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Hot Topics in Global Clinical Trial Agreements

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March 20, 2024

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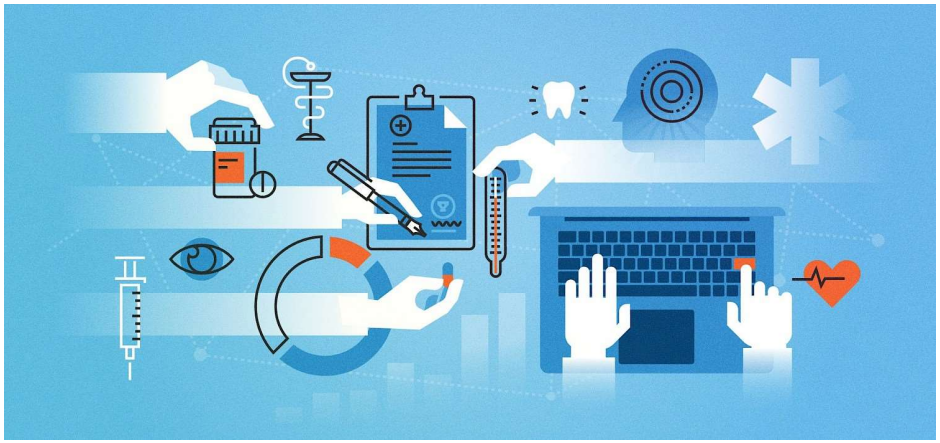
Agenda

01

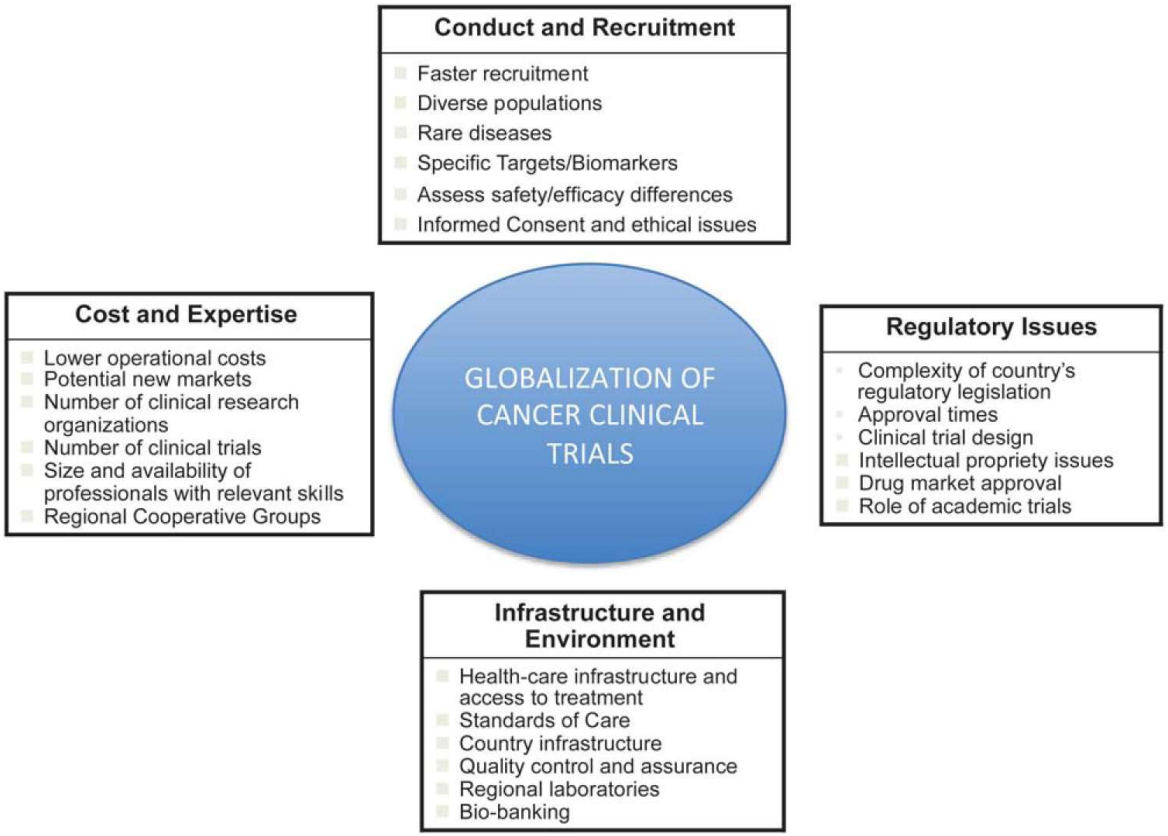
Initial Considerations

Case Study

- You work for a global clinical-stage biotech company that has investigational molecule A.
- Your company wants to work with a research institution recruit research participants with cancer X to receive your investigational molecule.
- What are the rights and obligations of each party with respect to the clinical trial?
- What are the key terms and conditions that will need to be negotiated by the parties?



Some Considerations in Global Clinical Trials



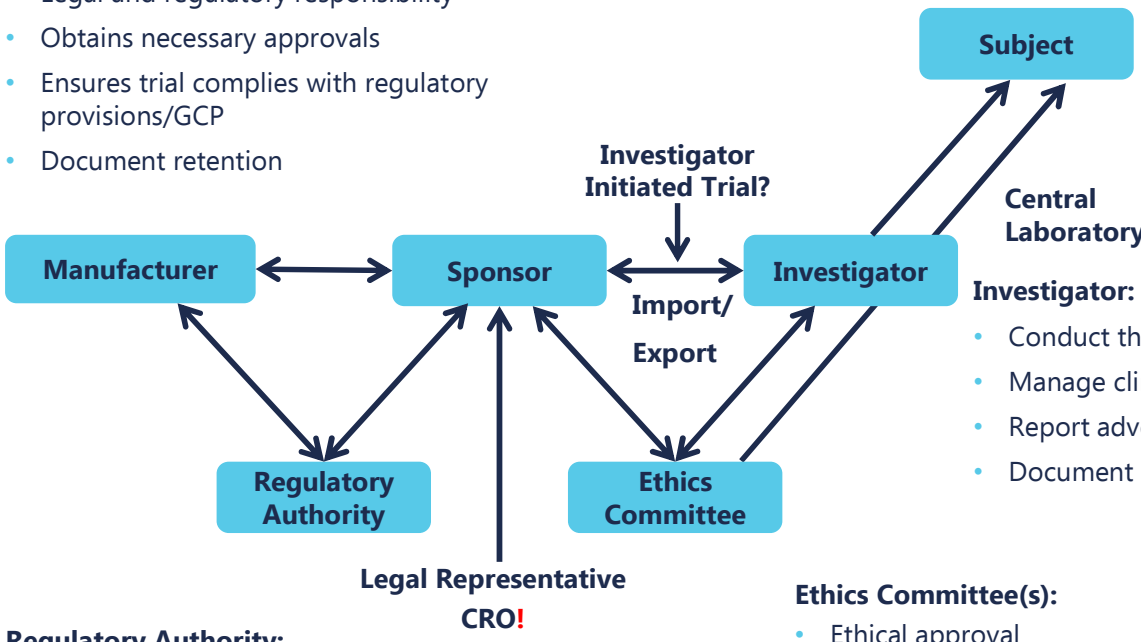
Initial Considerations

- Parties
- Locations
- Type of study/trial
- Status of Protocol
- Timings
- Value
- Template (ACTA)
- Negotiating position
- Previous dealings

The Parties

Sponsor:

- Legal and regulatory responsibility
- Obtains necessary approvals
- Ensures trial complies with regulatory provisions/GCP
- Document retention



Subject:

- Informed consent
- Data rights

Investigator:

- Conduct the ICH-compliant trial
- Manage clinical team
- Report adverse events
- Document retention

Regulatory Authority:

- Grant of authorization
- Review adverse event reports
- Hopefully regulatory standards mirror GCP

Ethics Committee(s):

- Ethical approval
- Review documentation
- Certain countries may have multiple bodies

02

Intellectual Property & Confidentiality

IP Basics

- What types of IP can be generated during/after clinical trials?
- What rights does that IP give you?
- How long for?
- How can you lose IP protection?
- Beware joint ownership

Who Owns the IP?

Sponsor owns everything that results from the study

(ONE POTENTIAL OUTCOME)
Sponsor owns investigational product-related inventions
+
Exclusive option and non-exclusive licenses for other inventions

Site owns everything that results from the study

Things to consider

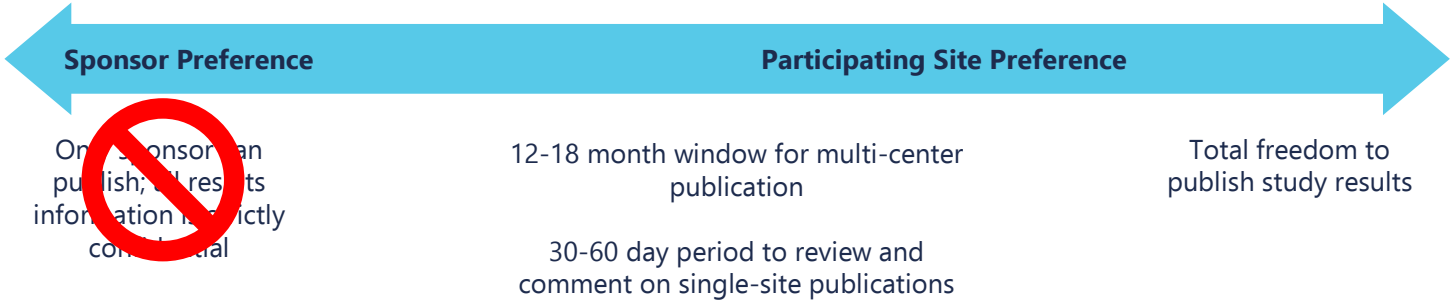
- Likelihood of inventions (phase and nature of study, site contribution, etc.)
- Differing sponsor approaches to invention ownership
- Are there any third-party licenses?
- Extension of non-exclusive licenses to collaborator
- Control of patent prosecution
- Separate treatment of Study Data -- increased negotiation around study data/record retention

Publication

" The Institution and the Principal Investigator shall be entitled to publish the results of, or make presentations related to, the Study."

What changes will the Sponsor want to make to this clause?

Publication



Potential issues:

- Study site access to complete dataset
- Study site request for pre-agreed authorship status
- How to harmonize different publication expectations across multiple international sites

Confidentiality

All sponsor information is confidential (regardless of marking), for a long time

No protection for incoming information

Reasonable marking; exception for information obviously of a confidential nature

Limited protection for non-study related information observed in monitoring

Only marked information is confidential, and only for a short time

Mutual confidentiality

Things to consider:

- Flexibility in time limits, depending on phase and nature of study
- Practical implications of strict enforcement
  - No confidentiality in informed consent documents
  - Much information about Phase 2+ trials routinely publicly available
  - Details of large, phase 3 trials virtually impossible to keep secret

Proposed Use of AI

- Increasingly, sponsors are addressing use of AI by sites and vendors
- Sites and vendors use AI to negotiate agreements, recruit and determine eligibility of patients, enter study data and more
- Consider whether to (i) ask the CRO to disclose use of AI tools and (i) audit the AI tools in advance
- Contractual language to define parties' rights and obligations with respect to AI tools

03

Risk Allocation

Reps, Warranties and Indemnities

	Description	Remedy
Representations	Statement by one party which induces another party to enter into a contract	Misrepresentation rescission and/or damages
Warranties	Statement or assurance about factual matter shall be as it is stated or promised (implied indemnification)	Damages
Covenants	Promise by a party by which it pledges that something is either done, will be done or shall not be done	Damages or specific performance
Indemnities	Contractual promise to reimburse the other party for damages associated with an identified occurrence	Being made whole for losses caused by the trigger event (subject to terms of the agreement)

Indemnification

Mutual indemnification for negligence and intentional misconduct, with carve-outs for other party's negligence and intentional misconduct

Potential options:
Silence
Responsibility vs. Indemnification

Only indemnification of site by sponsor

Things to consider

- Statutory or medical malpractice insurance limitations
- Indemnification for use of results or intellectual property
- Proposed limitations of liability (consider carving out potentially catastrophic damages such as intentional misconduct; IP or confidentiality breaches)

Navigating Indemnities

- Reciprocity
- Liability cap
- Excluding losses caused by indemnified party
- Third party claims
- Exclusion of indirect loss
- Duty to mitigate
- Process for claims
- Settlement payments
- Associated costs and expenses
- Constitutional, legal and policy limitations may affect state institutions

Termination of Study Agreements

- Parties may want to terminate early in various circumstances e.g.:
  - risks to health, safety or well-being of subjects
  - recruitment failure
  - debarment (in the U.S.)
  - unavailability of the investigator
  - for breaches of applicable transparency/anti-corruption laws
  - for material breach
  - insolvency
- Liability for costs arising from termination?
- What (if any) obligations should survive termination?
  - Transition of services can be key

Data Privacy and Security

More Data = More Privacy

- More Data in Clinical Trials = More Data Privacy and Security Considerations
- In remote clinical trials – sponsors, CROs, others may have access to more identifiable and electronic data
- Use of patient-focused apps and wearables adds even more data and systems outside of the traditional systems used for clinical trials
- Depending on who is hosting the app/facilitating remote monitoring/etc., it may be difficult to pseudonymize (key-code) the data
  - Need to protect it AND
  - Need to segregate it from other identifiable data
- Consider data minimization

Use of Deidentified and Anonymized Data in Clinical Trials

- Understand the context in which the data/samples were collected
- Transparency is key – were individuals told about the deidentification and anonymization of data?
  - Is consent necessary?
- Ensure appropriate procedures are in place to prevent reidentification
- Understand differences in global privacy laws and how that impacts removal of identifiers from data
  - US – deidentification under HIPAA – data can be key-coded
    - That is pseudonymized data under many other privacy laws
  - Anonymized data cannot be key-coded or otherwise able to be reidentified

How to Control the Cyber Threat?

Policies and Governance	Risk Assessment and Management	Access Controls	Encryption
Vulnerability Management	HR Procedures	Detection	Audit
Third-Party Management	Physical Security	Business Continuity and Disaster Recovery	Incident Response and After-Action

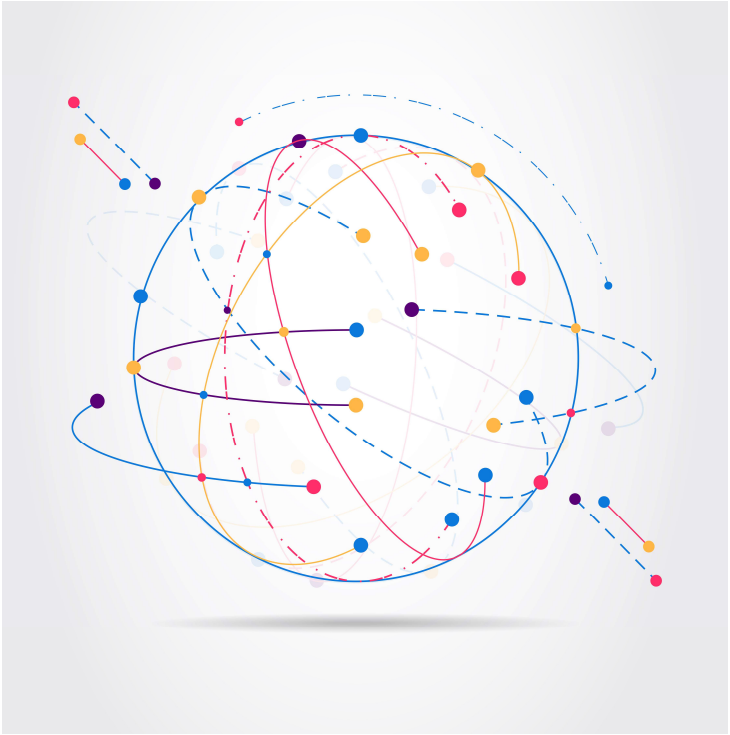
Audit, Assess, Oversee

- Check in on systems containing troves of identifiable patient data
- Make sure your third parties are adequately protecting data – not only through contract but through information security questionnaires, assessments and auditing
- Think about and consider how data will be stored after the end of the trial – how to delete, what to keep, etc.
- Critically – limit access and onward uses of patient data

Managing Data-Related Risks

- Address data security and breach risks and responsibilities
  - Set forth clear processes and remedies in advance
    - Including communications with regulators and other breach-related notifications
  - Audits
  - Allocate any associated costs
  - Consider corporate compliance policies
- Indemnification
  - Generally: Covers breaches of the agreement, including breaches of applicable law and data-related reps, warranties and covenants
- Insurance
  - Cyber-insurance may be particularly important
    - Particularly important when the counterparty is a start-up
- Limitations of liability
  - Indemnification, breaches of confidentiality and breaches of data protection obligations are typically uncapped

Cross-Border Data Transfers



General rule: Cross-border data transfers are subject to specific conditions

- **Possibilities for the transfer of personal data**
  - Adequacy decisions for particular countries ensuring an adequate level of data protection
  - Implementation of appropriate safeguards (e.g., standard contractual clauses, binding corporate rules, technical measures)
  - Applicability of derogations for specific situations (e.g., for legal defense)
- **Specific restrictions for health data**
  - Localization requirements due to sensitivity of health data
  - Limitations due to national security concerns (e.g., EO on bulk sensitive personal data)
- **Important questions in relation to clinical trials**
  - Will personal data be transferred to a recipient based in a third country?
  - Which jurisdictions apply to the transfer of personal data? Is the transfer generally allowed under such jurisdictions?
  - Does the transfer require the implementation of specific technical measures (e.g,. encryption) and/or creation of documentation (e.g., TIA)?

Speakers

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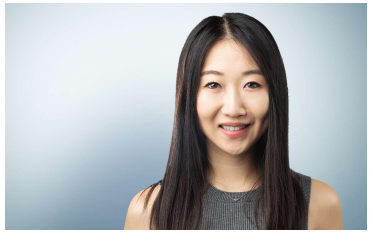

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Q&A
Questions · Answers

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