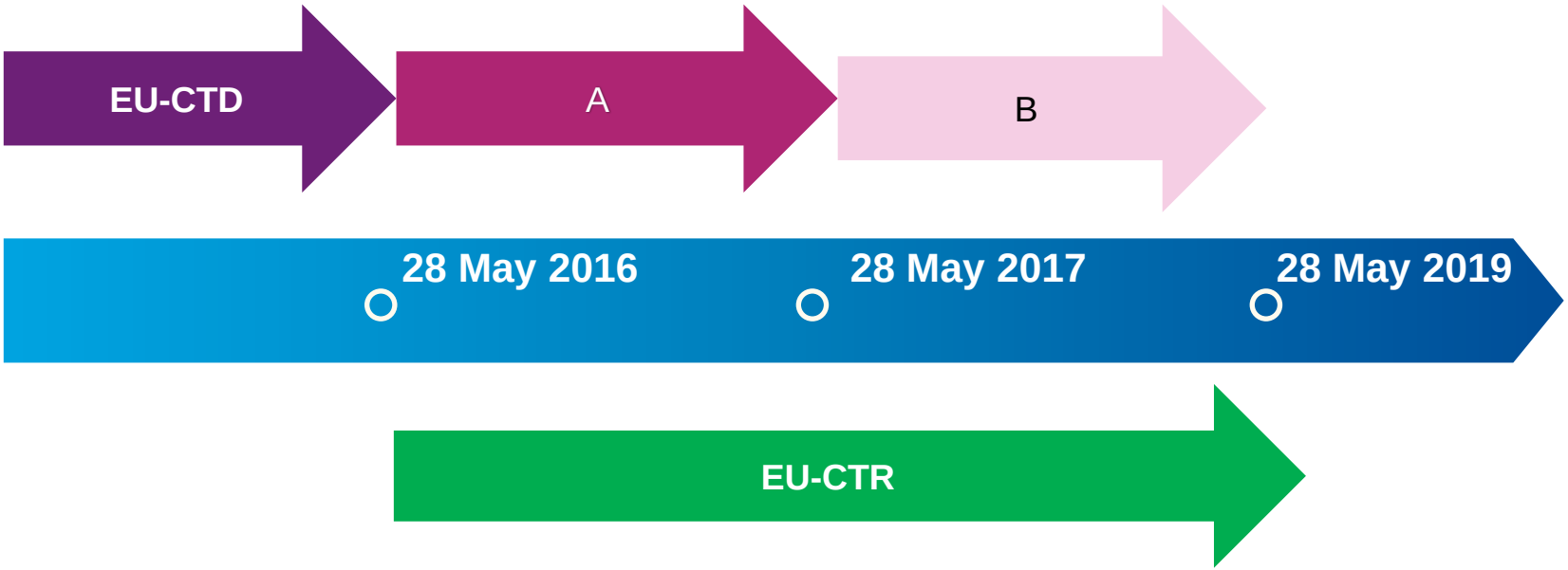
“How will the Single Portal work for a Phase I CRO?”

Professor Elizabeth Allen
Quintiles Drug Research Unit at Guy’s hospital.
London UK.

Areas of Impact

QUINTILES

Transition Period for Implementation



A. Clinical trials may still be submitted and started under the EU-CTD
B. Clinical trials submitted under A will continue to be governed by the EU–CTD until 28th May 2019 28 May 2016

The EU-CTR Portal and Database

The EMA together with Member States will develop the EU portal and database

- The single interface for CTA dossier submissions and associated processes and documents

Full functionality will be verified by an independent audit which will be published in the *Official Journal* once this is complete

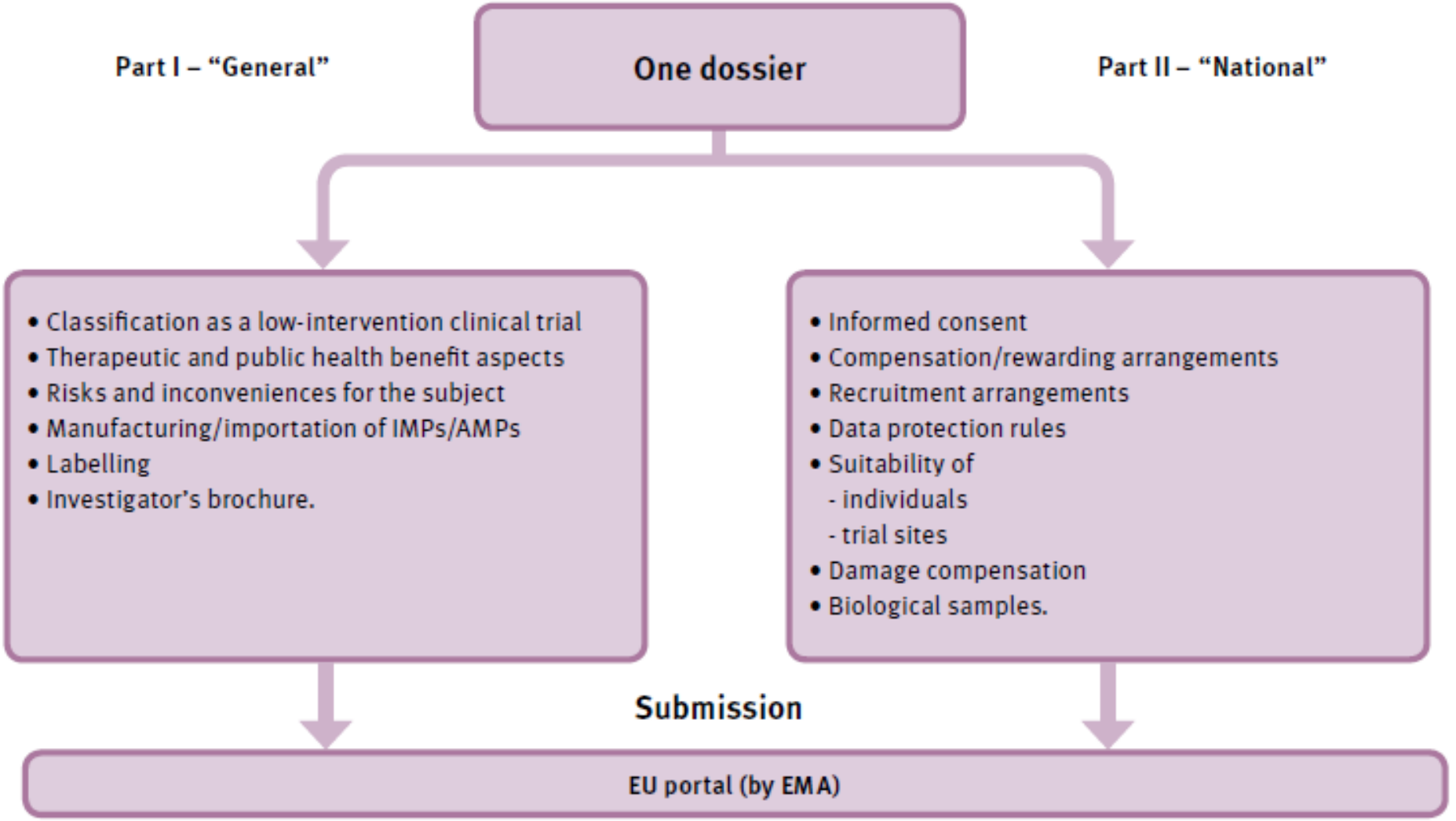
The EU-CTR will apply *6 months* after this publication

- Any delays in the development of the portal will affect the implementation date of the EU-CTR

The EU database will *supersede* existing regional and national databases

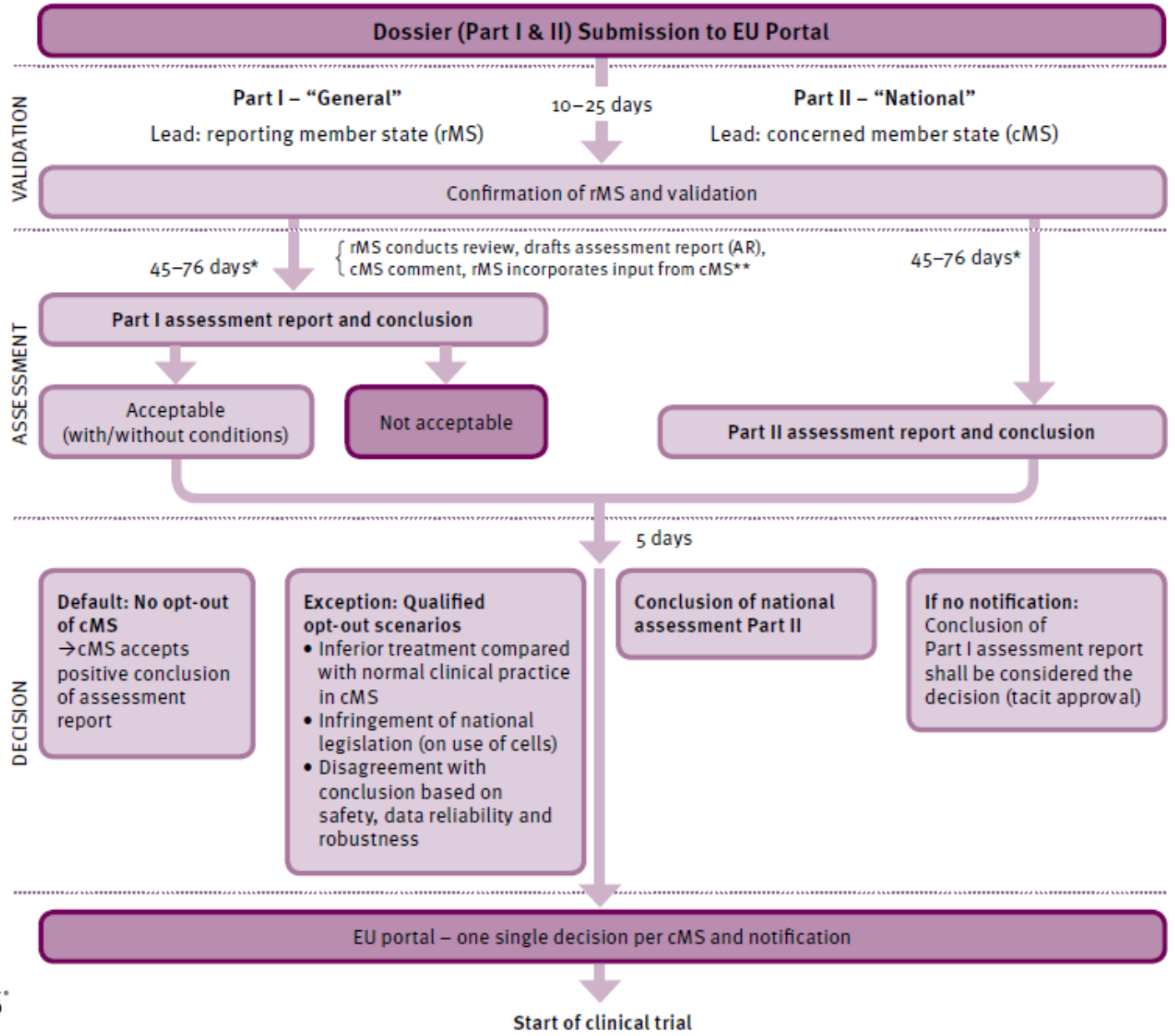
- Publically accessible unless confidentiality is justified (e.g. CCI)
    - CTA submission dossier, CT summary results, lay summaries, intermediate analyses
    - Notifications
    - Serious breaches
- Facilitate Member States with safety analyses

The new CTA submission process



Herrero-Martinez, Regulatory Rapporteur, TOPRA, Vol 10, No 11, Oct 2014

Assessment Process



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CTA timelines in EU-CTR

Procedures	Validation period	Assessment Parts I and II	Clock stop Response to Questions	Decision period from Assessment	Total
Initial submission Parts I and II	10-25 days	45-64 days	12 days	5 days	60-106 days
Additional member states	N/A	52-71 days	12 days	5 days	52-83 days
Substantial modifications Part I and II	6-21	38-57 days	12 days	5 days	49-95days

Some member states have stated that they intend to keep to their current timelines for phase 1 studies

Submission Options

Through flexibility comes complexity!

Initial CTA submission

- Part I + Part II for all countries (all country-specific docs must be available to do this)
- Part I + Part II for some countries (other countries to be submitted later)
- Part I only (ie. no country information yet available)
- Part II only (ie. previous ‘Part I only’ submission authorized)

Additional Member state submission

- Part I + Part II

Substantial Modification submission

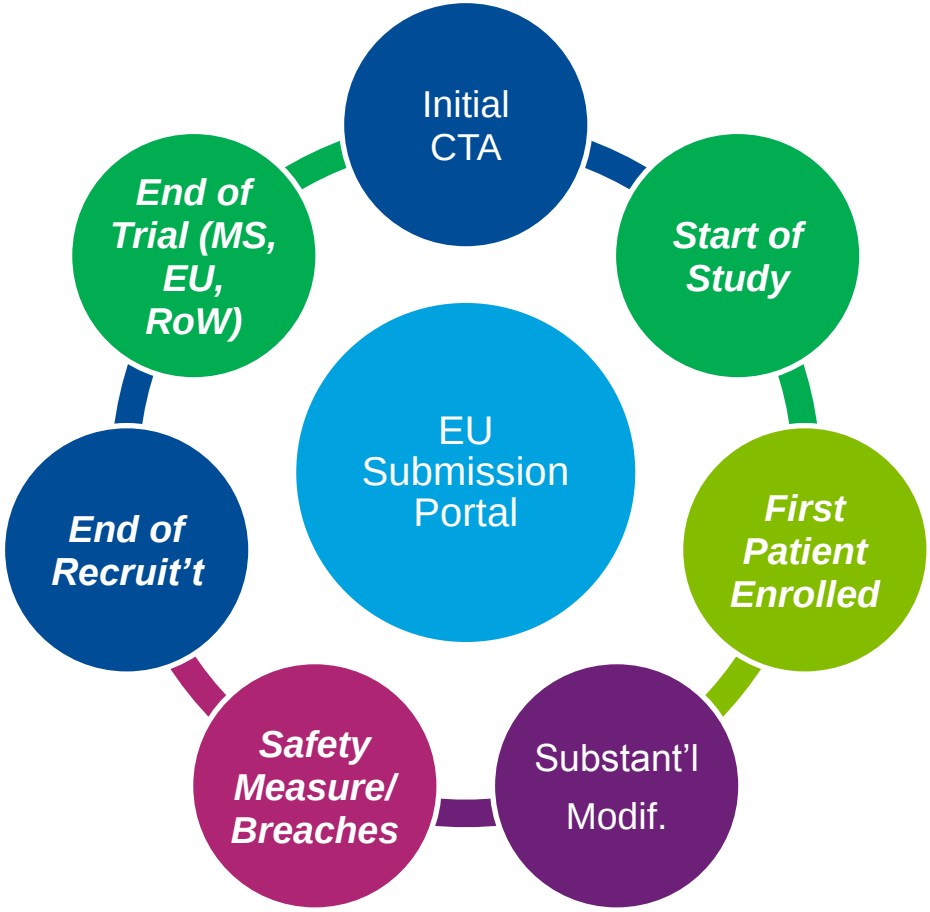
- Part I only
- Part II only
- Part I + Part II (for all countries)

Phase 1 applications are unlikely to require such complexity

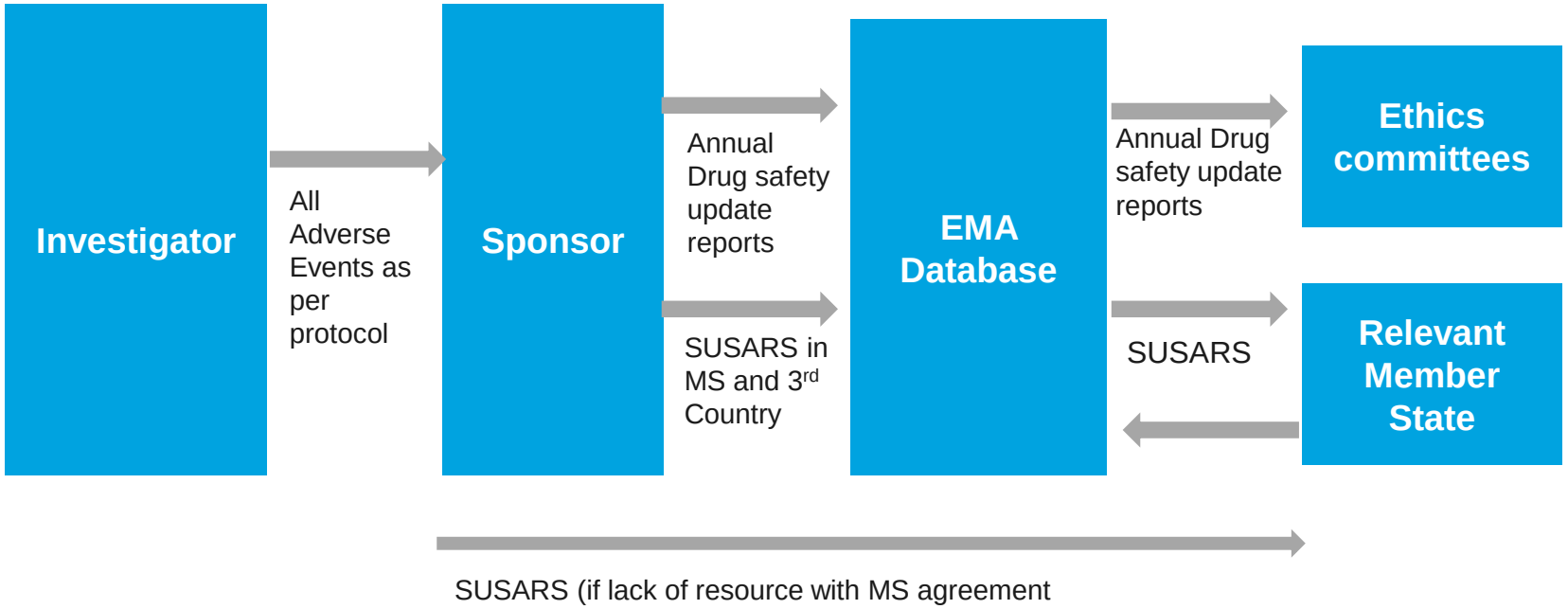
Notifications required during a study

All notifications must be made within 15 days or will be non-compliant with the regulation

Consider the relatively short study times lines in Phase1



Outline of Safety Reporting in EU-CTR



Unclear how Ethics Committees will get access to SUSARS or if they will be reported separately

Impact on Phase1

Identify roles and responsibilities with Sponsor

- Submission
- Notifications
- Reporting of safety data
- Clinical trial results

Access to Portal and EMA Database

- Large Pharma vs Small Biotech
- Hardware and software compatibilities
- IT support

Additional notifications within required timelines (15 days)

- Overall study timelines shorter in Phase 1 studies

Phase1 studies usually conducted within 1 member state

- One submission – more efficient
- Same member state to lead Part1 and Part II assessments
- Check required language of submission

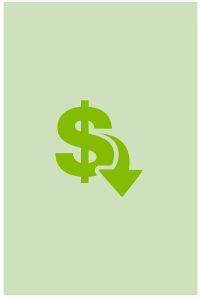
Impact on Phase1

Approval Timelines

- Appear to be much longer
- Some Member States have already indicated that they will maintain current timelines for Phase1 studies

Transparency

- Increased requirements
  - Data from a clinical trial submitted in support of a Clinical Trial application can only be used if that clinical trial was registered on a public data free of charge
- Definition of commercially sensitive information still to be determined
- Registration on a public database
- Publication of clinical trial results and lay summaries



Fees

- One payment per activity per Member state
- Likely to be less expensive for Phase1