Fostering Effective Collaboration: An In-Depth Look at Sponsor-CRO Co-Operation

Presented by Yen Phan, Sr. Clinical Data Scientist,
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Meet the Speaker

Yen Phan

Title: Sr Clinical Data Scientist

Organization: elderbrook solutions GmbH

Her knowledge and expertise have resulted in the successful development of data quality and data completeness reports, maintaining the highest levels of data integrity in SAS/R programming, data management, and regulatory submissions. Yen and the elderbrook team have been recognized in the industry for their high-quality deliverables in a CRO setting, where they have offered strategic insights to data management teams. Their proficiency in the development and submission of data in accordance with CDISC standards has been instrumental in their career.

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Agenda

1. The Landscape of Sponsor-CRO Relationships
2. Key Principles of Effective Collaboration
3. Joint Audits and Inspections
4. Technological Impact on Cooperation
5. Managing Vendor-Generated TMF Records
6. Interactive Dialogue and Q&A

1. The Landscape of Sponsor-CRO Relationships

Significance of Sponsor-CRO Collaboration

The collaboration between Sponsors and CROs plays a vital role in the successful execution of clinical trials. Here are some reasons why this collaboration is so important.

The Role of Sponsors

Sponsors in clinical trials are typically pharmaceutical companies, biotech firms, medical device companies, or academic institutions that initiate and are responsible for managing the clinical study. Their roles include:

- Study Design
- Regulatory Compliance
- Funding
- Selection of Investigators and Sites
- Data Management and Analysis
- Safety Monitoring
- Quality Assurance

The Role of CROs

CROs are third-party organizations hired by the sponsor of a clinical trial to oversee many aspects of the trial, including :

- Protocol Development and Study Design
- Site Selection and Management
- Patient Recruitment and Retention
- Regulatory Compliance
- Data Management and Statistical Analysis
- Safety Monitoring and Pharmacovigilance
- Quality Assurance and Auditing
- Reporting and Publication

The Landscape of Sponsor-CRO Relationships

The nature of relationships between Sponsors and CROs has evolved significantly over the years. What were once transactional, short-term partnerships have often transformed into strategic, long-term collaborations.

The current state and nature of Sponsor-CRO relationships

Quantifying the Importance of Sponsor-CRO Collaboration

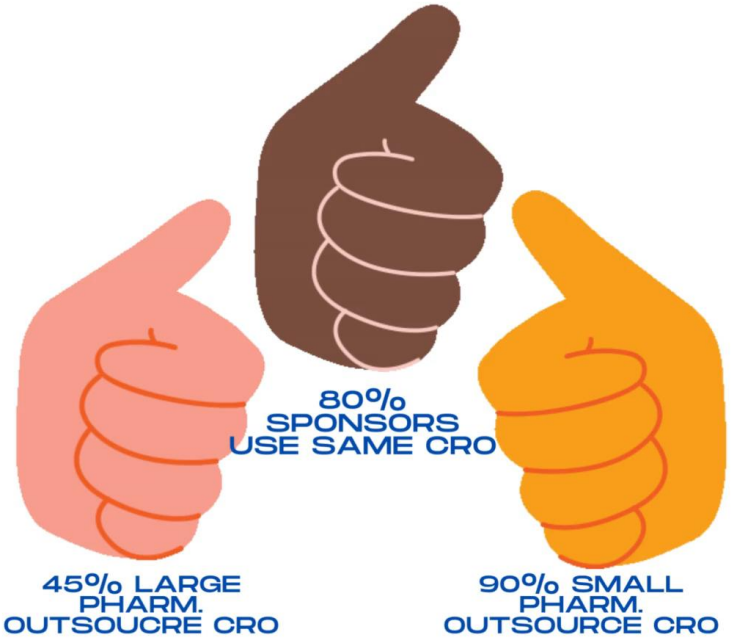
**CAGR: Compound Annual Growth Rate*

Quantifying the Importance of Sponsor-CRO Collaboration

- A 2019 study by the Association of Clinical Research Organizations (ACRO) found that 70% of pharmaceutical companies believe that their partnerships with CROs have been successful in meeting their clinical trial goals. (1)
- A 2020 study by the Tufts Center for the Study of Drug Development found that the average cost of a clinical trial has increased by 60% over the past decade. However, the study also found that CROs can help to reduce the cost of clinical trials by up to 20%. (2)
- A 2021 study by the Clinical Trials Transformation Initiative (CTTI) found that clinical trials with CROs are more likely to be completed on time and within budget than trials conducted by sponsors without CROs. (3)

Quantifying the Importance of Sponsor-CRO Collaboration

Outsourcing trends and sponsor satisfactions



2. Key Principles of Effective Collaboration

Mutual Understanding

- Mutual understanding between Sponsors and CROs ensures that both parties are aligned on study objectives, protocols, regulatory requirements, and their respective roles.
- This facilitates effective communication, reduces potential misunderstandings, fosters trust, and allows for efficient problem resolution, ultimately leading to successful, efficient, and compliant trial execution.

Transparent Communication

- Ensures alignment of objectives, improves efficiency and productivity, and fosters a culture of trust and partnership.
- Enables early identification and resolution of challenges, stimulating innovation and proactive risk management
- Ensures regulatory compliance, with regular updates and discussions helping both parties stay abreast of regulatory changes and understand their responsibilities

Trust Building

- Facilitates open communication, streamlines decision-making, enables effective risk management, and encourages innovation
- Fosters stronger, long-term relationships by facilitating understanding and respect for each other's working styles, expectations, and goals
- Enhances quality assurance, signifying belief in the CRO's commitment to uphold the highest standards of quality, ethics, and regulatory compliance

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Case Studies

Here are a few examples of successful Sponsor-CRO collaborations

Sponsor	CRO	Collaboration
AstraZeneca	IQVIA	In 2017, AstraZeneca entered into a strategic collaboration with IQVIA to accelerate the development of AstraZeneca's pipeline of biologics. IQVIA provided clinical development services from Phase I to regulatory approval in order to bring new medicines to patients worldwide
Novartis	Quintiles (now IQVIA)	In 2010, Novartis partnered with Quintiles in a unique clinical development agreement. Quintiles provided global resources to supplement Novartis' in-house capabilities, enhancing the flexibility and productivity of its clinical development programs.
Pfizer	ICON	Pfizer and ICON entered into a strategic partnership in 2011, with ICON selected as one of two preferred providers for clinical trial implementation. The collaboration aimed to enhance Pfizer's clinical trial processes and showed the benefits of a Sponsor entrusting a significant portion of its clinical trials to a CRO.
Eli Lilly	Covance	In 2008, Eli Lilly sold its Greenfield, Indiana, facility to Covance as a part of a long-term $1.6 billion contract. Covance took over some of Lilly's preclinical research, highlighting an innovative way for Sponsors and CROs to collaborate.
Boehringer Ingelheim	elderbrook solutions Gmbh	Since 2015, Elderbrook assisted Boehringer Ingelheim with Statistics, statistical Programming and Data Management, notably delivering two approved databases: Trajenta and Pradaxa, both databases were sanctioned by the governing authorities, underscoring the efficacy and success of their joint endeavors.

Case Studies

Successful Sponsor-CRO collaborations in 2022 and 2023

Sponsor	CRO	Collaboration
Merck	ICON	In 2022, Merck, a pharmaceutical company, partnered with ICON, a CRO, to conduct a clinical trial of a new drug for the treatment of cancer. The trial was completed on time and within budget, and the drug was approved by the FDA in 2023.
Pfizer	IQVIA	In 2023, Pfizer, a pharmaceutical company, partnered with IQVIA, a CRO, to conduct a clinical trial of a new drug for the treatment of Alzheimer's disease. The trial is still ongoing, but it is on track to be completed on time and within budget.
AstraZeneca	PRA Health Sciences	In 2022, AstraZeneca, a pharmaceutical company, partnered with PRA Health Sciences, a CRO, to conduct a clinical trial of a new drug for the treatment of asthma. The trial was completed on time and within budget, and the drug was approved by the FDA in 2023.
Novartis and Bristol Myers Squibb	Syneos Health	In 2022, Novartis and Bristol Myers Squibb, two pharmaceutical companies, partnered with Syneos Health, a CRO, to conduct a clinical trial of a new drug for the treatment of multiple sclerosis. The trial was completed on time and within budget, and the drug was approved by the FDA in 2023.
Gilead Sciences	Parexel	In 2023, Gilead Sciences, a pharmaceutical company, partnered with Parexel, a CRO, to conduct a clinical trial of a new drug for the treatment of hepatitis C. The trial is still ongoing, but it is on track to be completed on time and within budget.
Sanofi	PPD	In 2022, Sanofi, a pharmaceutical company, partnered with PPD, a CRO, to conduct a clinical trial of a new drug for the treatment of diabetes. The trial was completed on time and within budget, and the drug was approved by the FDA in 2023.
Boehringer Ingelheim	elderbrook solutions Gmbh	In 2022, Boehringer Ingelheim, a pharmaceutical company, partnered with elderbrook solutions GmbH, a CRO, to conduct a clinical trial of a new drug for the treatment of generalised pustular psoriasis (GPP). The trial was completed on time and within budget, and the drug was approved by the FDA in 2022.

Case Studies Discussion

3. Joint Audits and Inspections

Joint Audits and Inspections

- Role of Joint Audits and Inspections

Joint audits and inspections play a critical role in ensuring the integrity of clinical trials, with both sponsors and CROs participating actively in the process. They provide a platform for shared responsibility, giving both parties the opportunity to review and evaluate the trial conduct, data integrity, and compliance with regulatory requirements, protocols, and good clinical practice (GCP).

Joint Audits and Inspections

- Impact of Joint Audits and Inspections

Improved Compliance: They lead to improved regulatory compliance as discrepancies or deviations from standard operating procedures (SOPs) can be identified and corrected timely.

Risk Mitigation: Joint audits help in identifying potential risks and issues early, allowing for effective mitigation strategies to be implemented.

Strengthened Relationships: The process fosters better understanding and cooperation between the sponsor and the CRO, thus strengthening their relationship and making the collaboration more efficient and productive.

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Joint Audits and Inspections

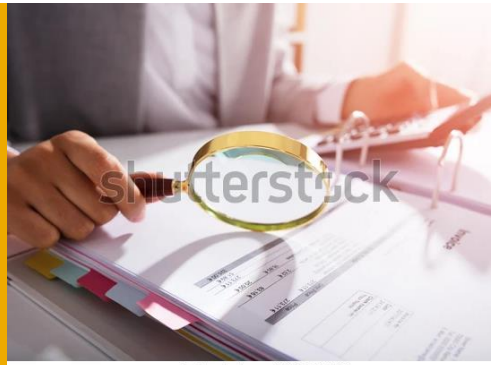
- Benefits of Joint Audits and Inspections

Enhanced Quality Control: Joint audits provide an additional layer of quality control, as both the sponsor and the CRO bring their perspectives and expertise to the process.

Shared Learning: They offer an opportunity for shared learning. Both parties can learn from each other's practices and experiences, leading to continual improvement of processes and procedures.

Increased Trust: Joint audits can increase mutual trust, as they provide transparency and open communication, reinforcing the sponsor's confidence in the CRO's ability to deliver quality data and adhere to regulations.

Consistent Standards: They ensure consistent standards across different aspects of the clinical trial, ensuring a uniform quality of trial conduct and data integrity.



4. Technological Impact on Cooperation

Introduction to the Role of Technology in Collaboration

1. Digital Connectivity:
- Seamless communication through tools like Zoom, Teams, and Slack.
- Instant sharing of data and real-time discussions.

2. Data Management & Analytics:
- Platforms like Medidata, Veeva Vault and Oracle's Clinical One centralize trial data.
- Advanced analytics tools offer insights, predictions, and facilitate decision-making.

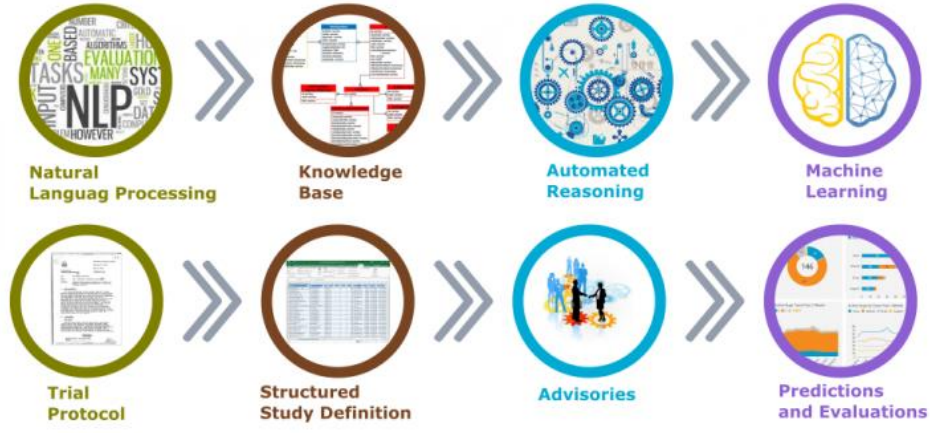
3. Cloud-Based Solutions:
- Ensure data accessibility and integrity.
- Foster collaboration by allowing multiple stakeholders to access and analyze data simultaneously.

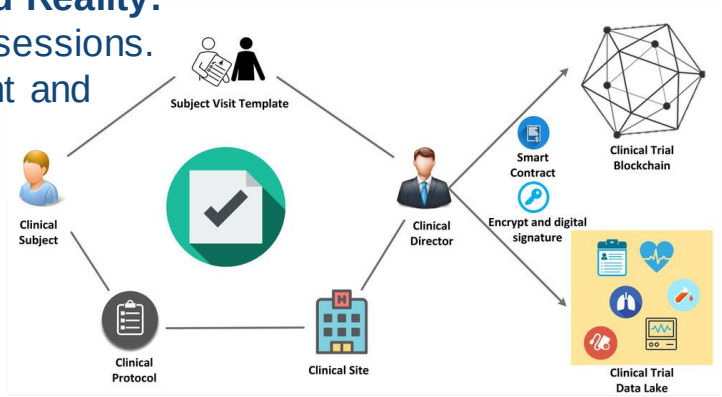
Introduction to the Role of Technology in Collaboration

4. AI & Machine Learning:
- Automate repetitive tasks.
- Predict potential roadblocks or challenges in clinical trials.
- Enhance efficiency and reduce errors.

5. Blockchain:
- Secure and transparent data sharing.
- Immutable records, enhancing trust and reliability.

6. Virtual Reality & Augmented Reality:
- Virtual site visits and training sessions.
- Enhanced patient engagement and understanding.





5. Managing Vendor-Generated TMF Records

The concept and role of eTMF systems in improving efficiency

What is an eTMF system?

- An electronic Trial Master File (eTMF) system is a software application that stores, manages, and tracks all the documents and data for a clinical trial.

Why use an eTMF system?

The concept and role of eTMF systems in improving efficiency

Benefits of using an eTMF system

Vendor-Generated TMF Records

Definition:

- Vendor-generated TMF records refer to the documentation and data produced by third-party vendors or service providers during a clinical trial.
- These can include labs, imaging centers, ePRO providers, and other specialized services.

Importance:

- Integral to capturing the full scope of a clinical trial.
- Ensures complete transparency and traceability of vendor activities.

Examples of Vendor-Generated Records:

- Central lab reports.
- Imaging scan results.
- Patient diaries from ePRO tools.
- Training materials
- Data from electronic data capture (EDC) systems.

Challenges:

- Standardizing formats across multiple vendors.
- Ensuring timely submission and integration into the main TMF.

Integration with eTMF Systems:

- Automated import of vendor records.
- Consistent categorization and indexing of vendor-generated content.

Managing Vendor-Generated TMF Records

Complexities in Management

Diverse Origins	• Records come from varied vendors – labs, imaging centers, ePRO tools
Inconsistent Formats	• Different vendors may use different formats and standards.
Timeliness	• Ensuring timely submission to integrate into the central TMF
Quality Assurance	• Verifying the accuracy and integrity of vendor-generated records.

Managing Vendor-Generated TMF Records

Strategies for Effective Management

Standardization Protocols	• Establish guidelines for vendors to follow uniform formats.
Automated Integration	• Use eTMF systems to automate the import of vendor records.
Regular Sync-ups	• Periodic meetings with vendors to discuss expectations and feedback.
Quality Checks	• Implement robust review processes to ensure the reliability of vendor records.
Training & Workshops	• Equip vendors with the necessary skills and knowledge for proper documentation.

Clear Agreements and Robust Systems

Why are clear agreements and robust systems important for managing TMF records?

- The accuracy and completeness of TMF records
- The compliance of TMF records with regulations
- The efficiency of the TMF management process
- The security of TMF records

What are the key elements of clear agreements for managing TMF records?

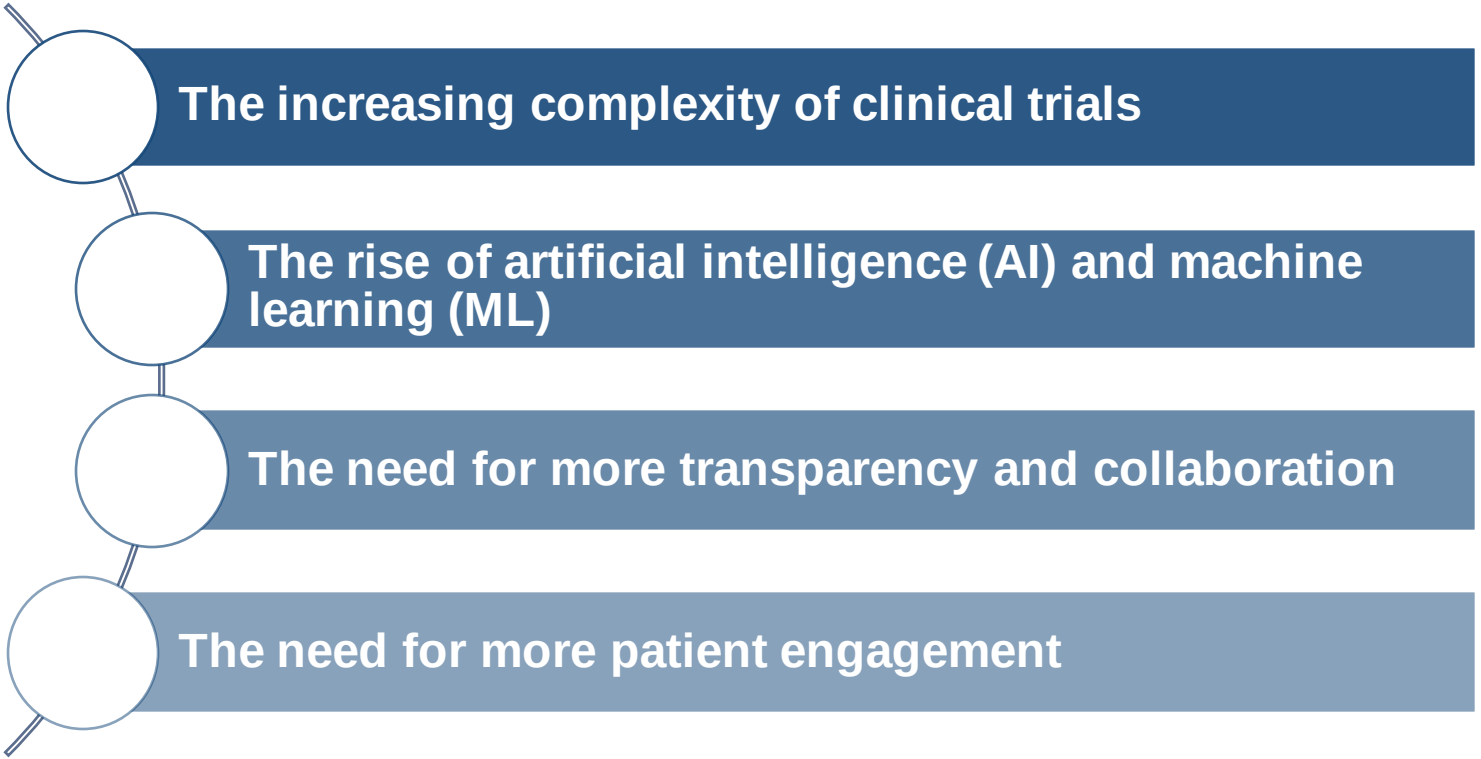
- The roles and responsibilities of the sponsor, CRO, and other stakeholders involved in the management of TMF records
- The procedures for creating, updating, and maintaining TMF records
- The procedures for accessing and sharing TMF records
- The procedures for protecting the confidentiality and integrity of TMF records

Clear Agreements and Robust Systems

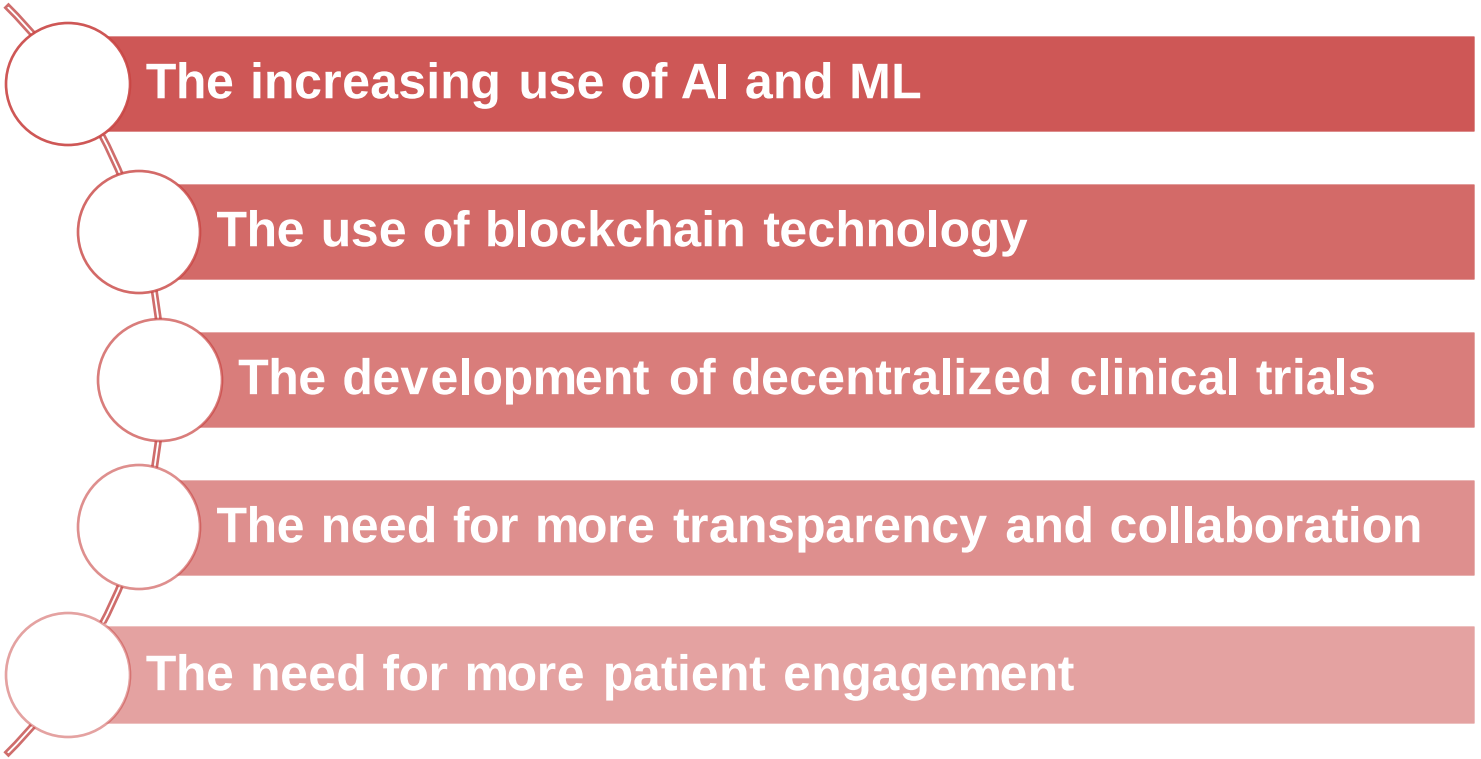
What are the key elements of robust systems for managing TMF records?

- An electronic TMF system that is secure, compliant with regulations, and easy to use
- A process for regularly reviewing and updating the TMF system
- A process for training staff on how to use the TMF system

The Way Forward



The future of sponsor-CRO collaborations



Final Note

In a world where ideas grow and thrive,
Sponsors-CRO together arrive.
Hand in hand, they begin their quest,

To discover, to test, and to do their best.
With hopes and dreams, side by side they stand,

Working together, across the land.
Challenges arise, but together they face,
Finding solutions, at a steady pace.
With trust and teamwork, they build and create,
A bond that's strong, a shared fate.
From the start to the finish, through thick and thin,

Their partnership ensures, together they win.
So here's to teamwork, to dreams that soar,

To the journey of discovery, and so much more.

Thank You!