

AVOID DELAYS: GETTING DEPLOYMENT RIGHT

ISNTD d³

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END-USER NEEDS

- **Who will be using the product**
- **How will they use it**
- **Under what circumstances will they use it**
- **Is the product design practical?**

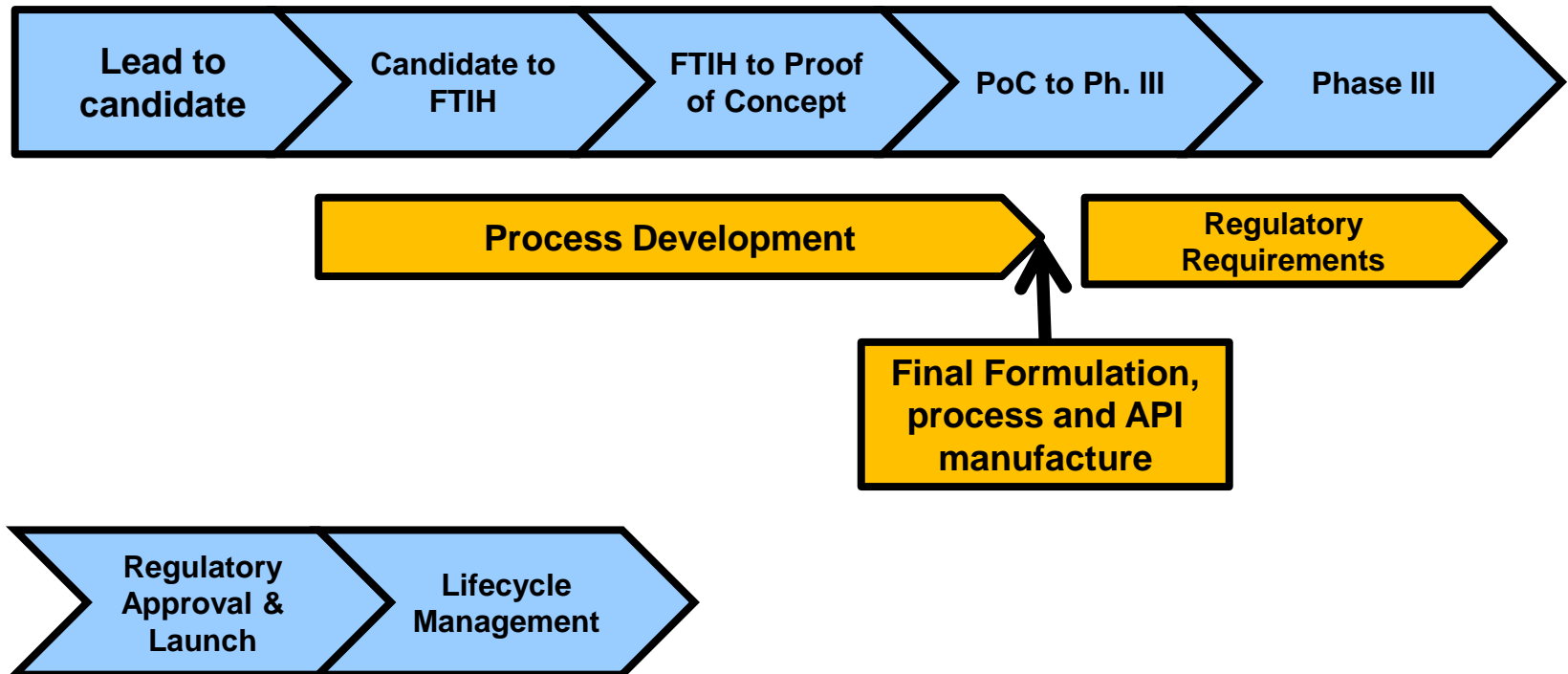
REGULATORY REQUIREMENTS

- **Which countries will it be used in?**
 - **What are their regulatory requirements?**
- **International guidelines**
- **Procurement agency requirements**
 - **Quality assurance**
 - **Supply chain management**

MANUFACTURING & PROCESS DEVELOPMENT

- **Fixing the manufacturing process early**
 - Little incentive for *post*-registration process improvement
- **Manufacturing location**
 - Regulatory requirements of changes
 - Impact on costs (incl. transport)

DEVELOPMENT ROADMAP



TIMING AND PLANNING

- **Avoid focusing only on clinical efficacy and safety**
- **Think ahead**
- **Plan ahead**
- **Get advice and assistance early**



THANK YOU