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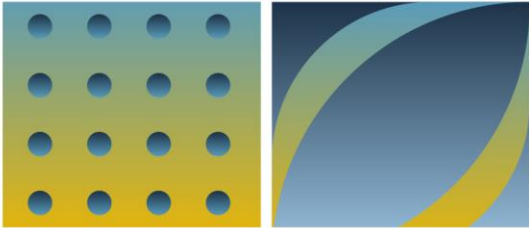
Clinical Project Management: Develop the Right Skills and Expertise for Efficiency and Compliance

Danielle Giroud
CEO, MD-Clinicals

Thanks Helene for allowing me to explain CPM in 30 min 😊



About the speaker



About Us



We're passionate about medical devices and IVD.

With over 35 years of experience in managing medical device/IVD clinical investigations around the globe, we have what it takes to move your product to market swiftly and cost-effectively, saving you precious time and money in the process.

Our unsurpassed clinical and regulatory expertise in medical device and in-vitro diagnostic market access is there to answer all your questions.

With **over 30 successful MDR approvals** including EU expert panels passed without any comments, we work with clients hand in hand to make things work.

With services tailored to your specific needs, we offer flexible solutions that are as unique as your product - to assure you the quickest and most effective path to market.

About Me



Danielle Giroud

- 40 years of experience within the medical device and in-vitro diagnostic industry,
- Founder and CEO of MD-Clinicals (<https://www.md-clinicals.com>), a medical device and in-vitro diagnostic-focused CRO with offices in Switzerland, Frankfurt, and Beijing.
- Founder and CEO of WMDO – online learning for medical device professionals (<https://www.wmdo.org>)
- Since 1998, convener for the expert group on clinical investigations (TC 194 WG4) for the ISO 14155 and 18969 on clinical evaluation.

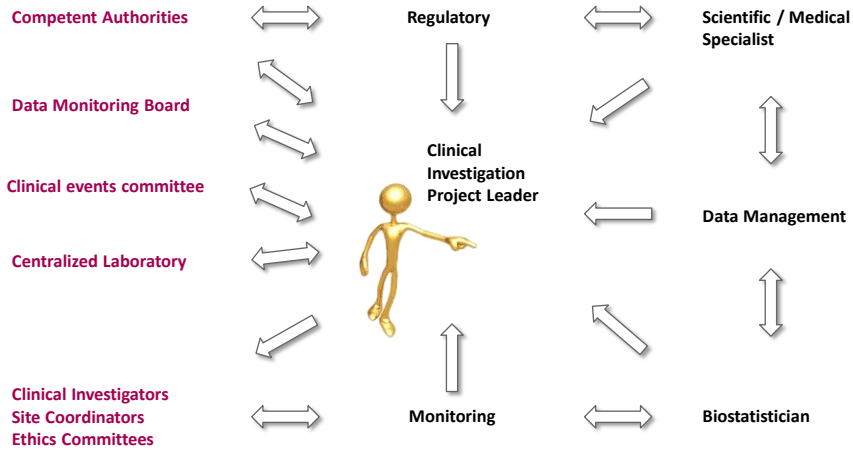
And there is still so much to do!

Firm believer in regulatory convergence



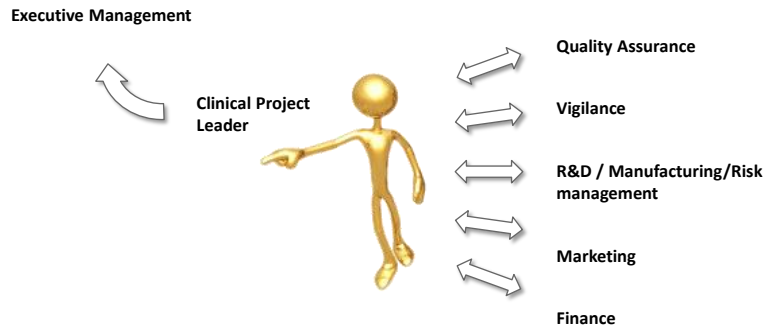
Clinical Project management complexities

Medical device CI project management - complexities



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Medical device CI project management - complexities



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Clinical Project management career

Medical device CI project management – career development

1. Develop the skills take time and practice

Learn the
basics step by
step



- Learn how to apply GCP by practicing monitoring first
- Learn and understand the regulatory requirements
- Understand product development and what comes before human use

2. Product and clinical environment

If you do not know the environment you cannot manage a project



- How does the device work?
- What is the clinical environment?
- What are the alternative treatments?
- Who are the users?
- What does the device do? How do we measure what the device does?
- How much do we know about the device already?

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3. Clinical development stages and related study designs

Each development phase has its specific questions



- Pilot phase – level of detail required to prepare a pivotal phase.
- Pivotal phase – get the data right to reach market approval
- Post market phase – focus on target data while satisfying outstanding scientific questions
- Understand basics of study designs and how to develop a protocol, where to find the basis for your study design
- Choosing the right control in the appropriate study design

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4. Getting the target data and get the data right

If you do not understand the environment, you may miss the important data points



- Who will generate the data i.e. Who are your investigators?
 - Design an efficient CRF and data base – its an art that takes years to master
 - Project plan:
 - Monitoring plan
 - Data management plan
 - Statistical analysis plan
 - Safety plan
- It's one big team to be orchestrated to reach harmony!*

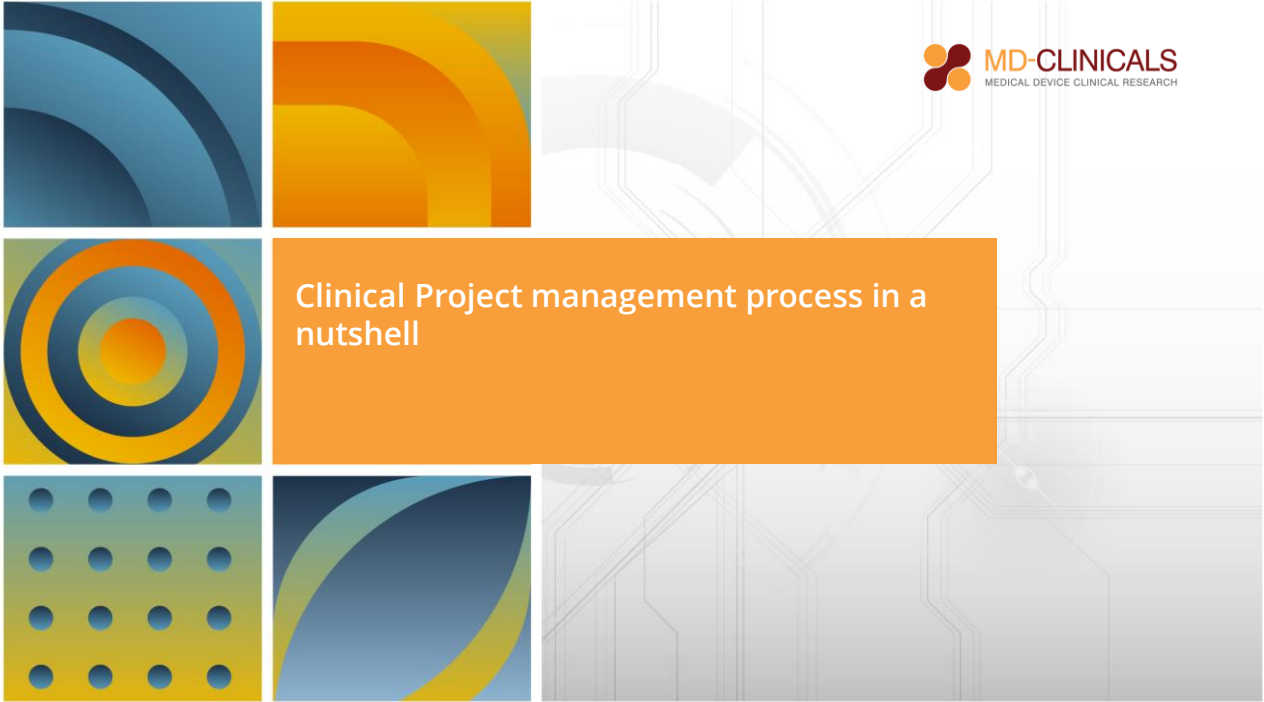
'I have a PhD and done extensive research in the lab, I know how to manage a project for a Class III device'

'Hi, I am a product manager and need to understand how the embassy can give me an approval for my study'

'I was a ghost writer for physicians writing their articles, I know very well how to write a protocol'

'our marketing manager knows very well the KOLs he can manage the pivotal study and learn the market'

'managing a clinical investigation project is like managing any other project, I can start tomorrow'



Good clinical project management

Optimize return on Investment (ROI)

- **Planning**
- Continuous **monitoring**
- **Communication** and reporting
- **Team management**
- **Contingency** plans

**RISK MANAGEMENT BOTH OF
DEVICE AND PROJECT**



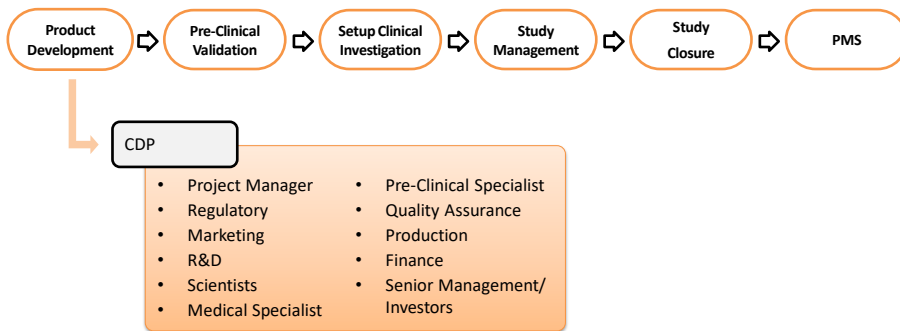
Good clinical project management



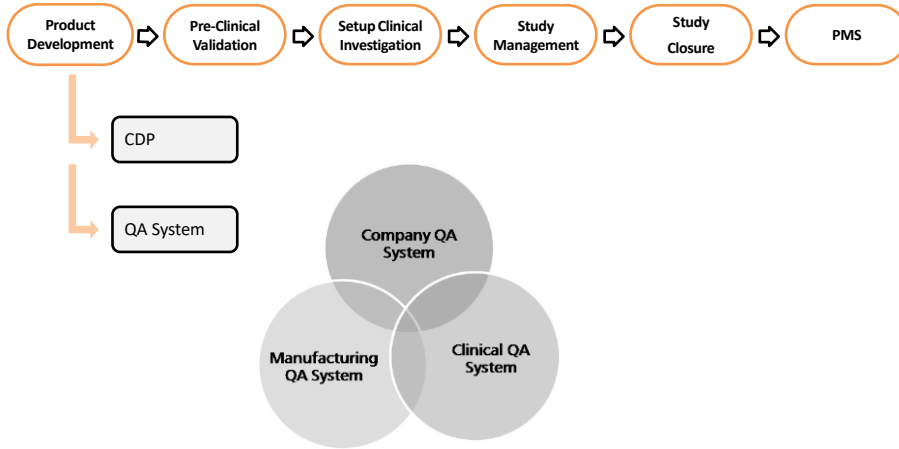
Optimize return on Investment (ROI)



Good clinical project management

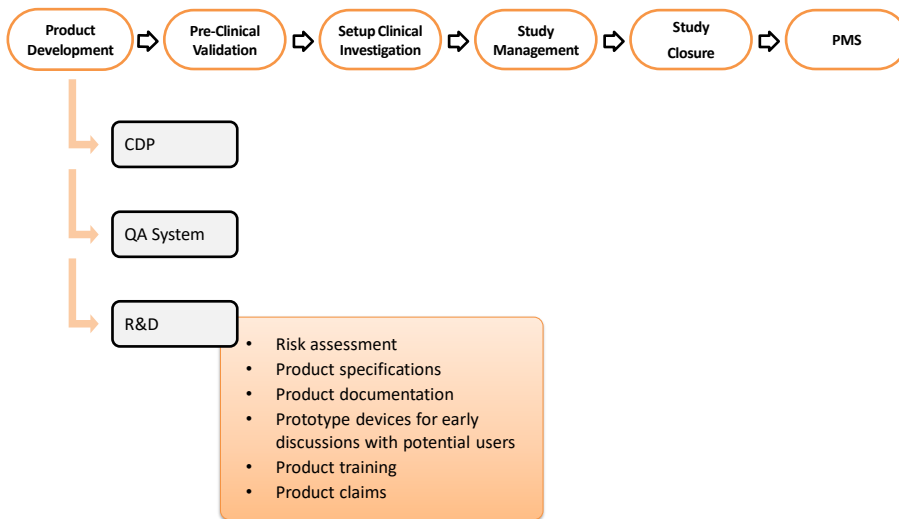


Good clinical project management



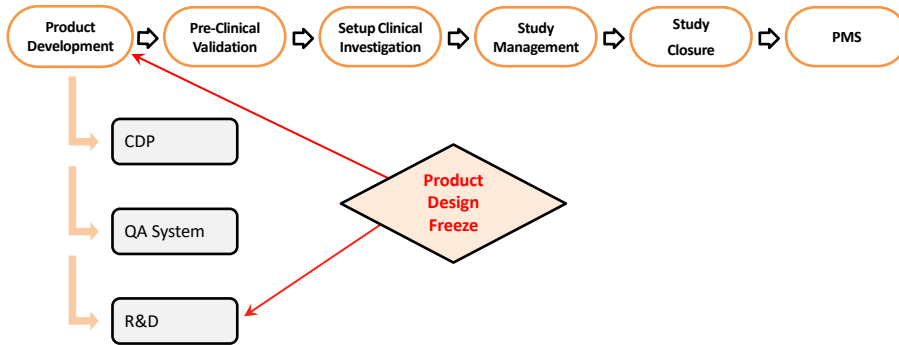
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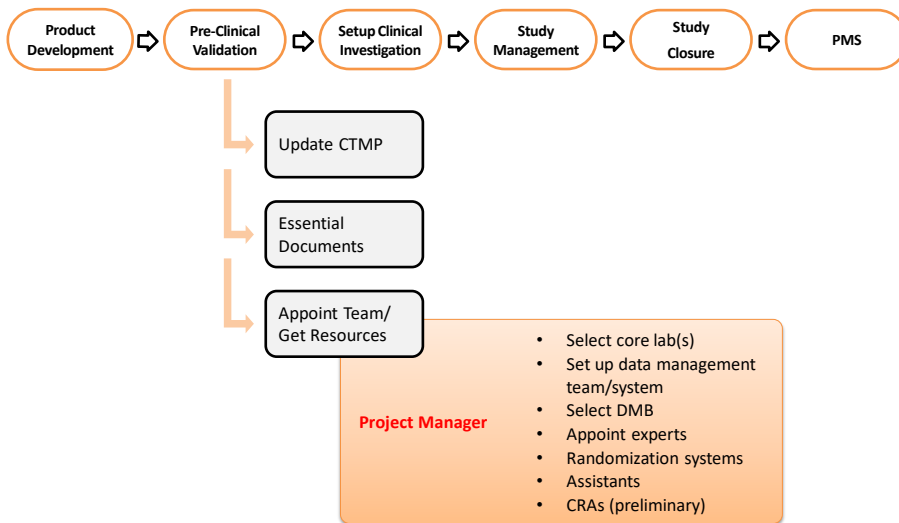
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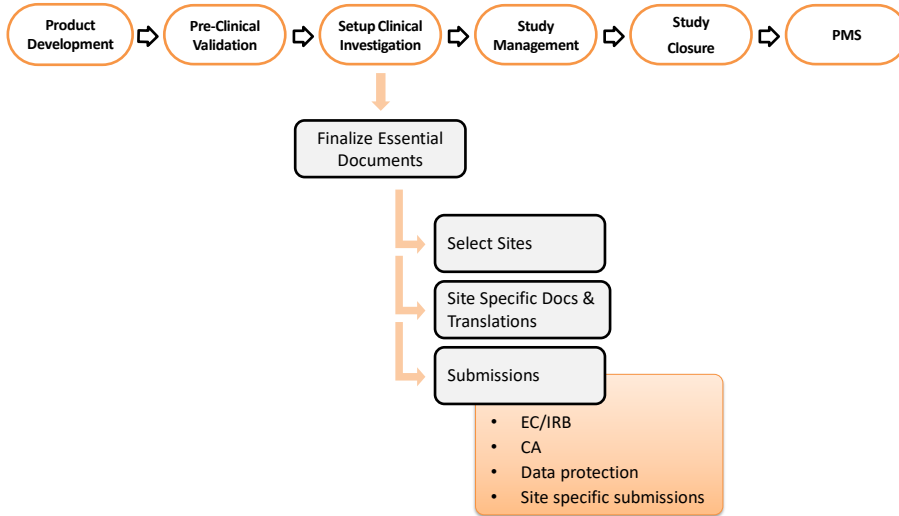
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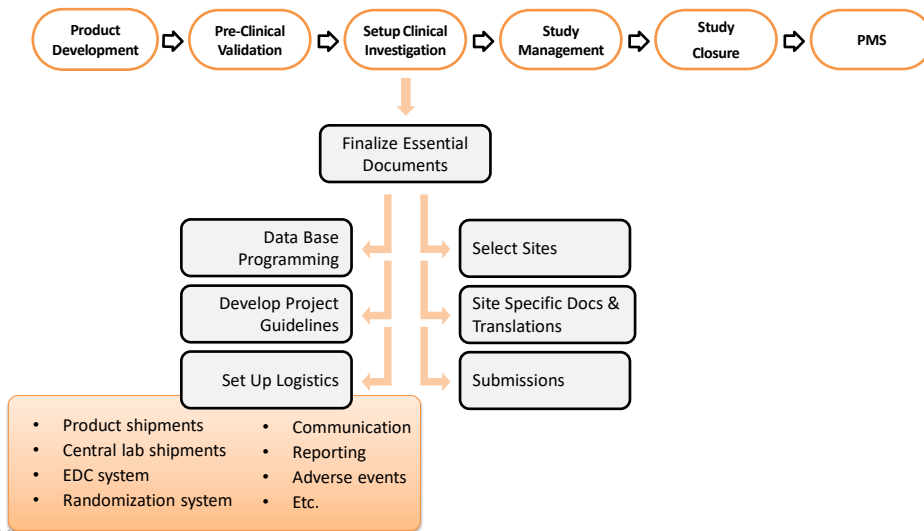
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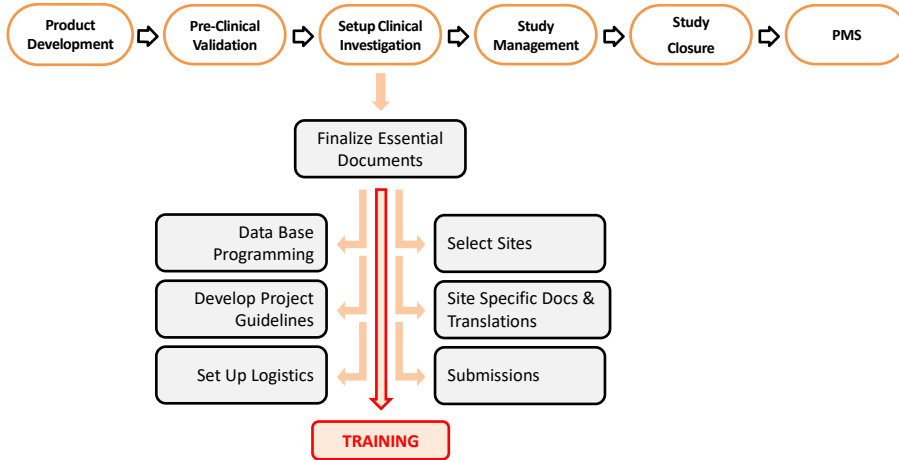
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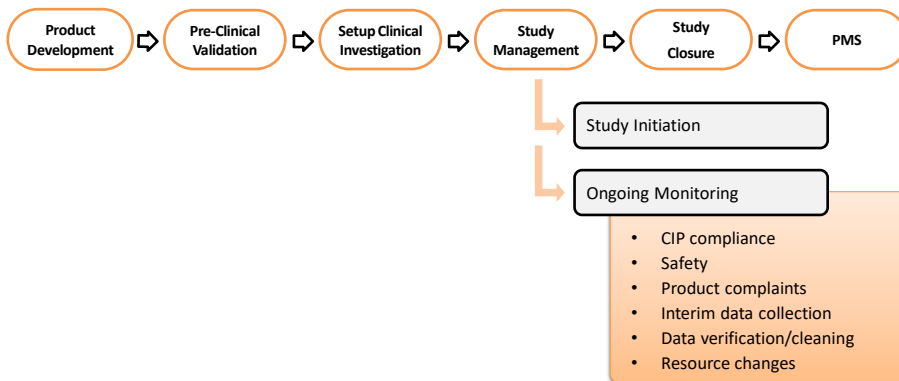
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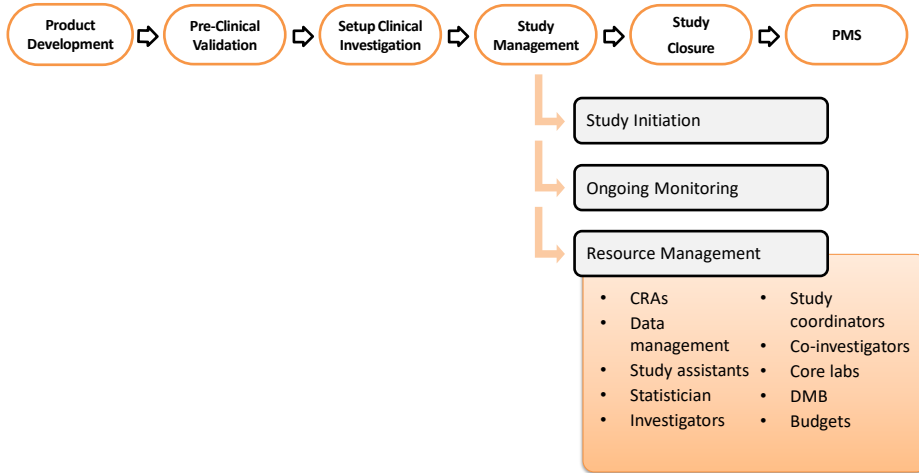
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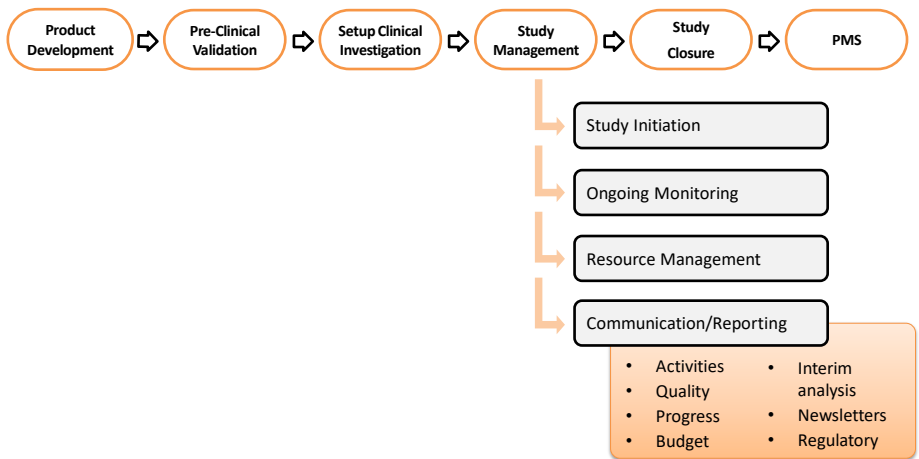
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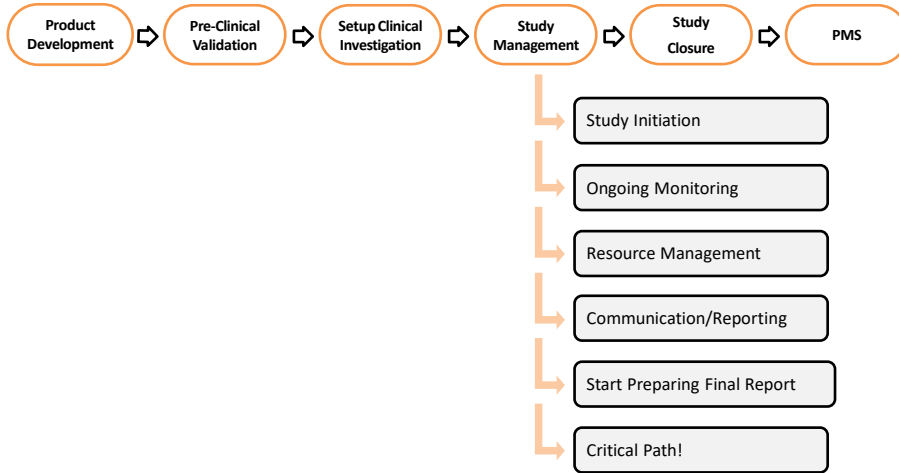
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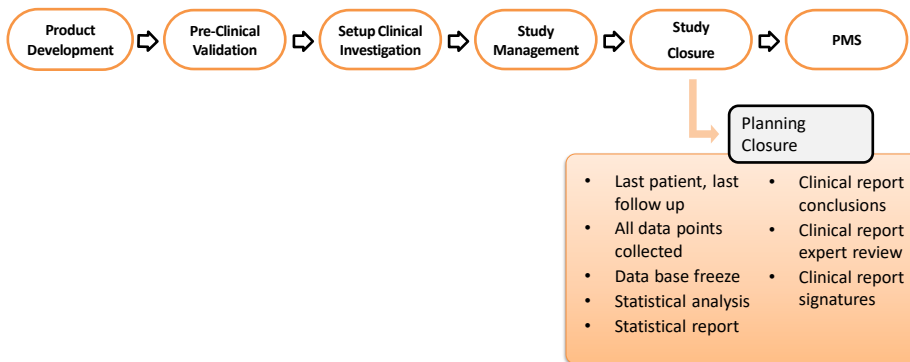
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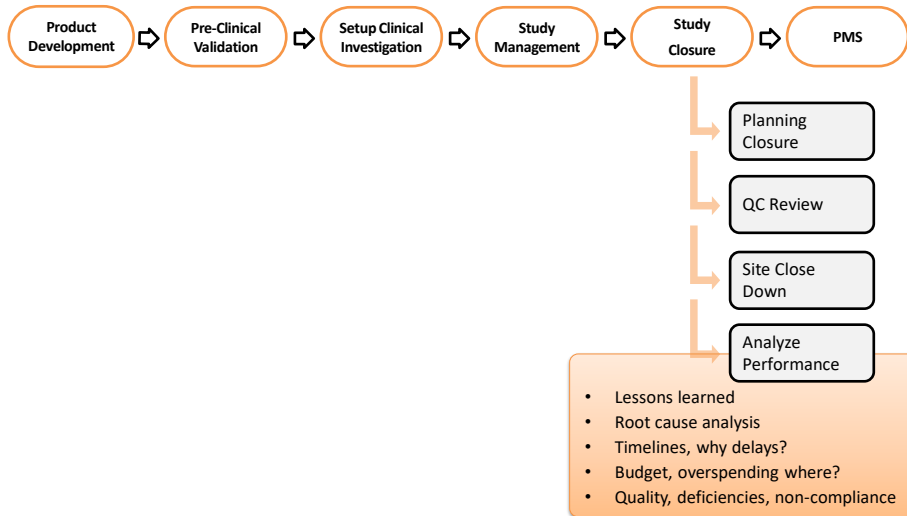
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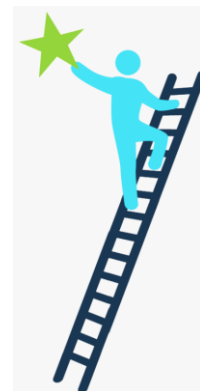
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Conclusion: how to reach the level of experienced clinical project manager for medical device studies

- Give yourself the time to gather expertise
- Learn from others – good team-work
- Learn from your mistakes – continuous improvement
- If it's your first time, have others review your work
- PLANNING and continuous measurements
- Talk to the experts and understand your environment
- Be eager/open to learn
- Understand your regulatory environment
- Be a super-hero in organisation, communication and logistics
- Know your limits – ask for help and avoid burnout.



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As promised last year, soon to come...



We hope to welcome you:

- As a member
- As a contributor
- As a volunteer

Questions & Answers



Thank you!

Now is the time to ask that question you had five slides back. ☺

Contact



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