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Key Elements for Effective and Successful Clinical Data Collection

CRITICAL ROLE OF CLINICAL INVESTIGATIONAL PLANS (CIPS) AND STUDY PLANS

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In this session…

- We will discuss the critical role of Clinical Investigational Plans (CIPs) and study plans in ensuring effective and successful clinical data collection.
- We will cover strategies for preparing and designing data collection with risk management in mind.
- We will see how effective data collection is crucial to avoid prolonged data collection, study analysis and failed outcomes.

Key Concepts

1. Designing Effective Data Collection
2. Ensuring Data Integrity
3. Analyzing Datasets and Results
4. Addressing the Human Factor

1 Designing Effective Data Collection

1. Planning

- Define clear objectives and endpoints for the study.
- Identify key data points needed to meet study objectives.
- Develop a comprehensive Clinical Investigational Plan (CIP).

2. Tools and Systems

- Utilize Electronic Data Capture (EDC) systems for real-time data entry and monitoring.
- Implement standardized Case Report Forms (CRFs) to ensure consistency.

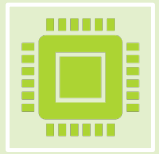
3. Risk Management

- Conduct a risk assessment to identify potential issues in data collection.
- Develop mitigation strategies to address identified risks. (Develop DMP, MP etc.)
- Continuously monitor and adjust the data collection process as needed.

Planning

- Define clear objectives and endpoints for the study
- Identify key data points needed to meet study objectives
- Develop a comprehensive Clinical Investigational Plan (CIP)

Tools and Systems



Utilize Electronic Data Capture (EDC) systems for real-time data entry and monitoring

Implement standardized Case Report Forms (CRFs) to ensure consistency

EDC Systems and CRFs

Facilitates accurate and timely data collection.

Ensures data integrity with automated validation checks.

Provides instant access to data for monitoring and analysis.

Standardized CRFs ensure that all sites collect data uniformly, reducing variability and improving the comparability of results across different study centers.

Ensures that all necessary data is captured systematically, supporting comprehensive analysis and accurate assessment of study objectives.

Simplifies the data entry process, reducing the burden on site staff, and minimizing the risk of data entry errors.

Risk Management

01

- Conduct a risk assessment to identify potential issues in data collection.

02

- Develop mitigation strategies to address identified risks.

03

- Continuously monitor and adjust the data collection process as needed.

2 Ensuring Data Integrity

Data Quality:

Implement quality control measures to ensure data accuracy and completeness.

Use automated checks and validation rules within EDC systems to identify discrepancies.

Consistency and Standardization:

Standardize data collection procedures across all sites.

Train site personnel thoroughly on data collection protocols and tools.

Auditing and Monitoring:

Conduct regular audits to verify data integrity.

Use centralized monitoring to identify and address issues promptly.

3 Analyzing Datasets and Results

Data Management:

- Develop a robust data management plan to handle data from collection to analysis.
- Ensure proper data cleaning and preparation before analysis.

Statistical Analysis:

- Collaborate with biostatisticians to plan appropriate statistical analyses.
- Predefine analysis plans to avoid data-driven biases.

Interim Analyses:

- Conduct interim analyses to monitor progress and identify issues early.
- Use interim results to make informed decisions about study modifications

4 Addressing the Human Factor

Training and Education:

Provide comprehensive training for all study personnel on protocols and data collection tools

Offer continuous education and refresher courses to maintain high standards.

Engagement and Communication:

Foster open communication channels between study teams and site personnel.

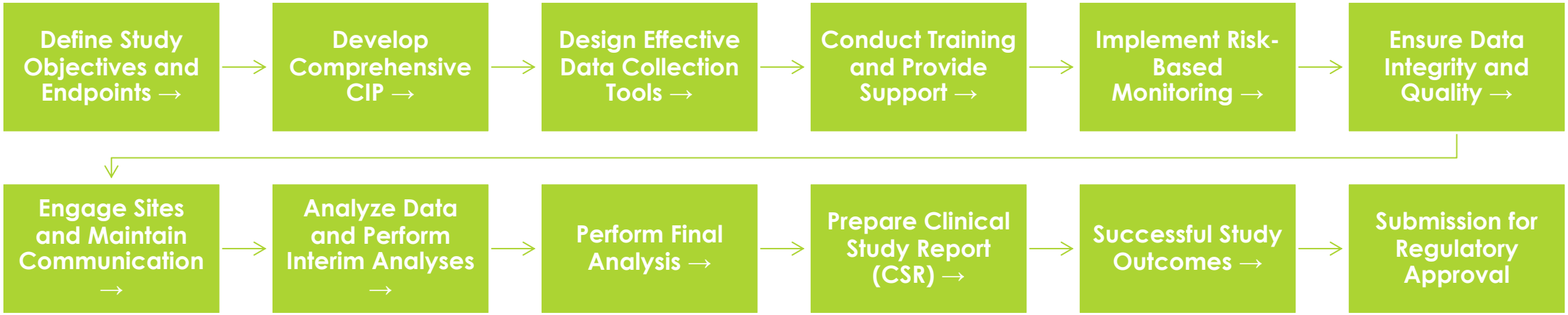
Engage site staff by involving them in decision-making processes and providing regular feedback.

Motivation and Support:

Recognize and reward high-performing sites and individuals.

Provide support to sites facing challenges to ensure they can meet study requirements.

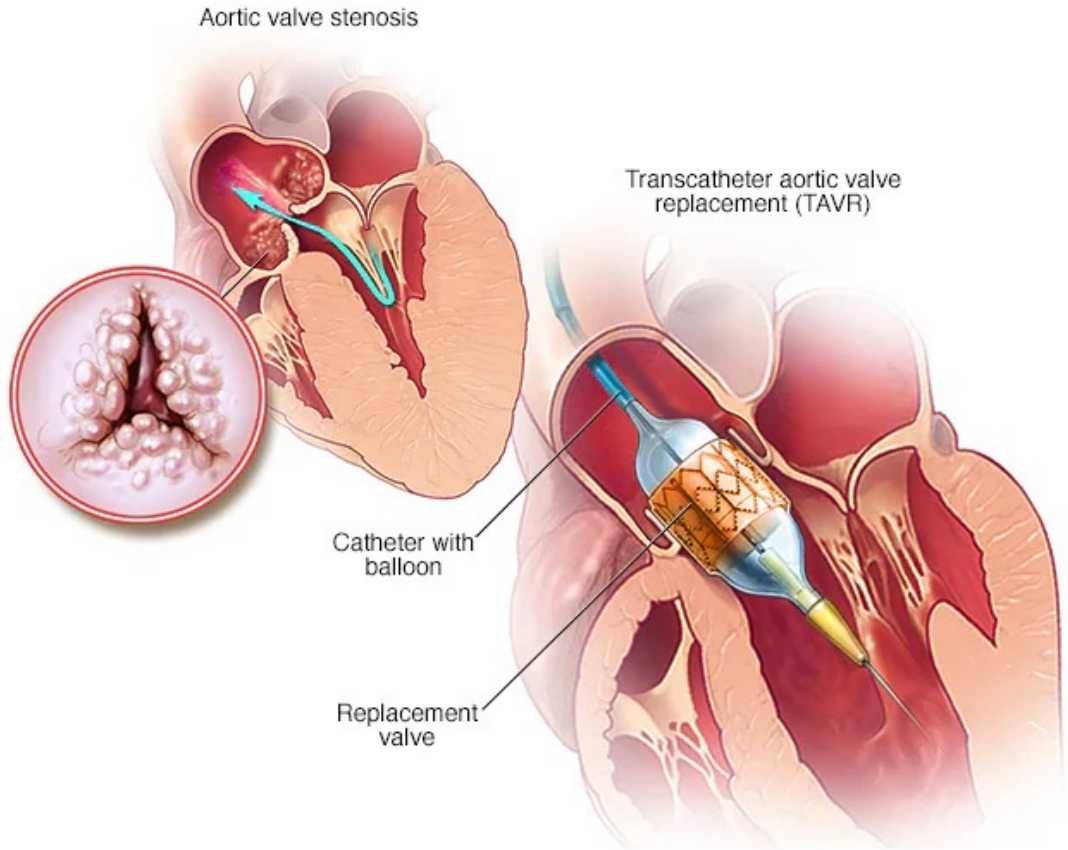
Roadmap to high-quality data and successful study outcomes



Case Example: Effective and Successful Clinical Data Collection

Effective and Successful Clinical Data Collection

- Define Clear Objectives and Endpoints for the Study
- Identify Key Data Points Needed to Meet Study Objectives
- Develop a Comprehensive Clinical Investigational Plan (CIP)



Example: Transcatheter Aortic Valve Replacement Study

Define Clear Objectives and Endpoints

Objective:

- To evaluate the safety and efficacy of a new transcatheter heart valve (THV) in patients with severe aortic stenosis who are at high surgical risk.

Primary Endpoint:

- All-cause mortality at 12 months post-implantation.

Secondary Endpoints:

- Incidence of major adverse cardiovascular and cerebrovascular events (MACCE) including stroke, myocardial infarction, and re-intervention.
- Improvement in New York Heart Association (NYHA) functional classification at 12 months.
- Change in valve hemodynamics as measured by echocardiography at 30 days, 6 months, and 12 months.

Identify Key Data Points

Demographic Data:

- Age, gender, comorbidities, and baseline characteristics of patients.

Clinical Data:

- Baseline and follow-up NYHA classification.
- Baseline and follow-up echocardiographic measurements (e.g., aortic valve area, mean gradient).
- Incidence and timing of adverse events (e.g., death, stroke, myocardial infarction).

Quality of Life Data:

- Patient-reported outcomes using standardized questionnaires (e.g., EQ-5D, SF-36).

Procedural Data:

- Technical success of the THV implantation.
- Procedural complications and device-related issues.

Develop a Comprehensive Clinical Investigational Plan (CIP)

Introduction:

Background and rationale for the study.

Summary of preclinical data and any prior clinical studies.

Objectives and Endpoints:

Clearly defined primary and secondary objectives and endpoints.

Study Design:

Detailed description of the study design (e.g., prospective, multicenter, randomized).

Inclusion and exclusion criteria for patient selection.

Study Procedures:

Step-by-step protocol for the THV implantation procedure.

Schedule of assessments and follow-up visits.

Data Collection and Management:

Methods for data collection, entry, and management.

Use of Electronic Data Capture (EDC) systems.

Safety and Risk Management:

Risk assessment and mitigation strategies.

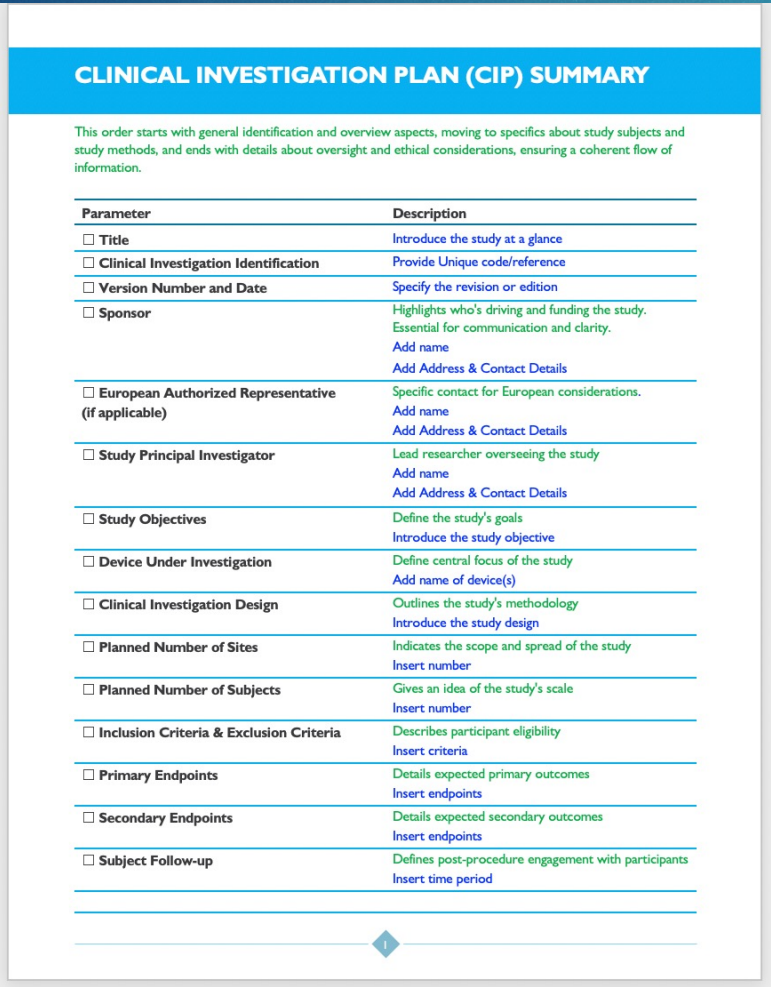
Monitoring and reporting of adverse events.

Statistical Considerations:

Sample size calculation and justification.

Statistical analysis plan for primary and secondary endpoints.

CIP Summary Template



CLINICAL INVESTIGATION PLAN (CIP) SUMMARY

This order starts with general identification and overview aspects, moving to specifics about study subjects and study methods, and ends with details about oversight and ethical considerations, ensuring a coherent flow of information.

Parameter	Description
☐ **Title**	Introduce the study at a glance
☐ **Clinical Investigation Identification**	Provide Unique code/reference
☐ **Version Number and Date**	Specify the revision or edition
☐ **Sponsor**	Highlights who's driving and funding the study. Essential for communication and clarity. Add name Add Address & Contact Details
☐ **European Authorized Representative (if applicable)**	Specific contact for European considerations. Add name Add Address & Contact Details
☐ **Study Principal Investigator**	Lead researcher overseeing the study Add name Add Address & Contact Details
☐ **Study Objectives**	Define the study's goals Introduce the study objective
☐ **Device Under Investigation**	Define central focus of the study Add name of device(s)
☐ **Clinical Investigation Design**	Outlines the study's methodology Introduce the study design
☐ **Planned Number of Sites**	Indicates the scope and spread of the study Insert number
☐ **Planned Number of Subjects**	Gives an idea of the study's scale Insert number
☐ **Inclusion Criteria & Exclusion Criteria**	Describes participant eligibility Insert criteria
☐ **Primary Endpoints**	Details expected primary outcomes Insert endpoints
☐ **Secondary Endpoints**	Details expected secondary outcomes Insert endpoints
☐ **Subject Follow-up**	Defines post-procedure engagement with participants Insert time period

Parameter	Description
☐ **Expected Duration of the Study**	Time estimate from start to finish Insert time period
☐ **Electronic Data Capture System**	Provider for data collection and analysis Add name Add Address & Contact Details
☐ **Steering Committee (if applicable)**	Expert group providing oversight of the scientific conduct of the study Add name(s) Add Address & Contact Details
☐ **Data Monitoring Committee (if applicable)**	Expert group providing safety and treatment efficacy oversight of the study Add name(s) Add Address & Contact Details
☐ **Clinical Event Committee (if applicable)**	Expert group providing adjudication of significant clinical events Add name(s) Add Address & Contact Details
☐ **Core Laboratories (if applicable)**	Provider and/or facilities handling specialized tests or analyses Add name(s) Add Address & Contact Details
☐ **Contract Research Organization (CRO) (if applicable)**	Provider and/or facility handling clinical study monitoring, safety analyses, or other sponsor responsibilities Add name Add Address & Contact Details
☐ **Safety & Adverse Event Reporting**	Brief overview of procedures (or reference to plan) for reporting any adverse events of incidents Specify the procedure or plan
☐ **Ethical Considerations and Approvals**	Summary on ethical guidelines followed (such as ISO 14155 GCP Standard) and approvals obtained for the study Specify the procedure or plan
☐ **Publication and Data Sharing Plans**	Brief overview (or reference to plan) how to disseminate results and share data with the broader scientific community Specify the procedure or plan

Develop a Comprehensive CRF

Section	Data Point	Description
Patient Demographics	Patient ID	*Unique identifier for each patient.*
	Age	*Age of the patient at the time of enrollment.*
	Gender	*Gender of the patient (e.g., Male, Female).*
	Medical History	*Relevant medical history (e.g., hypertension, diabetes).*
Pre-Procedure Assessment	NYHA Classification	*Functional classification of heart failure severity.*
	Aortic Valve Area	*Measurement of the aortic valve area (e.g., cm^2).*
	Mean Gradient	*Mean pressure gradient across the aortic valve (e.g., mmHg).*
Intra-Procedure Data	Procedure Date	*Date of the transcatheter valve implantation procedure.*
	Device Model	*Model of the transcatheter heart valve used.*
	Valve Positioning	*Positioning accuracy of the valve (e.g., correctly positioned).*
	Deployment Success	*Whether the valve deployment was successful (Yes/No).*
	Procedural Complications	*Any complications encountered during the procedure.*
Post-Procedure Follow-Up	Follow-Up Date	*Dates of follow-up visits.*
	NYHA Classification	*Post-procedure functional classification.*
	Aortic Valve Area	*Post-procedure measurement of the aortic valve area.*
	Mean Gradient	*Post-procedure mean pressure gradient.*
	Adverse Events	*Any adverse events reported since the procedure.*
	Hospitalizations	*Any hospitalizations since the procedure.*
Quality of Life	EQ-5D Score	*Patient-reported quality of life score.*

CRF Example

Poorly Designed CRF:	Data Point
Intra-Procedure Data	Procedure Date
	Device Model
	Valve Positioning
	Deployment Success
	Procedural Complications
Post-Procedure Follow-Up	Follow-Up 30 days
	NYHA Classification
	Echo Measurements
	Adverse Events
	Hospitalizations
Quality of Life	EQ-5D Score

Data Collected	**Details**
April 5	Missing data
Model A	Missing data
Adequate	Vague terminology
Yes	Vague
Yes	No specifics provided
Yes	Vague
Improved	Vague terminology
Improved	No specific values recorded
Yes	No details on type or severity
Not recorded	Incosistent considering AE
Not recorded	Missing data

Bad example

Data Collected
April 5, 2024
Model A, version 1.1
Correctly Positioned
Full
Yes - Paravalvular Leak, Managed
Yes – AE reported
Improved from III to II
AVA: 1.5 cm^2, Mean Gradient: 20 mmHg
Yes - Stroke on Day 10
Yes
75

Good example

Maria Nyåkern, Ph.D.

- Maria Nyåkern, Ph.D., is an accomplished leader and entrepreneur with two decades of expertise in the healthcare and MedTech industries. She has successfully established and expanded several consulting firms focused on medical device innovation and clinical research. As the founder of AKRN Scientific Consulting, a leading Madrid-based medical device CRO, Maria spearheaded significant business growth, culminating in the strategic acquisition of AKRN by the North American CRO, NAMSA, in 2022. This acquisition significantly enhanced clinical development and commercial capabilities in the medical devices sector.
- Maria is celebrated for her extensive expertise in the clinical evaluation and investigation of medical devices, particularly those integrated with AI, adhering to stringent EU MDR 2017/745 and ISO 14155:2020 standards. Her dedication to advancing medical technology and fostering emerging scientific talent has been recognized on a European level, underscoring her contributions to scientific progress, technology transfer, and societal improvement across Europe.

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