Angio Consult

How the use of Clinical Specialists can positively impact high-level regulatory studies

ACTIONABLE ADVICE ON HOW TO ENHANCE YOUR CLINICAL STUDY

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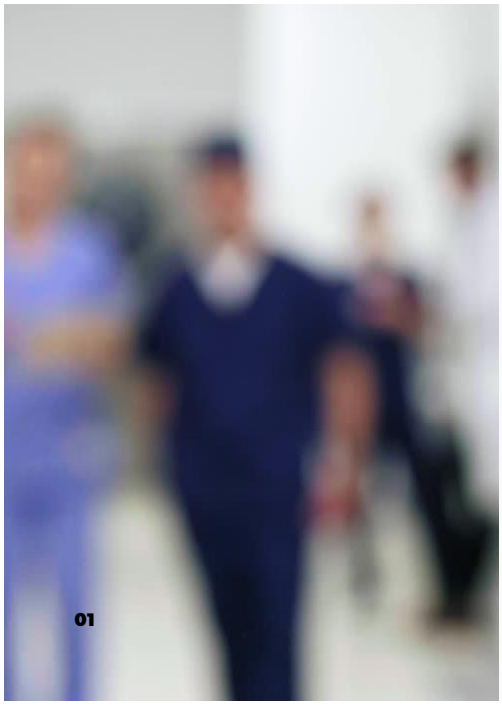
London, May 29th, 2024



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Importance of Regulatory Studies in Medical Device Approval

Facts first:
There are more than two million kinds of medical devices on the global market.

MDR Article 62: Clinical investigations shall be designed and conducted in such a way that the rights, safety, dignity and well-being of the subjects participating in a clinical investigation are protected and prevail over all other interests and the clinical data generated are scientifically **valid, reliable and robust.**

Clinical Data in Medical Device Studies

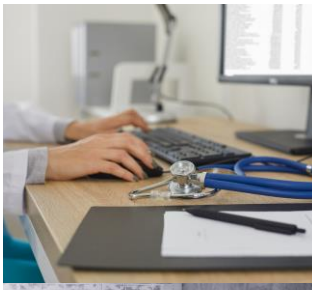
Clinical data is the base of a successful clinical study.

Why do we need clinical data for medical devices?

1. Safety of the device/technology
2. Clinical benefit (non-inferiority / superiority)
3. **Clinical performance of devices/ technologies**
4. **Risk analysis and management**
5. **Finding the balance between innovation and safety**

What is the importance of <u>good</u> clinical data?

1. Regulatory requirements / approval
2. Supporting in funding efforts
3. Supporting on commercialization progress
4. Clinical performance of devices/ technologies
5. Risk analysis and management



	PRE-MARKET			POST-MARKET	
Clinical Development Stage	**Pre-Clinical**	**Pilot**	**Pivotal**	**Post-Market Surveillance (PMS)**	
Type	Exploratory	Exploratory & Confirmatory	Confirmatory		Observational
Descriptors	- In-Vitro - In-Vivo - Bench-test	- First-in-Human - Pilot Study - Safety Study - Exploratory Study - Early/Traditional Feasibility Study - Proof-of-Concept - Investigator Initiated*	- Pre-Market CI/Study - Pivotal CI/Study - PMA CI/Study - Phase III Study	- Post-market CI/Study - Investigator Initiated* - PMCF Study - Post-Authorization Study (PAS) - Validation Study	- Post-Market CI/Study - PMCF Study - Investigator Initiated* - Registry - Survey - Case Series - Cohort - Post-Authorization Study (PAS)
Burden to Human Subject	**None**	**Interventional**			**Non-Interventional**

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*Investigator-Initiated Studies can be interventional and non-interventional. Investigator-initiated Studies don't have to be sponsored by investigators.

Challenges faced

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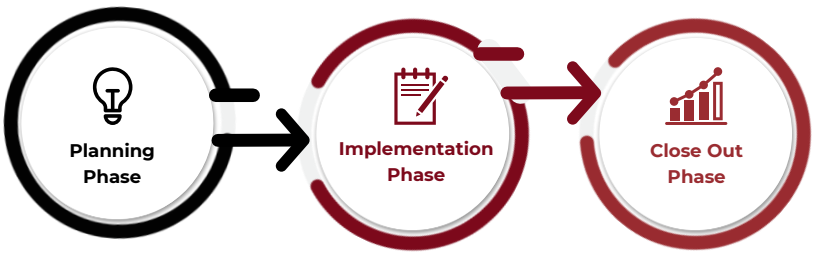
There are many challenges associated with starting clinical trials.



Lack of personnel
Identifying suitable sites
Time investments
High costs/lack of budget
Creating study documents
Approval by authorities

Insufficient device and procedure training
Study protocols are too complex
No suitable patient recruitment
High costs
Frequent protocol adjustments
Low compliance in follow-up schedule
Missing enrollment target
Lack of on-site guidance during clinical cases

Data analysis
Aggregating and publishing results

Whereas CEOs concentrate on regulations and CROs,

Clinical specialists put their focus **on the medical personnel** and their role in the study.

Did you know?
More than 70% of MedTech companies are outsourcing at least some of their clinical activities. **But why?**

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So much to do. So little time.

Clinical studies are an equilibrium of multiple groups of people running multiple tasks simultaneously.

STAGE 1	STAGE 2	STAGE 3	STAGE 4	STAGE 5	STAGE 6	STAGE 7
Innovation: Device Ideation & Prototyping	**Strategy: Clinical Strategy Preparation & Pre-Submission Planning**	**Execution: Clinical Investigation & Study Execution**	**Compliance: Regulatory Submission**	**Launch: Product Launch**	**Assess: Post Market Surveillance**	**Manage: Regulatory Maintenance**
Design Concept	**Clinical Trial Site Selection**	Clinical Study Build	Market Application Submission	Clinical Trial Refinement	PMCF, PMS, Peer Reviews, SSCP	Supplements
Identify Regulatory Path	Regulatory Planning	**Patient Recruitment/Enrollment**	Query Resolution	Data Assessment	Clinical Study Surveillance	Amendments
Clinical Study Plan Create	Clinical Investigation Planning	Clinical Electronic Data Collect	Clinical Trial Monitoring	Insights & Analytics	Data Safety Monitoring	Annual Reports
	Data & Risk Management Method & Process	**Site & KOL Communication**	Device Performance & Efficacy	Market Assessment	Post-Market Patient Registries	
	Device & Procedure Training	**Clinical Support**	Reimbursement Services	**Product Presentation**	Risk Modeling & Future Study Plan	
			Product Economic Analysis	**Market Adaption**	Market Growth Analyis	

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CLINICAL SPECIALISTS

- Clinical Support
- Experience and knowledge in regard to clinical environment, clinical procedures and tools
- Device Training
- Patient management
- Support in screening process
- KOL & site management
- Reporting to engineering
- Reporting to CRO data management

CRO

- Data management
- Regulatory submission
- Follow-up monitoring

- Clinical case support
- KOL engagement
- Direct communication with study sites
- Study site selection

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ENGINEERS

- Expertise device/technology
- Ability to make changes on the device

- Specialist for this specific device
- No experience in clinical environment
- No medical knowledge
- No didactic training in communication with medical staff

Case Study: Protembis

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Embolic protection during TAVI

Startup Management
- Creation of the business plan
- Preparation of the pitch deck

Fundraising Consulting
- Connecting with investors
- Communication with investors

European Market Analysis
- Creation of market report
- Market analysis
- Collection and analysis of facts and figures of the embolic protection and TAVI market

Project Development
- Coordination, planning, organization, execution and controlling of all project steps
- Dual strategy: strategic planning (consulting competence) and operational support
- Staffing
- Site selection and qualification
- SIV's

Clinical Case Support
- Worldwide case support and case proctoring with the ProtEmbo System in Cathlab and Hybrid OR on site
- Site communication
- Procedure and device training
- Establishment of online training program
- Case data management

Study Management / Execution
- Development of study strategy
- Active management of the study
- Execution of all study types: FIH, CE approval, IDE
- Local vendor support: e.g. CRO selection

Case Study: TVA

Minimally invasive vascular access solution for patients with chronic kidney disease requiring hemodialysis

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Reimbursement Strategy
- Development of reimbursement strategy
- Guidance in application process

Approval Process Consulting
- Guidance through the process with Notified Body

Marketing Activities
- Strategic and operational study marketing
- Preparation of product launch
- Preparation of commercialization

Congress Participation
- Strategic planning (e.g. mission) and on-site congress participation
- Logistics planning
- Meetings with KOL
- Personnel support at booths

Distribution Management
- Establishment of the direct sales structure

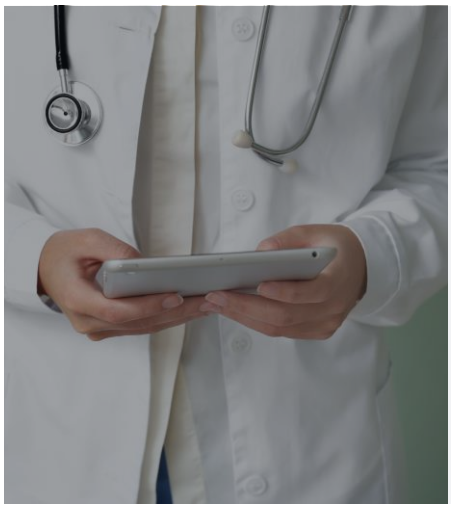
Case Study: CardioValve

CardioValve

Novel transcatheter valve replacement system

Status Quo
- No patient enrollment despite active sites
- Lack of CRO engagement
- Insufficient training of proctors

Change Management
- Engagement of additional sites
- Take-over of CRO management
- Creation of a new training & education set-up
- Enhancement of patient safety
- Adequate case support



Clinical Specialists are experts in **gathering data and overseeing its transfer** among all stakeholders, enhancing efficiency for both the study sites and the sponsor, **leading to the successful completion of the study.**

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Practical Takeaways

Overcoming challenges with the support of Clinical Specialists.

		Experience in Clinical Consulting	Practical Expert
		High Compliance in Follow-Up Schedule	On-Site Guidance during Clinical Cases
Ideal Site Selection	Professional Device & Procedure Training	Meeting of Enrollment Targets	Adequate Patient Recruitment

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Let’s chat.

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