
PD03: Programming for Early and Late Phase – really that different?

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Agenda

- Question: “Programming for Early and Late Phase – really that different?”
- To try and answer this question, I will consider:
 - Typical studies across the phases (QUIZ!)
 - Technical and ‘soft’ skills required from programmers
 - Possible options for organising teams across the phases
 - Conclusions
 - Questions

Typical studies across the phases Quiz

Phase I, II or III?

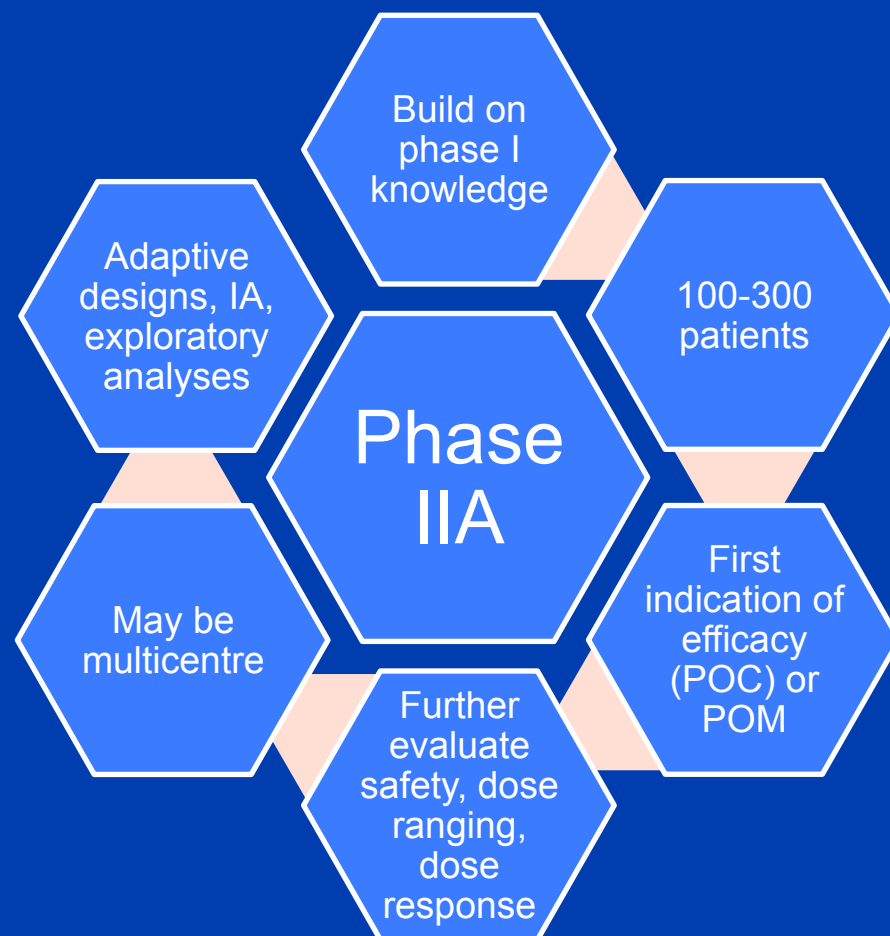
- **Example 1:** Study in patients, ~400 patients with depression, randomized (drug at 3 dose levels or placebo as adjuvant therapy), Bayesian interim futility analysis to drop ineffective arms, DMC (data monitoring committee), double-blind, multi-centre, study length ~19 months, efficacy, safety, PK, PD, exploratory endpoints
- **Phase II (A)**
- **Example 2:** Study in patients with acute coronary syndrome, ~300 patients, randomized (drug at one dose level or placebo added to usual care), double-blind, multi-centre, study length ~10 months, efficacy, safety
- **Phase III**

Typical studies across the phases Quiz

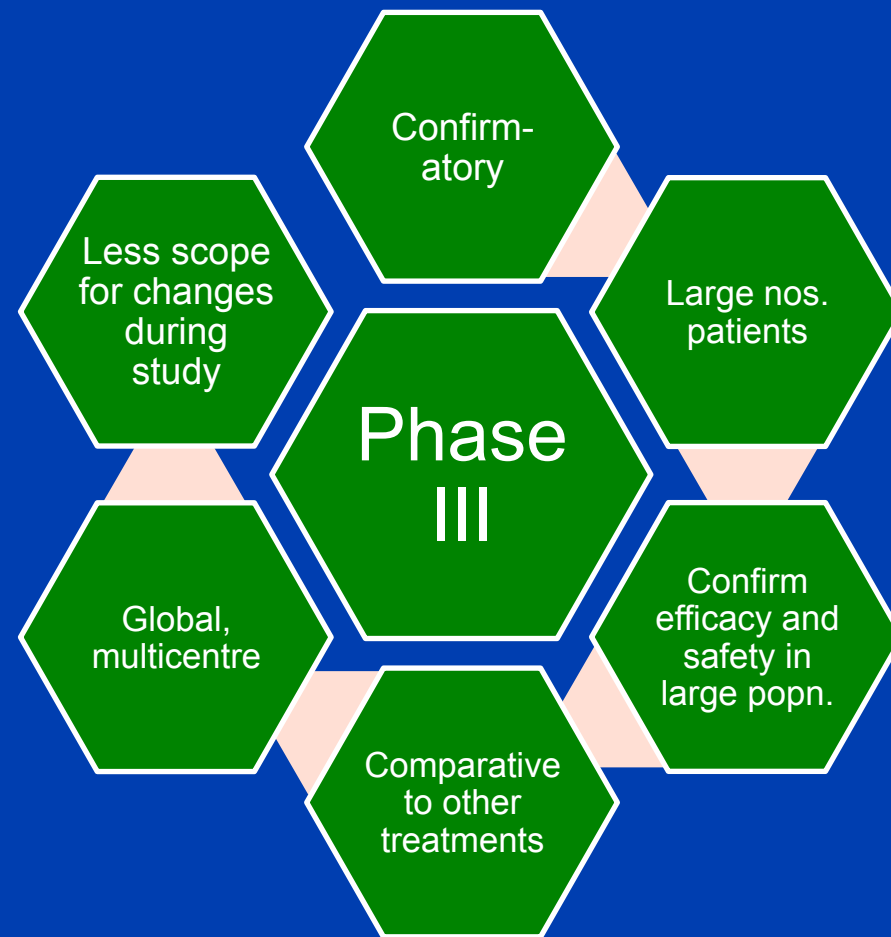
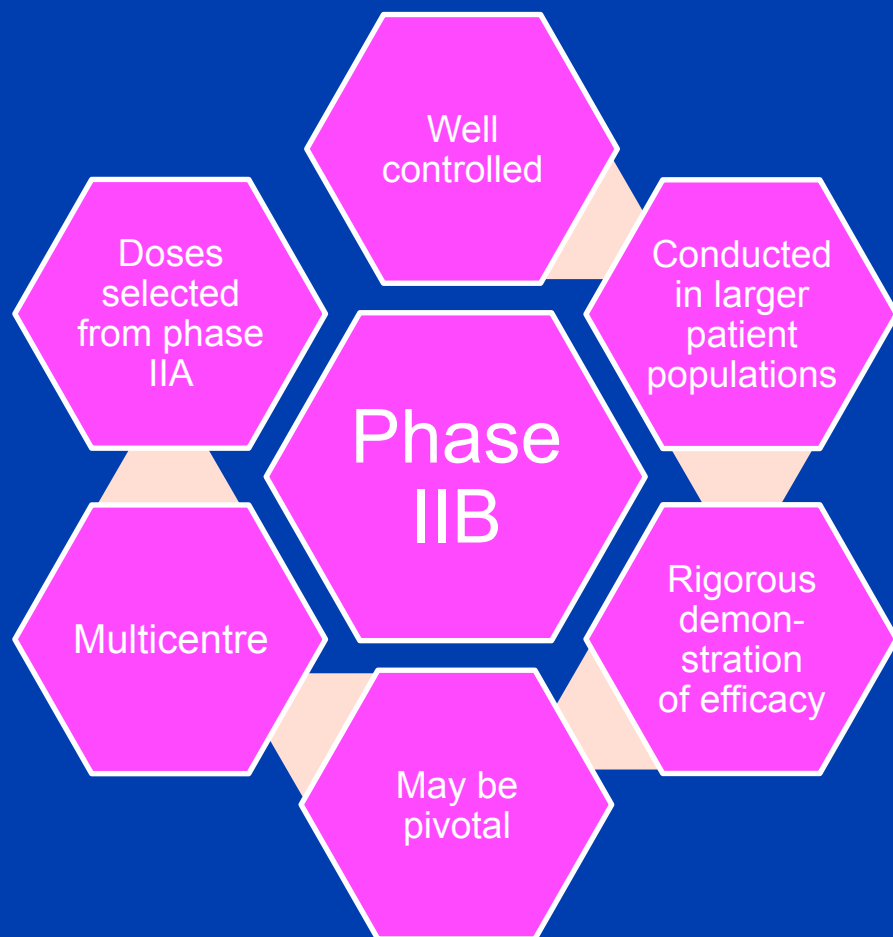
Phase I, II or III?

- **Example 3:** Study in healthy volunteers, 64 subjects in 8 cohorts, single centre, single-blind, randomized (6:2 per cohort), study length ~11 months, safety, tolerability, PK, PD, exploratory endpoints. Includes objectives to evaluate effect of food, activated charcoal, formulation, i.v. microdose of drug
- **Phase I**
- **Example 4:** Study in patients with RRMS (relapsing remitting multiple sclerosis), ~200 patients, dose ranging, randomized (drug at two dose levels or placebo added to usual care), partially-blind, multi-centre, study length ~> 3 years, efficacy including MRI scans, safety
- **Phase II (B)**

Typical studies – early phase



Typical studies – late phase



Agenda - progress

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Technical Skills: early vs. late

Study designs /
therapeutic
area / data
knowledge

Programming
efficiency /
consistency /
strategy

QC and
specifications

Submission /
filing preparation

Graphics

Soft Skills: early vs. late

Team working

Planning

Communication
skills

Organisational

Flexibility

Agenda - progress

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Organising teams

- Many factors may influence how programming teams can be organised
- Some options:

‘Separate early /
late phase’

‘Everyone does
everything’

‘Something in
between’: Safety
group, HV group

Organising teams

'Separate early/late phase'

Pros

- Efficiency gains
- Opportunities
- Reflects different needs
- Mirrors organisations

Cons

- Consistency
- Comms early <-> late phase
- Line early / late arbitrary
- Oncology/pts

'Everyone does everything'

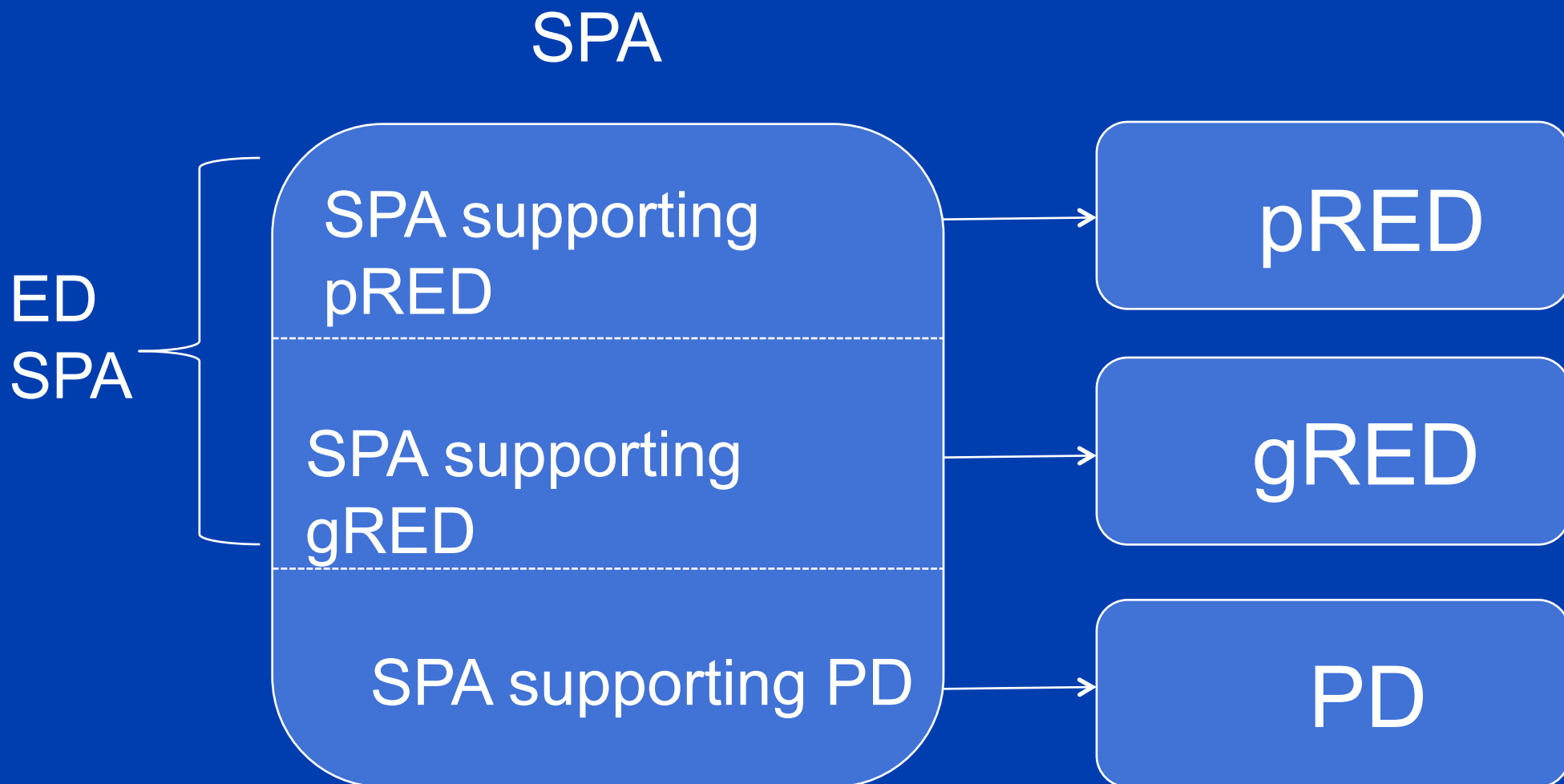
Pros

- Consistent approach
- Flexibility of resources
- Comms
- Follow the project

Cons

- Inefficiencies
- Unlikely to follow project
- Start of project = phase I

Example from Roche



Agenda - progress

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 - *Possible options for organising teams across the phases ✓*
 - Conclusions
 - Questions?

Conclusions

- Question: “Programming for Early and Late Phase – really that different?”
- Answer YES : different objectives, speed, focus, data types, standard programming, QC strategy, documentation and forward-thinking required
-but also NO : both need flexible programmers with good programming skills, knowledge and communication skills, but perhaps in different areas and with different partners
- Questions?



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