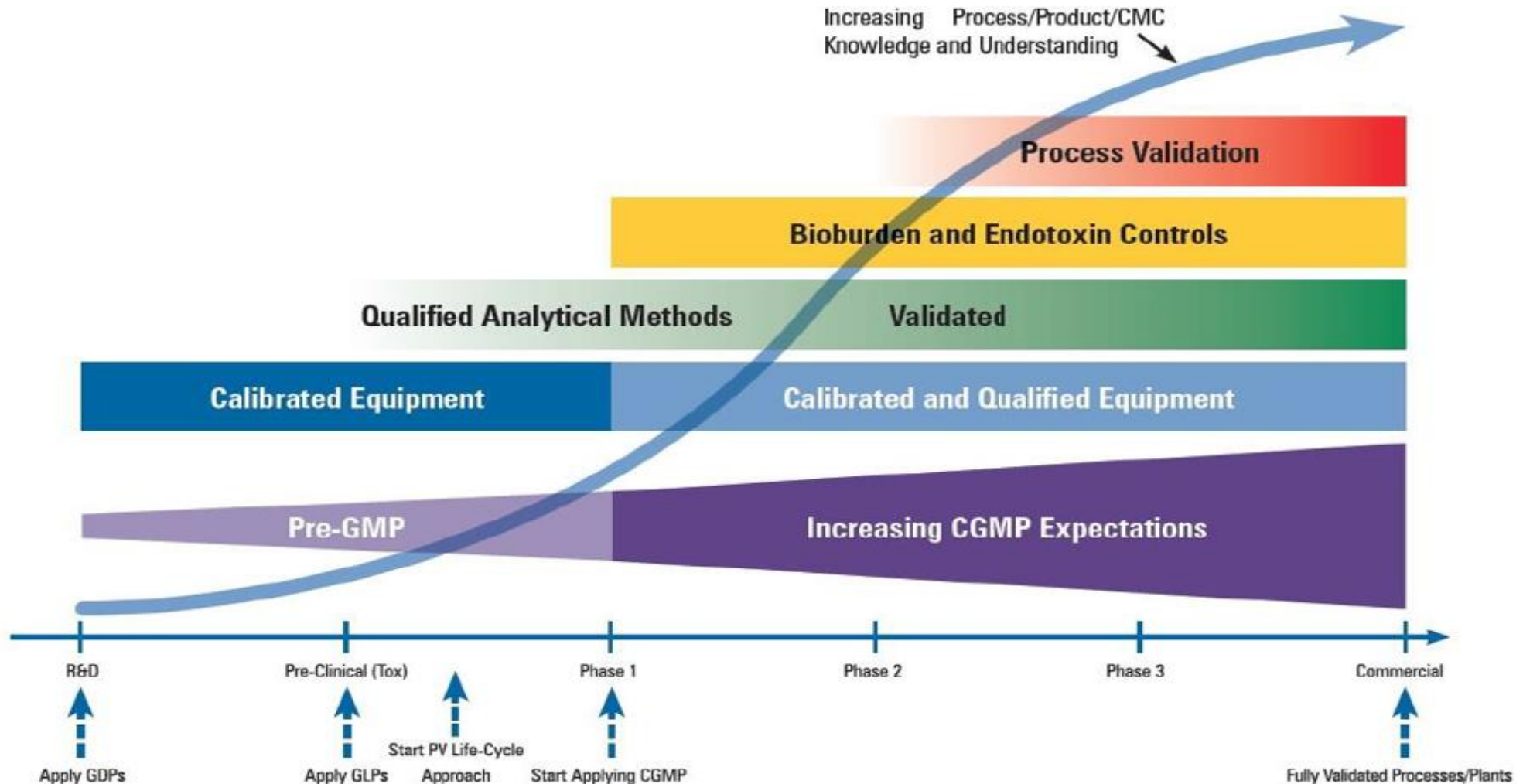
Maintaining Open Communication with Manufacturers to Address Precise Trial Needs and Perfect Demand Planning

Phase Appropriate Quality & Regulatory Expectations/Requirements



What's Expected At EVERY Stage/Phase??

Phase Appropriate Quality & Regulatory Expectations/Requirements



Phase Appropriate Quality & Regulatory Expectations/Requirements

Good Data Integrity & Documentation Practice Standard

Attributable: Who performed an action or changed a record

Legible: Data must be recorded permanently in a durable medium and be readable

Contemporaneous: Data must be recorded at the time it is generated

Original: Original record (pen to paper)

Accurate: Data must contain no errors or editing performed without documented amendments

Complete: All entries are documented, and document/record has been reviewed/approved

Consistent: Data must be documented the same throughout document, record and others

Enduring: Documentation will last for the lifetime of the document/record

Available: Accessible for review/audit for the lifetime of the document/record

Good Data Integrity & Documentation Practice Standard

Objectives of GDDP

Good Data Integrity & Documentation Practice Standard

Good Data Integrity and Documentation Practices describe standards by which records are created and maintained

Applies to both paper and electronic records

Required by the FDA, EMA, other worldwide regulatory guidelines

Ensure product Safety, Identity, Strength, Quality, Purity/Potency (SISQP)

Provides evidence to regulatory agencies that procedures were followed, and you are manufacturing your products as claimed

Preserves data integrity and prevents fraud

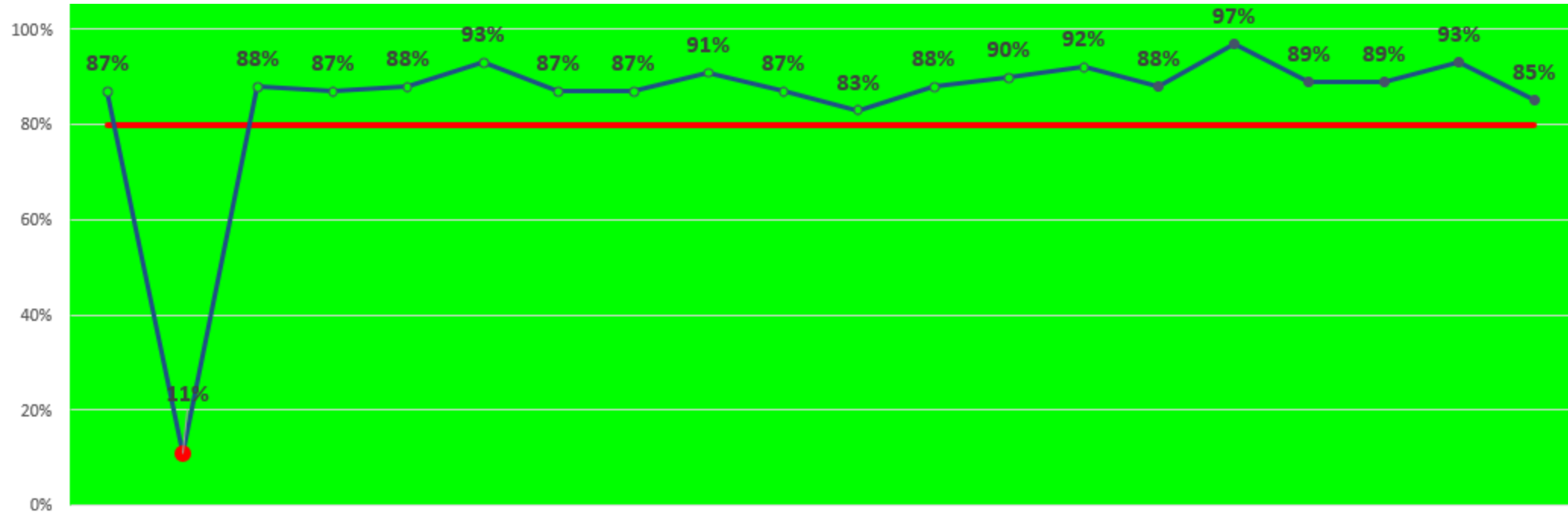
Impacts regulatory scrutiny and oversight

Establishes confidence in the quality of your manufacturing, testing and final products AT EVERY STAGE/PHASE

Establishes your employees & organization's reputation

Maintaining Open Communication with Manufacturers to Address Precise Trial Needs and Perfect Demand Planning

Quality Assurance On The Floor Production Record Review (Real Time During Manufacturing)



2023 MOST COMMON CLINICAL INVESTIGATOR INSPECTIONAL OBSERVATIONS

- Failure to comply with Investigator Statement (Form FDA 1572) requirements, protocol compliance
- Failure to follow the Investigational Plan; protocol deviations
- Inadequate and/or inaccurate case history records; inadequate study records
- Inadequate accountability and/or control of the investigational product
- Safety reporting; failure to report and/or record adverse events
- Inadequate subject protection; Informed consent issues

2023 MOST COMMON INSTITUTIONAL REVIEW BOARD INSPECTIONAL OBSERVATIONS

- Failure to have **minutes of IRB meetings** in sufficient detail **to show attendance** at the meeting; vote actions, quorum issues
- Failure to **conduct initial** and/or **continuing review of research**
- Failure to have a **majority of IRB members present for review** of proposed research for other than expedited reviews
- Failure to **keep members of the IRB advised of research proposals** that have been approved under an expedited review procedure
- Failure to follow **FDA regulations** regarding **expedited review procedures**
- Failure to **prepare and maintain documentation of IRB activities**; **inadequate copies** of research proposals and related documents

2023 MOST COMMON SPONSOR/CRO INSPECTIONAL OBSERVATIONS

- Failure to ensure **proper monitoring of the study** and **ensure study is conducted in accordance with the protocol and/or investigational plan**
- Failure to **meet the abbreviated requirements for investigational device exemptions (IDEs)**
- Failure to **maintain and/or retain adequate records** in accordance with **21 CFR 312.57**; accountability for the investigational product; **Investigator Statement (Form FDA 1572)**; Financial disclosures
- Failure to **submit an Investigational New Drug (IND) application**; IND safety report
- Failure to **submit current list of all participating investigators** to FDA at six-month interval after FDA approval of the study

2023 MOST COMMON SPONSOR-INVESTIGATOR INSPECTIONAL OBSERVATIONS

- Failure to **maintain and/or retain adequate records** in accordance with **21 CFR 312.57**; accountability for the investigational product; **Investigator Statement (FDA 1572)**; Financial disclosures
- Failure to **select qualified investigators and/or monitors, ensure proper monitoring of the study and ensure the study is conducted in accordance with the protocol and/or investigational plan.**
- Failure to **submit an Investigational New Drug (IND) application**
- Inadequate subject protection; **Informed Consent** issues.
- Failure to **notify FDA of termination of investigator**

All Quality Management Systems Aren't Built The Same



Is Meeting 21 CFR Part 11 Enough?

- **WHAT:** Electronic Records; Electronic Signatures
- **WHEN:** Pre-Study through Study Close-Out
- **WHY:** Ensure Authenticity, Integrity, & Confidentiality of Clinical Trial Data
- **HOW:** Approvals, Traceability, Audit Trails, etc.

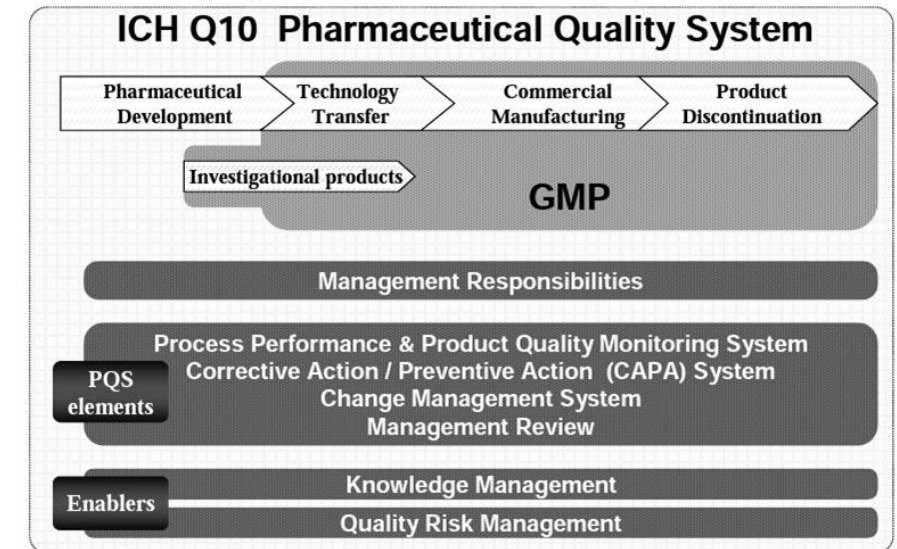
Is This Enough? How Do You Know?

All Quality Management Systems Aren't Built The Same

Most QMSs **DO NOT** serve the needs of Clinical Trial Management

1. Controlled Document Management Module
2. Training Management Module
3. Change Management Module
4. Audit Management Module
5. Issue/Event Management Module
6. CAPA Management Module
7. Risk Management Module

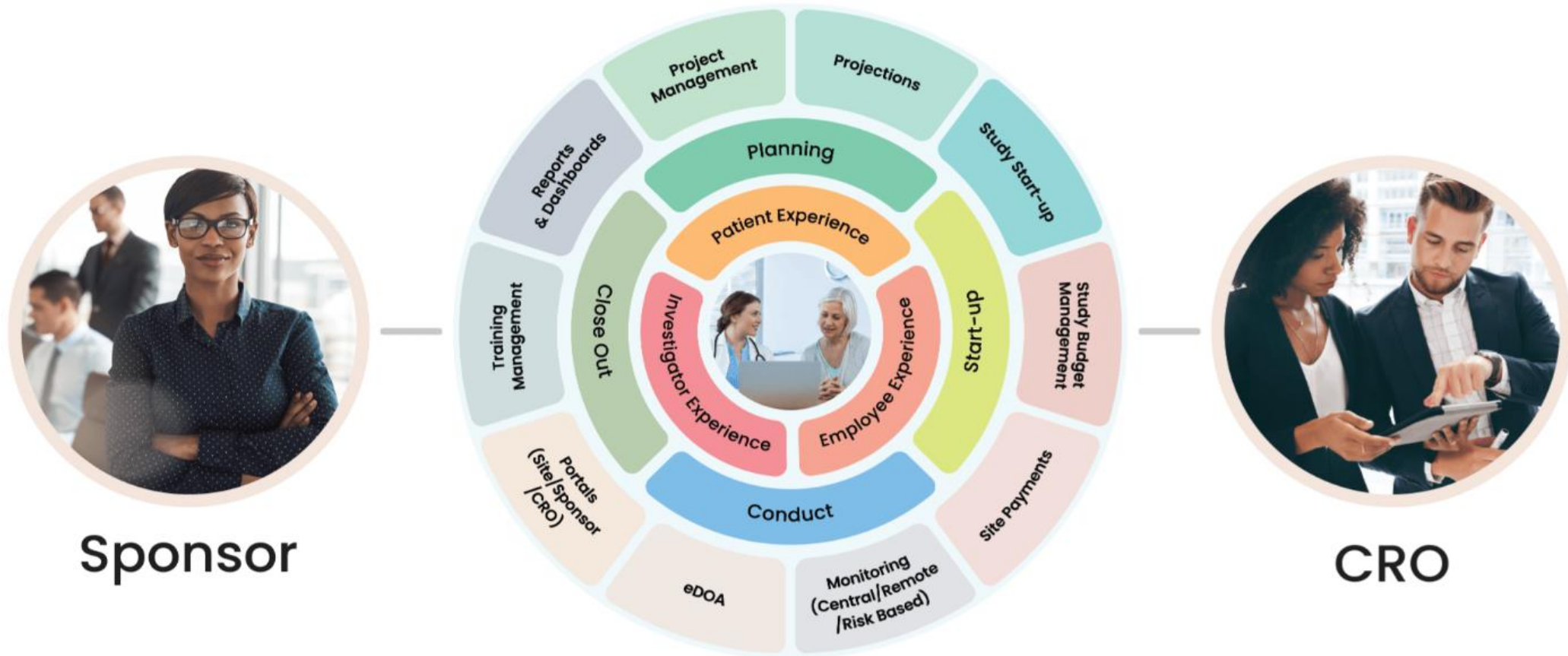
Diagram of the ICH Q10 Pharmaceutical Quality System Model



These are all great QMS features, but how does an organization **KNOW** what and where to focus on in terms of clinical trial management areas of responsibility?

All Quality Management Systems Aren't Built The Same

Disruptive Clinical Trial Management Solutions (Built by Clinical Regulations)



Gaps in Quality Management Systems In Clinical Trials

All Quality Management Systems Aren't Built The Same

Disruptive Clinical Trial Management Solutions (Built by Clinical Regulations)

1. Project & Study Management

The screenshot displays a web-based interface for managing a clinical study. At the top, the study is identified as 'Actazin Clinical Study' with a status of 'Approved'. A progress bar shows the study is in the 'Approved' phase. The main navigation menu includes tabs for Details, Planning, Projections, Start Up, Visit Plan, Financials, Clinical Site, Subjects, Study Conduct, Study Templates, and More. The 'Planning' tab is active, showing a list of milestones and tasks.

Milestones (6+)

Milestone Name	Status	Progress Status	Plan Start Date
Develop materials and establish plans for tra...	Approved	<div><div></div></div>	6/30/2020
Subjects Enrollment	Completed	<div><div></div></div>	5/21/2020
Study protocol	Completed	<div><div></div></div>	1/1/2020
Budget proposal for U01 application	Completed	<div><div></div></div>	2/12/2020
Intervention Documents (Investigator's Broc...	Completed	<div><div></div></div>	6/2/2020
Program study database	Completed	<div><div></div></div>	7/8/2020

[View All](#)

Tasks (6+)

TS ID	Name	Unit	# Units
TS-000125	Provide IP information	Monthly	2.0
TS-000242	Send Feasibility Survey	Monthly	1.0
TS-000243	Follow-up on Feasibility Surveys	Per Site	2.0
TS-000244	Make the final decision	Monthly	5.0
TS-000245	Review I/E Criteria with Dr. Dave	Each	2.0

Activity

Filters: All time • All activities • All types

Upcoming & Overdue

- Send Quote: Aaron Josh logged a call with Lauren Boyle (Oct 22)
- Send Letter: Aaron Josh logged a call (Oct 22)

November • 2020 (Last Month)

- Call: Aaron Josh had an event with Lauren Boyle (8:00 PM | Nov 16)

October • 2020 (2 Months Ago)

- Follow-up with Fred: Aaron Josh had a task with Liz D'Cruz (Oct 22)

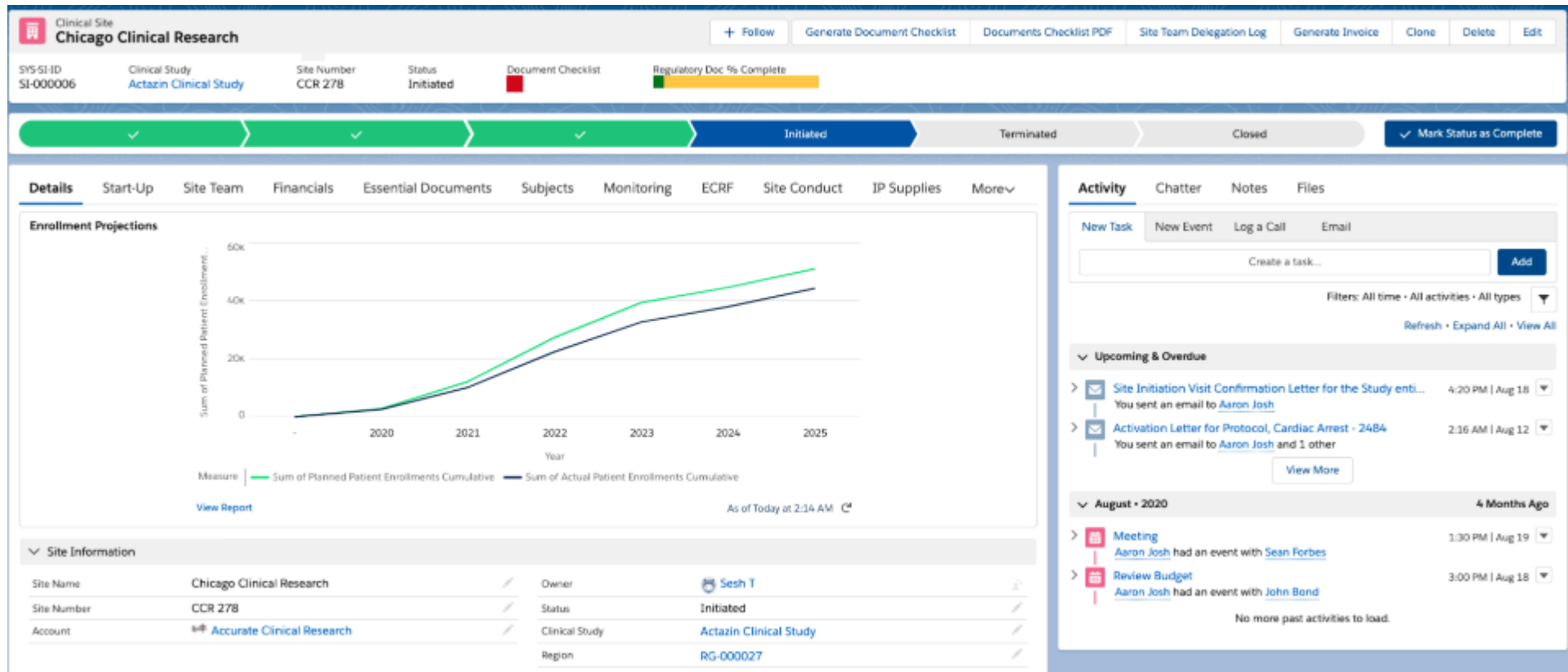
August • 2020 (4 Months Ago)

Gaps in Quality Management Systems In Clinical Trials

All Quality Management Systems Aren't Built The Same

Disruptive Clinical Trial Management Solutions (Built by Clinical Regulations)

2. Site Management



Gaps in Quality Management Systems In Clinical Trials

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3. Site Feasibility

Clinical Study
Cardiac Arrest - 2284

[Generate Study Start-Up Checklist](#) [CDISC/CDASH Export](#) [Generate Invoice](#) [Create Random Numbers](#) [Edit](#) [Clone](#) [Sharing](#)

Status [Enrolling](#)

Phase Phase IV

Therapeutic Area Cardiology

Intervention/Treatment Treatment

Estimate Site Enrollment 30

Estimate Subject Enrollment 100

✓

✓

✓

✓

Enrolling

Completed

On-Hold

Terminated

✓ Mark Project as Complete

Details

Planning

Financials

Projections

Start Up

Clinical Sites

Monitoring

Feasibility

More ▾

Feasibility Survey (40)

[View All Responses](#)

View by: Question [Contact](#) [+](#)

Search

📍 📄 📅 ⬇

<input type="checkbox"/>	PI Name ↓	Feasibility Template	Address *	Survey Sent *	Status	Feasibility Status	
<input type="checkbox"/>	Dr. Peter Rogers	Cardiac Arrest_1	CA, USA	5/23/2019	Submitted	Not Feasible	👁️ ⬇
<input type="checkbox"/>	Dr. Ramsey	Cardiac Arrest_2	CA, USA	4/19/2019	Inprogress	Feasible	👁️ ⬇

Study Interest

Item	Question	Response
1.01	Is your site interested in participating in this study?	Yes

Email

Activity

Chatter

Notes

Files

Selected Contacts (8)

[Dr. Peter Rogers](#)

Peterrogers@cloudbyz.com

✓ Feasible

✕

[Dr. Peter Rogers](#)

Peterrogers@cloudbyz.com

✓ Feasible

✕

[Dr. Peter Rogers](#)

Peterrogers@cloudbyz.com

✓ Feasible

✕

Download

Send Feasibility Mail

Gaps in Quality Management Systems In Clinical Trials

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4. Subject Management

The screenshot displays a clinical trial management system interface for Subject J1. At the top, there is a header bar with a subject icon and name 'J1', followed by action buttons: '+ Follow', 'Send ReConsent', 'Create Subject Visit', 'Subject Visit Wizard', 'Edit', 'Clone', 'Delete', 'eClinRO', and 'ePRO'. Below this, a summary bar shows 'Clinical Study: Actazin Clinical Study', 'Gender: Male', 'Site: SI-000006', 'Product', 'Status: In Treatment', and 'Version: 1.00'. A progress bar indicates the subject's status: 'In Treatment' (active), 'Patient Dropped', 'Patient Withdrew', and 'Completed'. A 'Mark Status as Complete' button is also present.

The main content area is divided into two panels. The left panel, titled 'Details', contains several expandable sections:

- Information:** Subject Number (J1), Reason Excluded (NA), SYS-SUB-ID (Sub-000005), Ineligible? (checkbox), Status (In Treatment), Study Arm(s), and Withdrawn Reason (NA).
- Dates:** Primary Informed Consent Date (1/2/2019), Screen Date (1/16/2019), Enrollment Date (1/31/2019), Informed Consent Signed Date (3/20/2019), Rescreen Date (3/30/2019), and Randomisation date (4/15/2019).
- Protocol Information:** Protocol, Protocol Deviation (checkbox), Protocol Number, and Version (1.00).
- Site Information:** Clinical Study (Actazin Clinical Study), Site (SI-000006), Site Number (CCR 278), Region (RG-000027), Site Name (Chicago Clinical Research), and Investigator Name (Dinesh Kashyap).

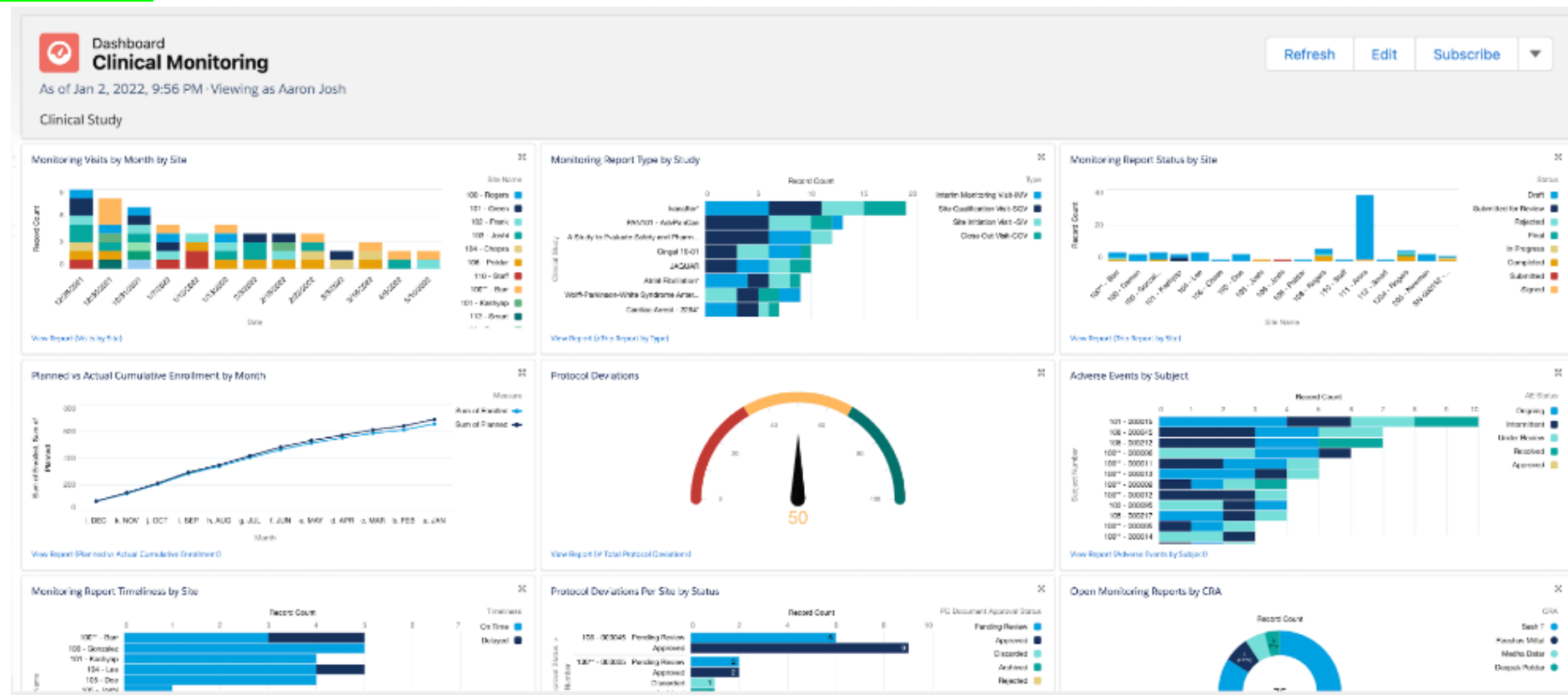
The right panel, titled 'Activity', includes tabs for 'New Task', 'New Event', 'Email', and 'Log a Call'. It features a 'Create a task...' input field with an 'Add' button. Below this, filters are set to 'All time', 'All activities', and 'All types'. A section titled 'Upcoming & Overdue' shows 'No next steps. To get things moving, add a task or set up a meeting.' and 'No past activity. Past meetings and tasks marked as done show up here.'

Gaps in Quality Management Systems In Clinical Trials

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Disruptive Clinical Trial Management Solutions (Built by Clinical Regulations)

5. Clinical Monitoring



All Quality Management Systems Aren't Built The Same

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6. eTMF/eReg

The screenshot displays the eTMF interface. On the left, a sidebar shows a hierarchical folder structure under 'Studies'. The selected folder is 'Cardiac Arrest - 2284', which contains sub-folders for '1 - Holding Area', '2 - Study Level', '3 - Country Level', and '4 - Site Level'. Under '4 - Site Level', there is a folder 'Site 100 - Barr', which contains '01 Trial management', and under that, '01.01 Trial Oversight'. The '01.01 Trial Oversight' folder contains three sub-folders: '01.01.01 Trial Master', '01.01.02 Trial Manage', and '01.01.03 Quality Plan'.

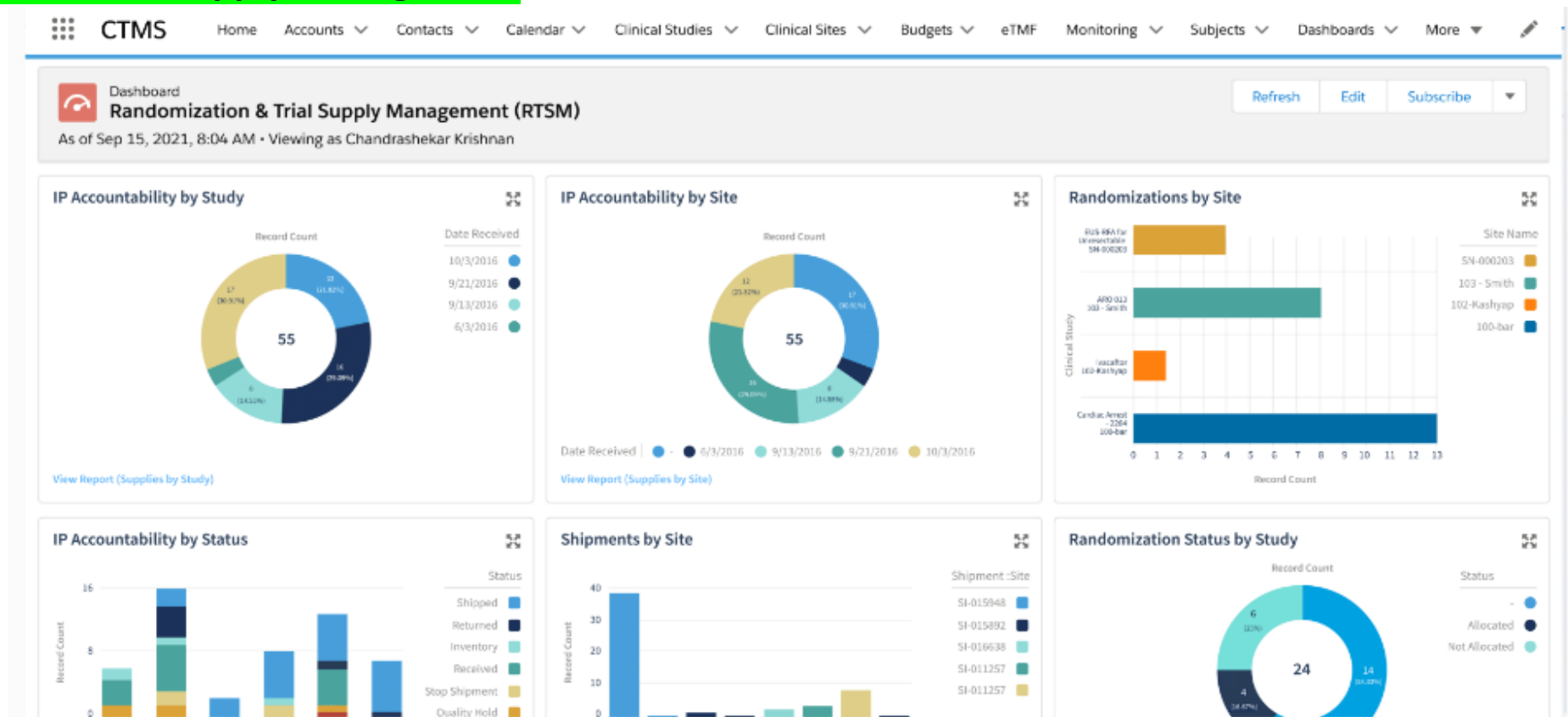
The main content area on the right shows the '01.01.01 Trial Master File' details. It includes a 'Folder Name' field with the value '01.01.01 Trial Master File'. Below this, there are two circular icons: one with a folder icon and the number '20' (labeled 'Total Files'), and another with a magnifying glass icon and the number '10' (labeled 'Pending Review'). There is also a search bar labeled 'Search for trial folders'. Below the search bar, there is a section titled '01.01 Trial Oversight (5)' with a dropdown menu. At the bottom, there is a table with the following data:

DOCUMENT NAME	SITE NAME	ARTIFACT #	DATE UPLOAD
100 - Barr_ Trial Master File Plan	100 - Barr	1589656	06-10-2020

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7. Randomization & Trial Supply Management



Gaps in Quality Management Systems In Clinical Trials

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8. Budget Management

Ctazin Study Budget

Clinical Study: Ctazin Clinical Study	Status: Draft	Budget Type: Study	Rate Card: Ctazin Budget Rate Card
Sponsor: Ctazin	Number of Sites: 30	Number of Subjects: 400	Indirect Cost %: 20.00
Version: 1	Withholding %: 10.00		

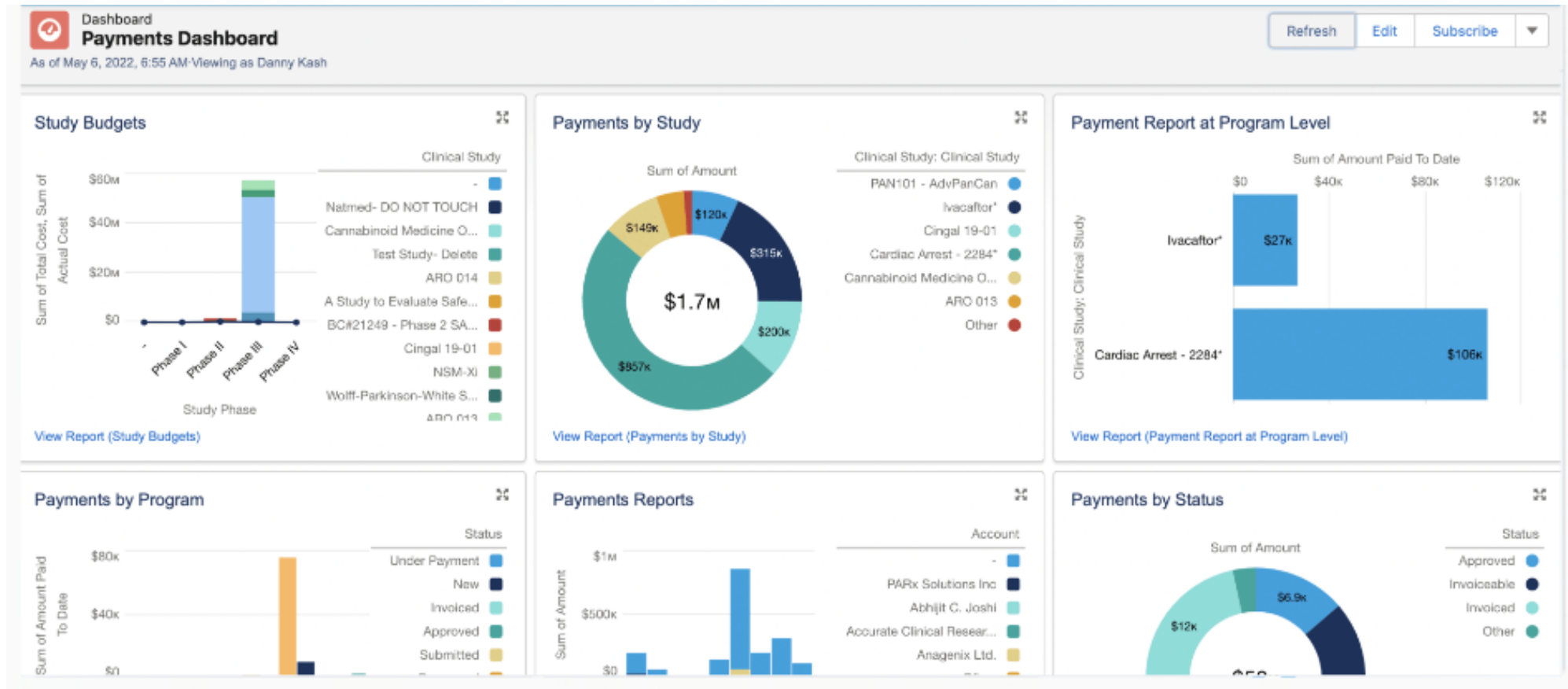
Central Lab Data Management Investigator Grant Medical Monitoring Pharmacovigilance Qualities Regulatory Affairs Study Management Study Meetings Summary

+	Task	Cost / Unit	# of Units	Unit	Total Cost
+	Identify and select central laboratory vendor	800.00	1.0	Per Vendor	800.00
+	Review data transfer plan	60.00	2.0	Plan	120.00
+	Provide test result reports	2312.00	3.0	Document	6936.00
+	Develop CRO/Vendor/Sponsor project communications plan	500.00	4.0	Per Vendor	2000.00
+	Ship lab kits to Investigational Sites	15000.00	1.0	Per Site	15000.00
TOTAL DIRECT COST					24856.00
INDIRECT COST					4971.20
TOTAL COST					29827.20

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Disruptive Clinical Trial Management Solutions (Built by Clinical Regulations)

9. Payments

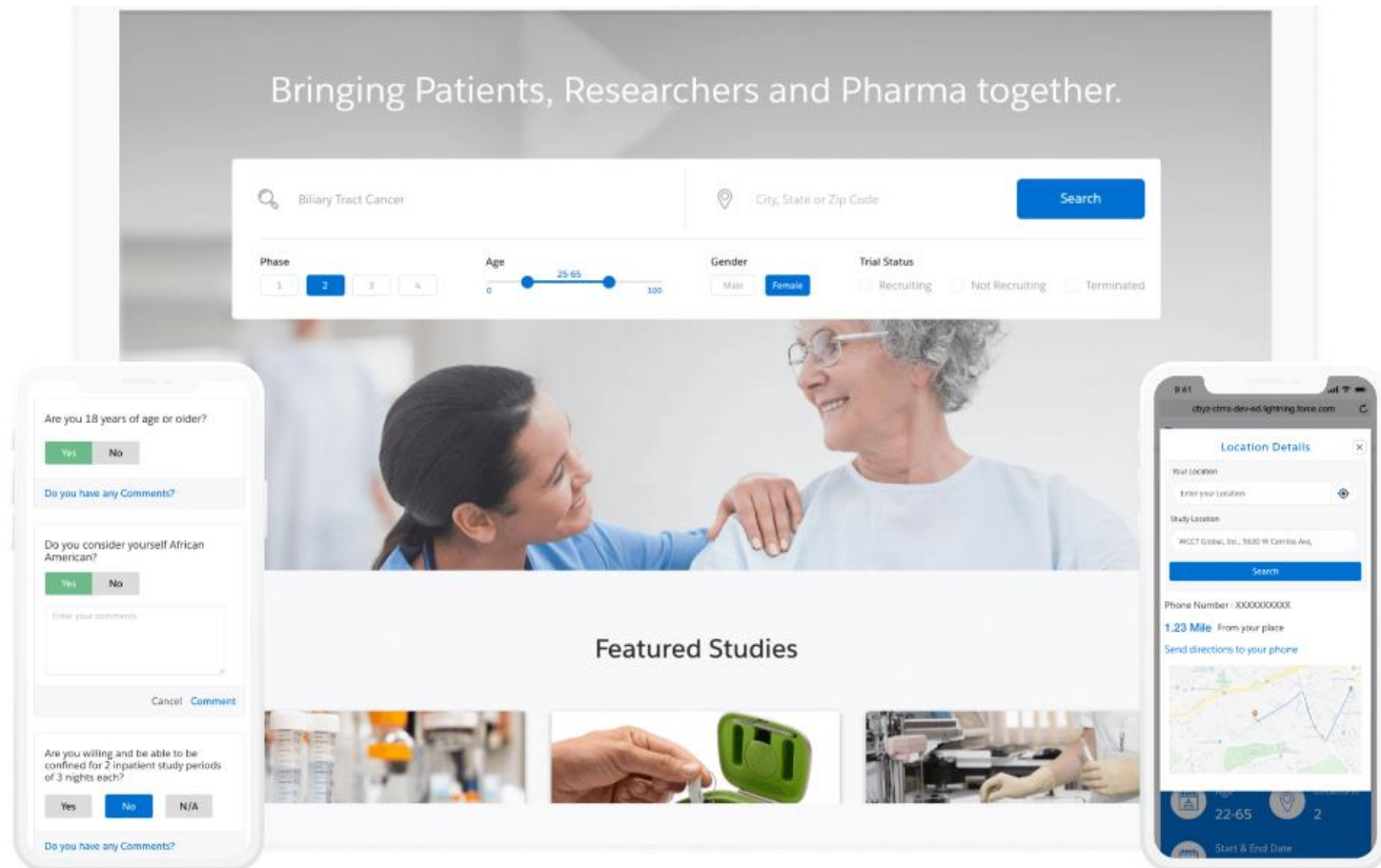


Gaps in Quality Management Systems In Clinical Trials

All Quality Management Systems Aren't Built The Same

Disruptive Clinical Trial Management Solutions (Built by Clinical Regulations)

10. Patient Recruitment

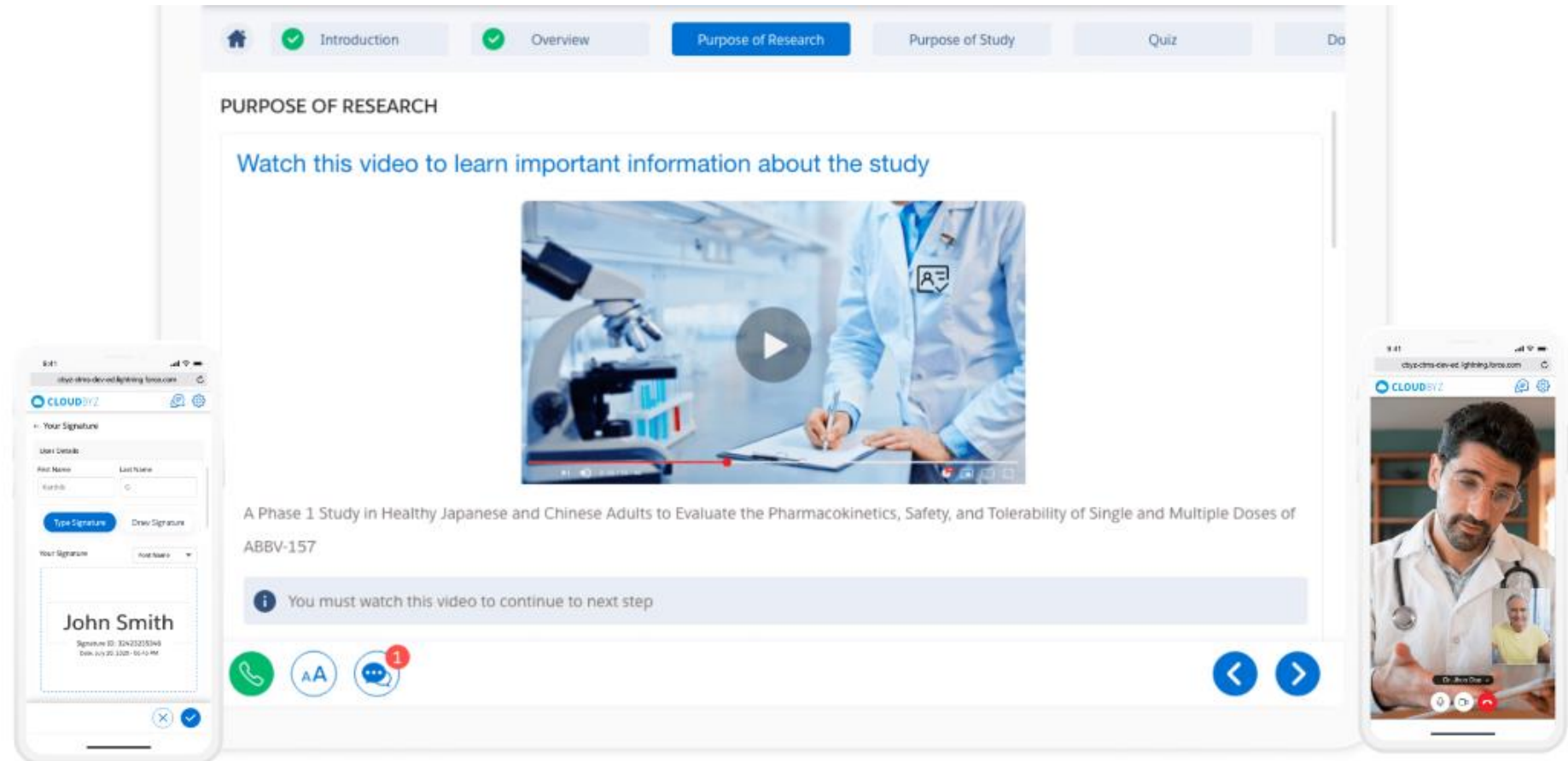


Gaps in Quality Management Systems In Clinical Trials

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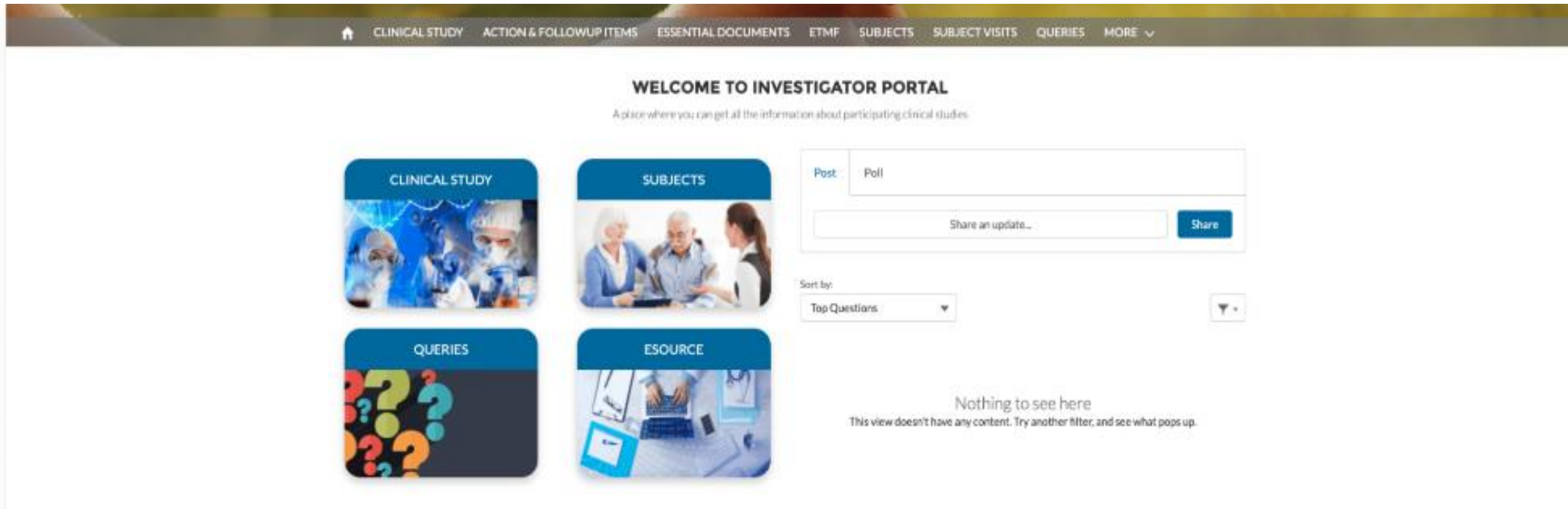
11. eConsent



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Disruptive Clinical Trial Management Solutions (Built by Clinical Regulations)

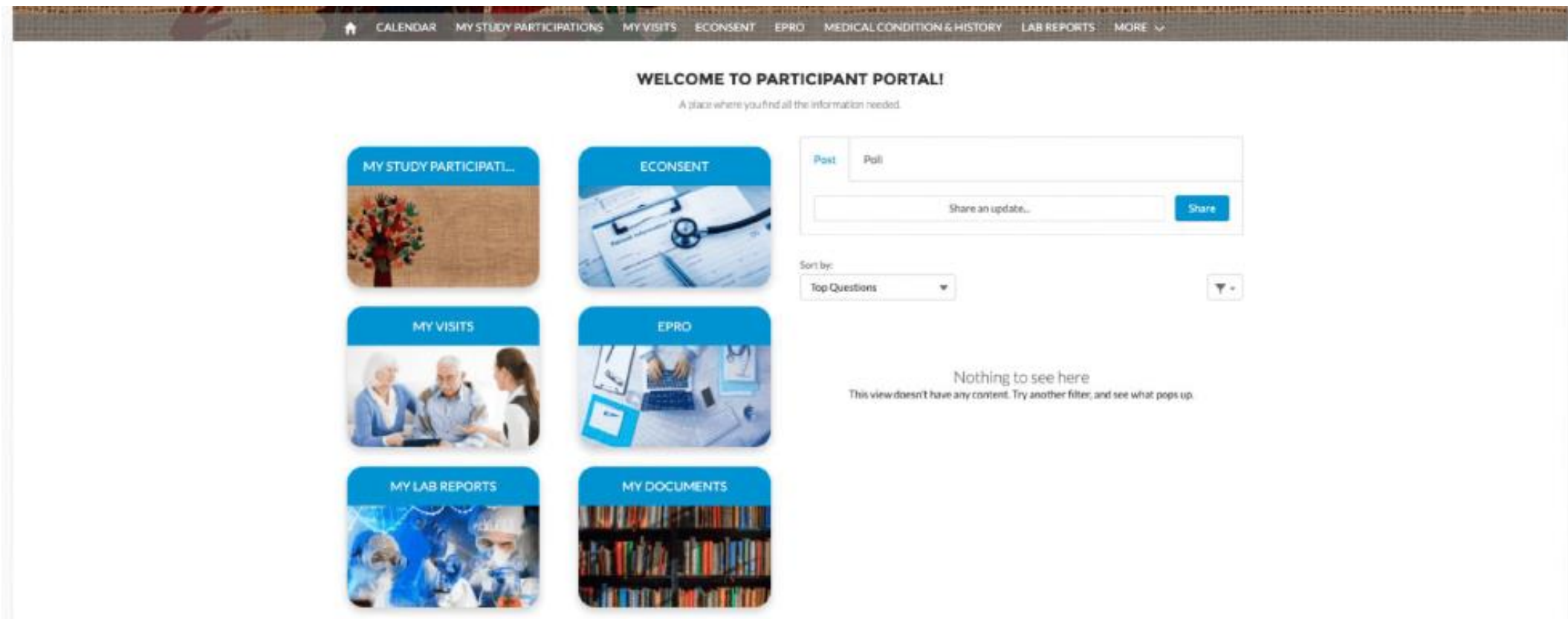
13. Other Features: Investigator Portal



All Quality Management Systems Aren't Built The Same

Disruptive Clinical Trial Management Solutions (Built by Clinical Regulations)

13. Other Features: Patient Portal

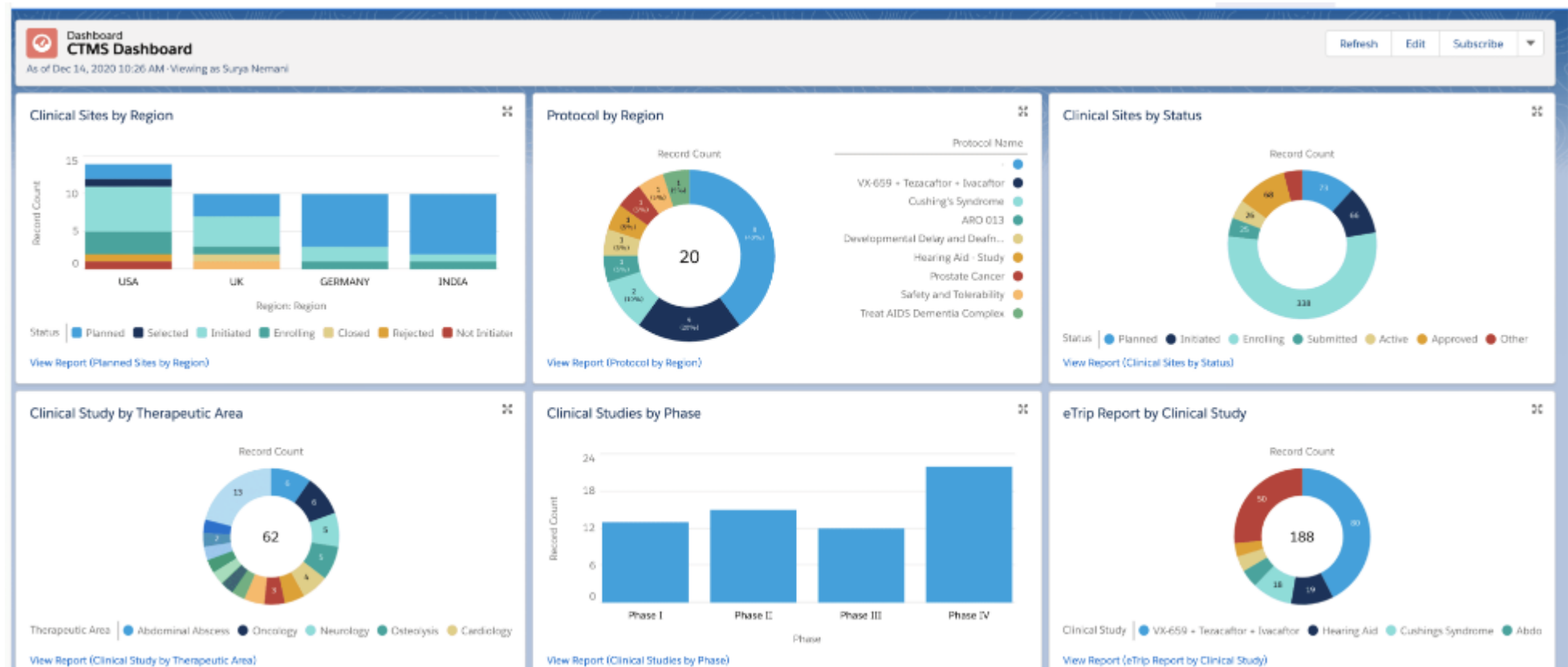


Gaps in Quality Management Systems In Clinical Trials

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13. Other Features: Reports & Dashboards



All Quality Management Systems Aren't Built The Same

Disruptive Clinical Trial Management Solutions (Built by Clinical Regulations)

CTMS SOLUTION OPTIONS

1. Florence eBinders
2. Viedoc
3. Clario CTMS
4. Rave CTMS
5. CloudByz
6. OnCore CTMS
7. TrialHub
8. BSI CTMS

Working in Tandem Across the Trial Ecosystem to Better Manage Demands for Increasingly Complex Clinical Supply Needs

Clin Ops

Study Management

IRT

Planning and Forecasting

CMO

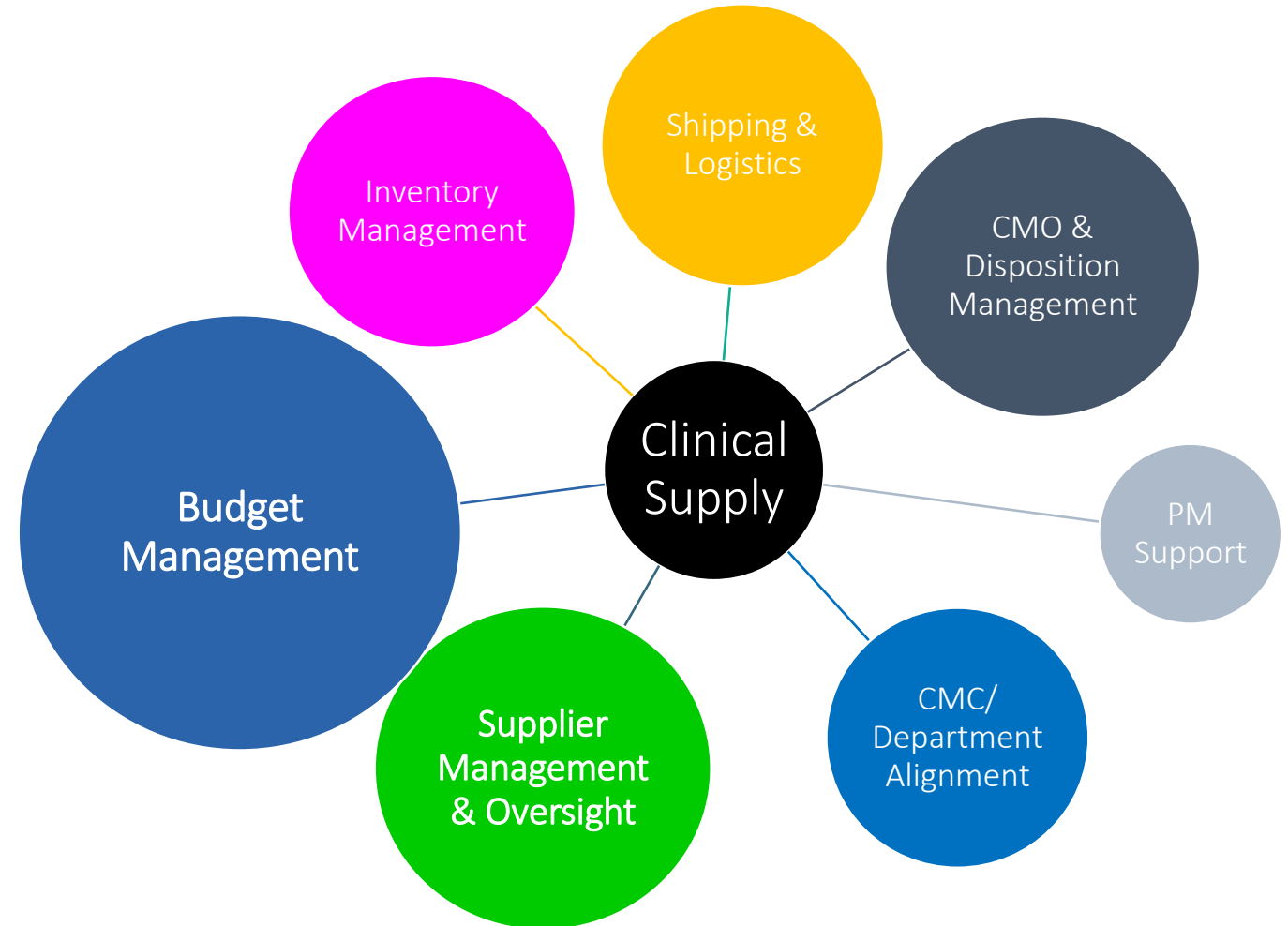
Manufacturing & Packaging

3rd Party Logistics

Distribution

Investigative Sites

Dispensing



QUESTIONS?

