

# *Product Development – a few keys & pitfalls*

*Enrico Bastianelli,  
Scientific & Business Biotech Advisor*

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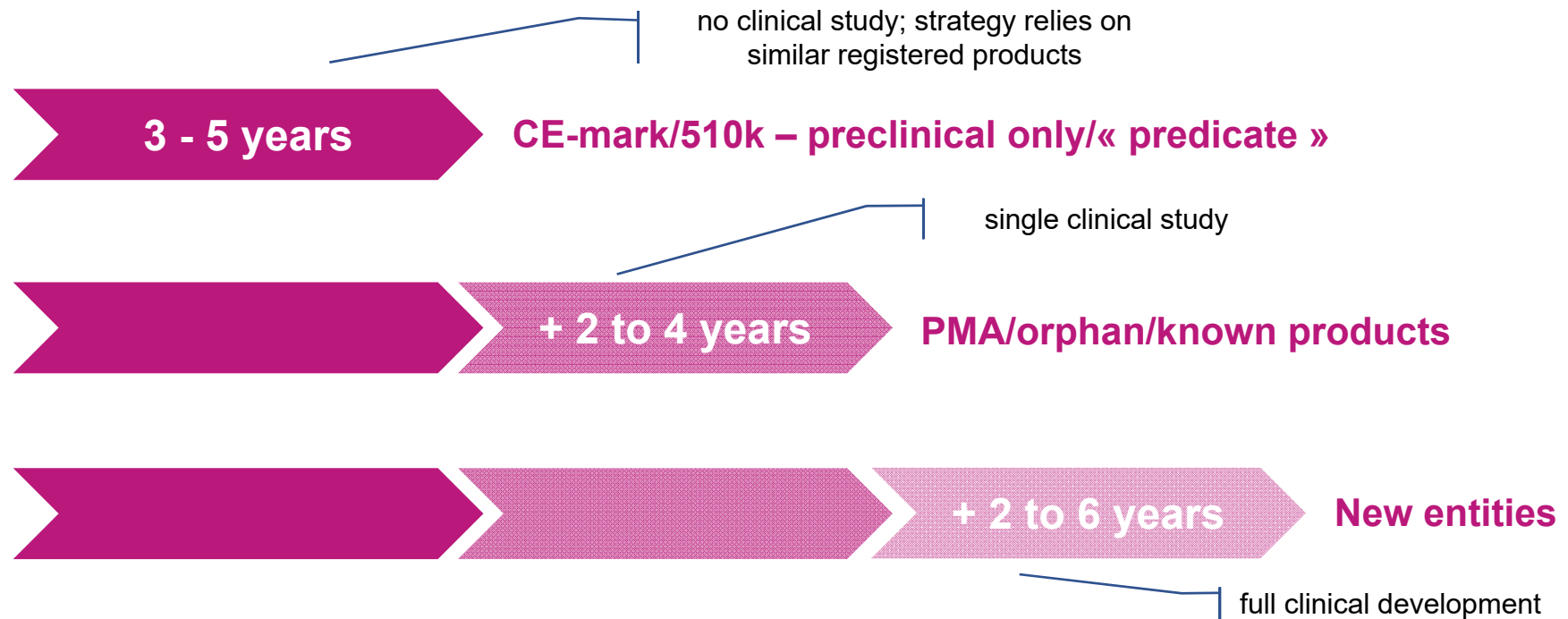
*A Brief Introduction to “Main”  
Development Paths*

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## Products - Main Development Paths



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## *Products - Main Development Paths*

### **Preclinical Med Dev.**

Cyto/genotoxicity, biocompatibility, histocompatibility, performance, acute/chronic toxicity...; industrialization

**CE-mark/510k**

### **Preclinical pharm/biotech**

GLP toxicity, reprotox, embryo-fetal development tox., carcinogenicity....

**New entities**

**Safety & PoC**

**Confirmation**

Phase IA, IIB, IIA, IIB, III – randomized controlled studies

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## *Products Development – A Common Trap*

Duration & (people) resources too often underestimated

A phase IIb study example: 2 groups, 50 patients & 12-month follow-up, CRO-managed...

12-m follow-up

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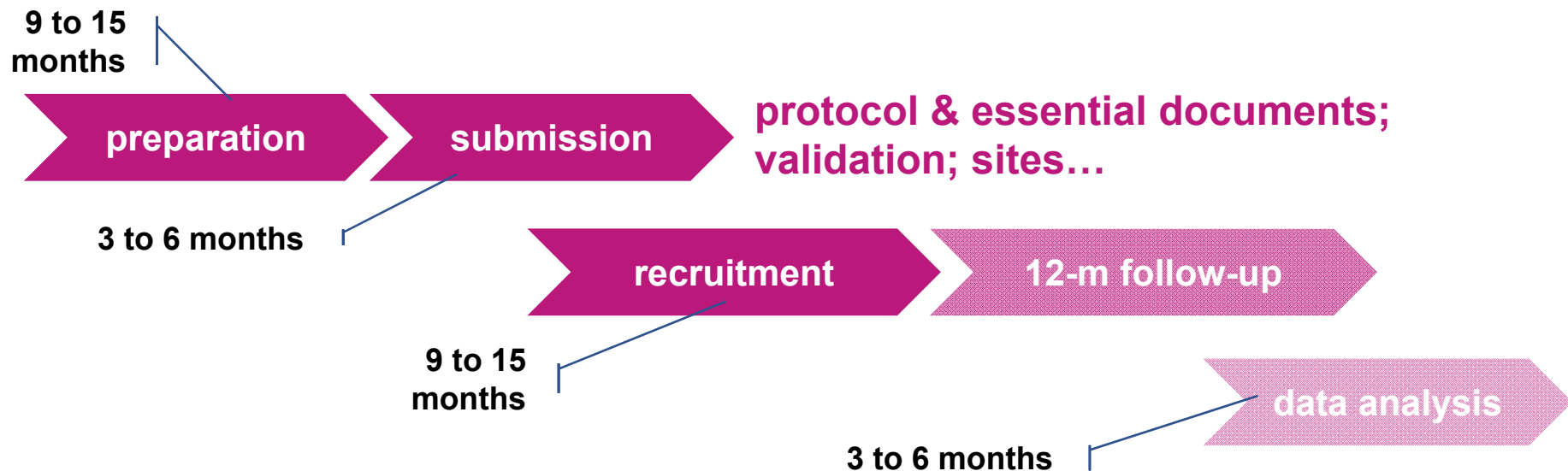
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## Products Development – A Common Trap

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## *Some Success Factors to Consider*

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## *Planning*

### The regulatory perspective first:

- Plan preclinical, production & clinical on market access strategy
- Plan from max to required
- Be prepared to be challenged / to challenge
- Validate through Scientific Advice/Protocol Assistance

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## *Planning*

Market and HTA impact into development and product success:

- Becoming a significant hurdle
- To be assessed very early on in the process: medical need, competition, price/reimbursement, costs...
- To be integrated into development plan

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## *Execution*

The key of a successful execution is keep control (of development) internally by adding to a well-thought/reasonable (retro-)planning:

- Enough (management) resources
- Right expertise
- Quality/excellence mindset

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## *Execution*

The (internal) Human Factor: challenge of talents:

- How to recruit? (Where is our attractiveness level)
- How to train: experience vs. « trial & error » / on the spot training
- How to retain?

Advices & Consulting:

- The same challenge

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## *Resources*

### “World-class” Walloon Ecosystem:

- Infrastructure (offices, labs, production...)
- Incubation(s) – support & services (acceleration, business development, international...)
- Networks (industrials, consultants, hospitals, patients...)

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## *Resources*

### Financials:

- Clinical studies cost from a few hundreds to millions of euros
- Growing basis of Business Angels & VCs to support company funding (from seed through series A/B/...)
- Has not caught up yet / still lagging

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## *Resources*

### Subsidies:

- Unique/top-class Walloon subsidies system
- A must-have in current “funding” landscape

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## *Conclusion*

=> Plan/prepare development with exit/next round in mind

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