Role of EMEA in Patient Registries

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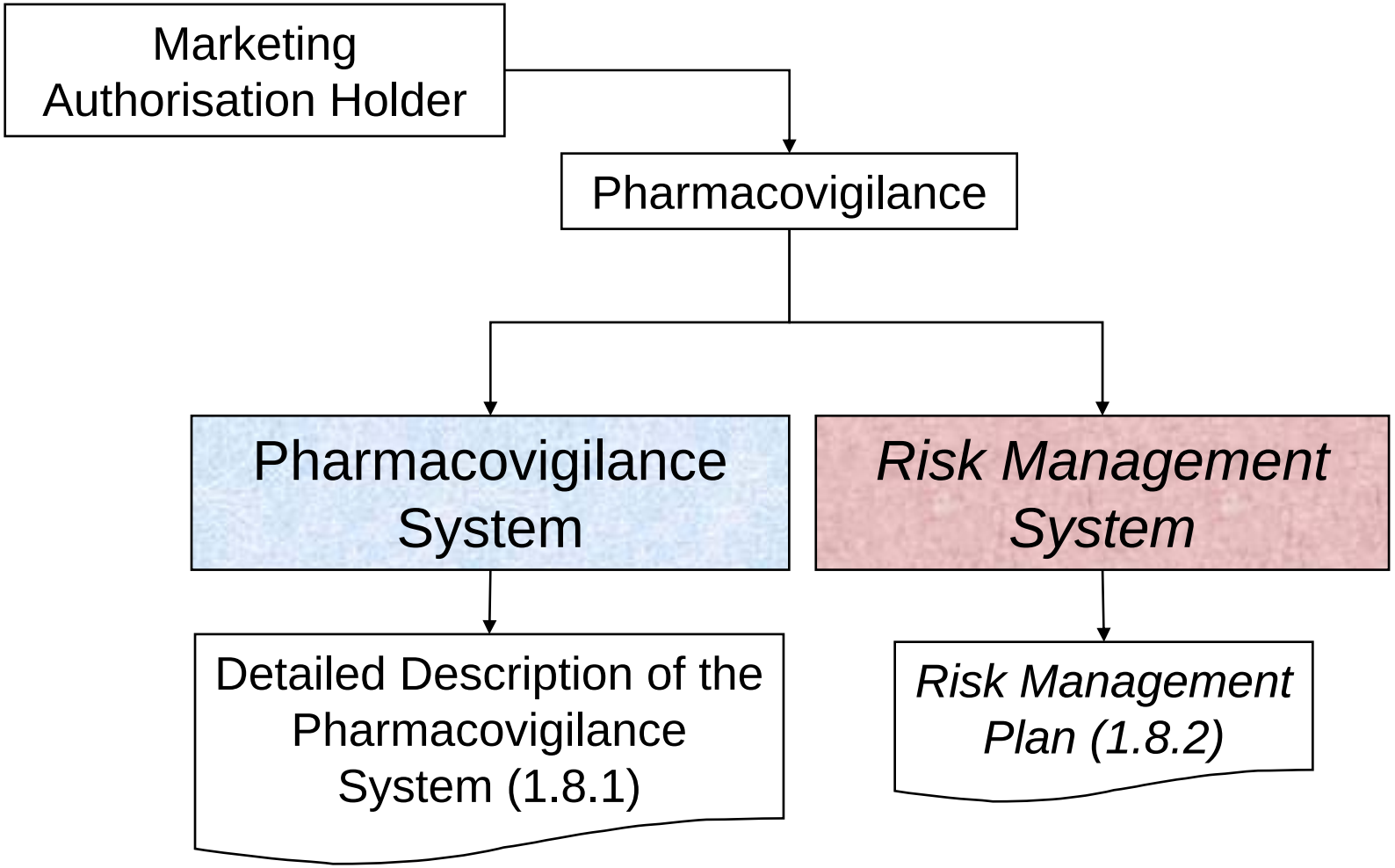
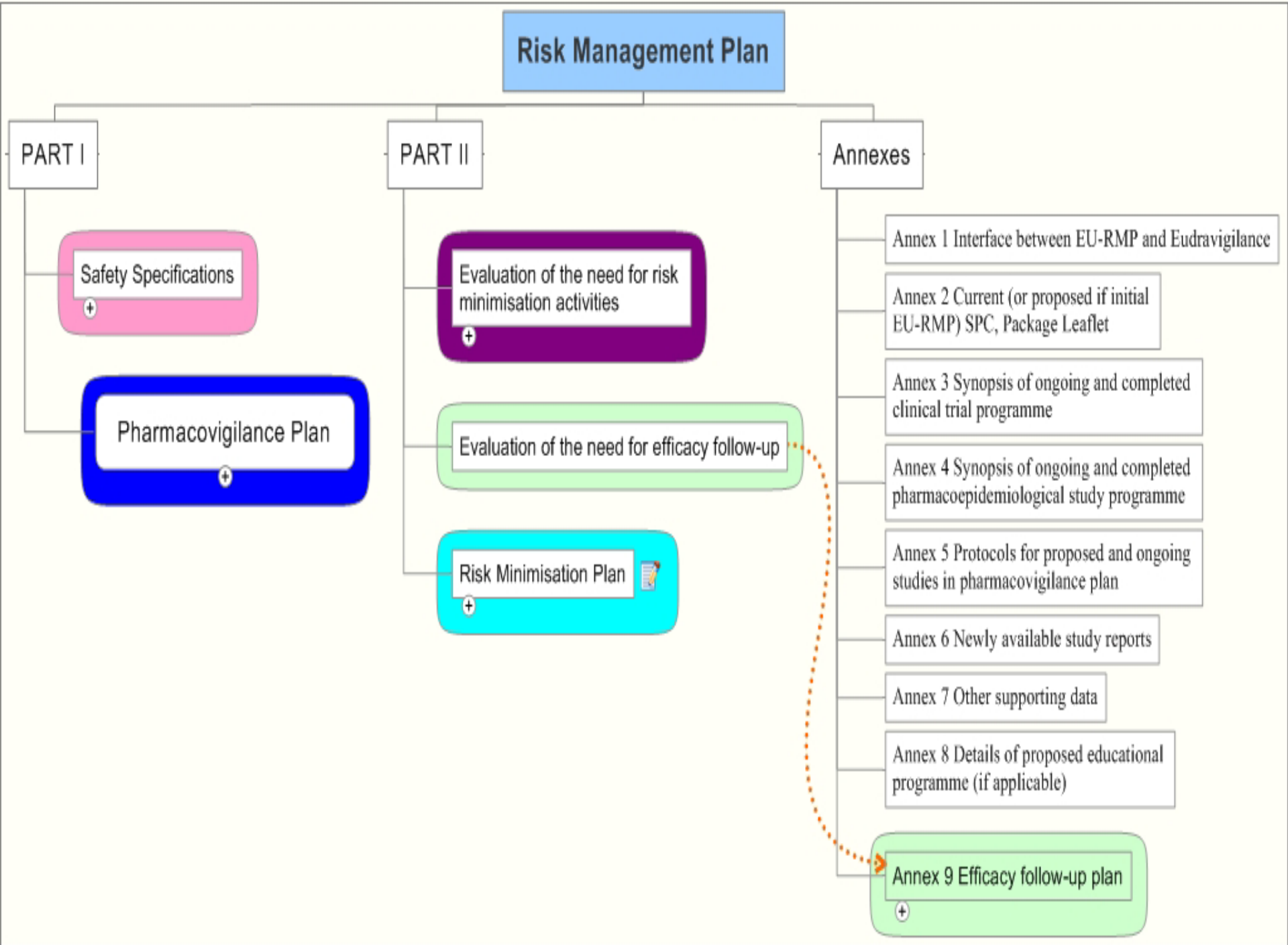
EMEA Pharmacovigilance and Risk Management

10-minutes overview

- EU - Risk Management Plans
- Examples of registries in place mandated by risk management plans
- EMEA scientific activities in post-authorisation safety follow-up

MAH's post-marketing surveillance




Risk Management Plan
PART I
PART II
Annexes
Safety Specifications
Pharmacovigilance Plan
Evaluation of the need for risk minimisation activities
Evaluation of the need for efficacy follow-up
Risk Minimisation Plan
Annex 1 Interface between EU-RMP and Eudravigilance
Annex 2 Current (or proposed if initial EU-RMP) SPC, Package Leaflet
Annex 3 Synopsis of ongoing and completed clinical trial programme
Annex 4 Synopsis of ongoing and completed pharmacoepidemiological study programme
Annex 5 Protocols for proposed and ongoing studies in pharmacovigilance plan
Annex 6 Newly available study reports
Annex 7 Other supporting data
Annex 8 Details of proposed educational programme (if applicable)
Annex 9 Efficacy follow-up plan

Approved Risk Management Plans

- Enbrel (etanercept)
- Remicade (infliximab)
- Humira (adalimumab)
- Kineret (anakinra)
- Mabthera (rituximab)
- Orencia (abatacept)
- Cimzia (certolizumab pegol)
- Simponi (golimumab)

EXAMPLES OF THE POST-AUTHORISATION STUDIES IN RISK MANAGEMENT PLANS

Enbrel (etanercept)

PhV studies in the Summary table of the RMP:

- BSRBR
- RABBIT
- ARTIS
- PMSS (Japan)
- RADIUS I/II
- BSPAR
- German JIA Registry
- LTE 20040210
- BADBIR
- LTE 20050111
- POSA
- OTIS

Remicade (infliximab)

PhV studies and registries in the RMP:

- C0168Z01 TREAT
- C0168X34 Wolfe
- CORRONA
- C0168T71
- C0168Z02
- PSOLAR
- ARTIS
- BIOBADASER
- BSRBR
- RABBIT
- BADBIR
- Pediatric IBD registry
- ENCORE
- OPUS P04808
- PsoBest

Humira (adalimumab)

PhV studies and registries in the RMP:

- DE019
- DE020
- DE013
- M03-634
- M03-606
- M03-607
- TBD
- M02-433
- M04-690
- P06-134
- M06-806
- M06-807
- M03-658
- P10-023
- M04-717
- M06-826
- M06-827
- M10-223
- DE038
- M10-444
- P10-262
- M03-604

Orencia (abatacept)

Registry studies in the RMP:

- NDB
- ARTIS
- BSRBR
- RABBIT
- DREAM

What is ENCePP ?

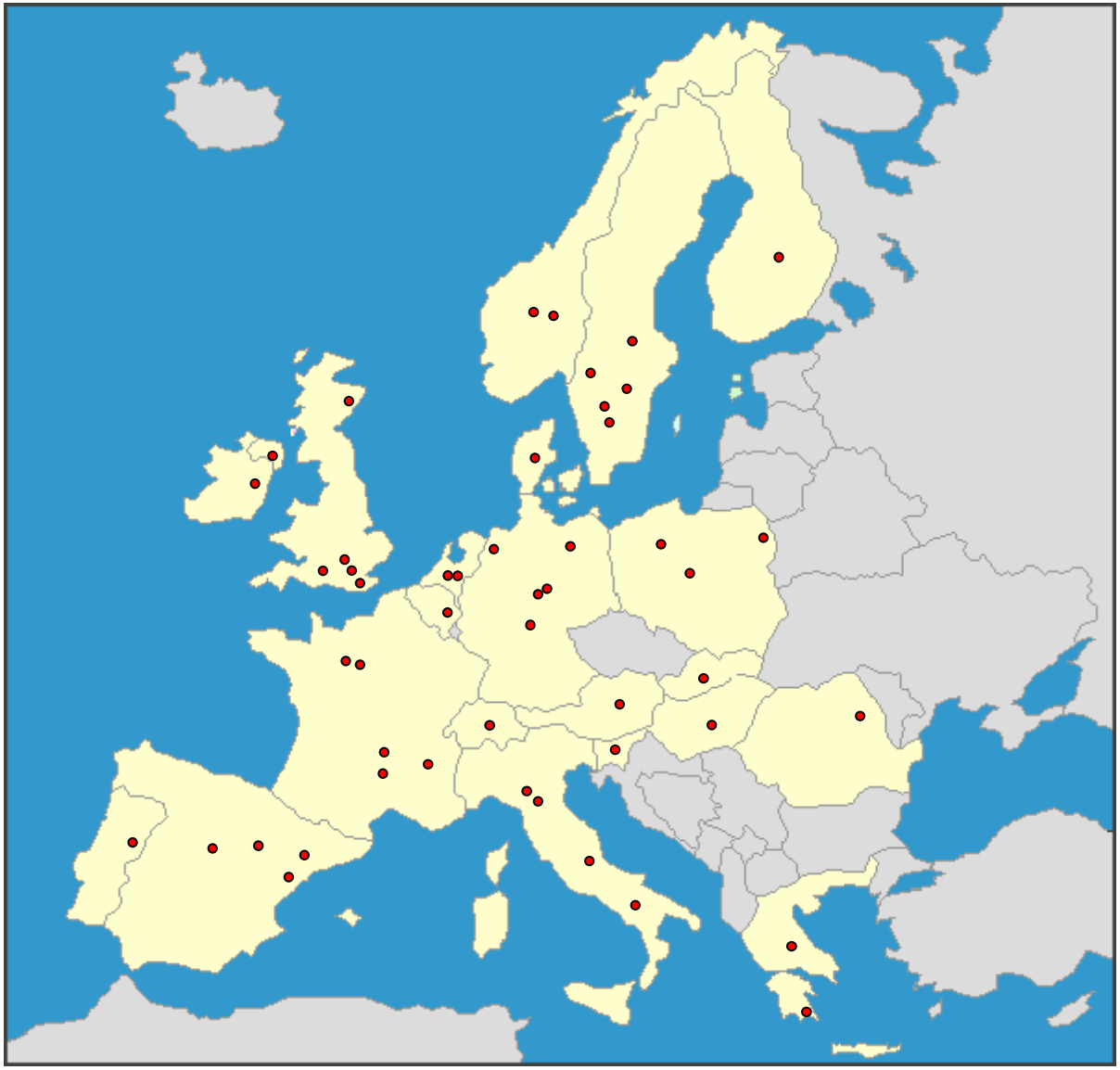
European Network of Centres for Pharmacovigilance & Pharmacoepidemiology

- ENCePP is an EMEA-led project to bring together the **available expertise and research experience** in the fields of **PhEpi** and **PhV** scattered across Europe in a **Network of Excellence**, comprising research and medical-care centres, healthcare databases, electronic registries and existing networks.

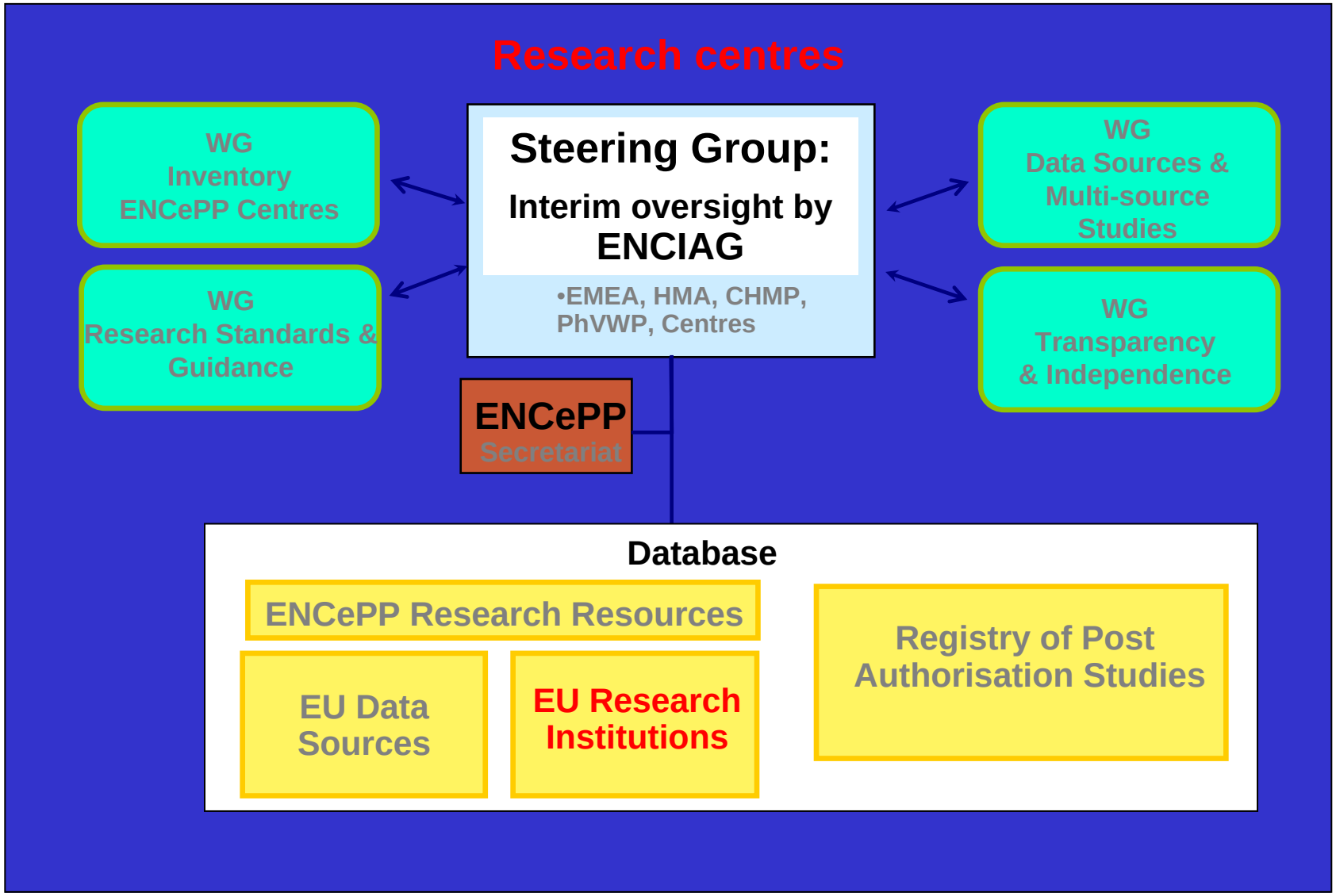
- The aim is to further **strengthen the post-authorisation monitoring of medicinal products in Europe** by facilitating the conduct of high quality, multi-centre, independent post-authorisation studies focusing on safety and benefit:risk.

ENCePP today - 2009

- 88 partner organisations
- In 21 European countries



Structure and main bodies



Potential EMEA use of ENCePP

Possible scope:

- class reviews of serious safety concerns where comparative safety information essential.
- research on off-patent medicines and multiple drug substances when no single sponsor for such research can be identified.
- increasingly necessary disease epidemiology research, e.g. background incidence of certain illnesses/ADRs in longitudinal databases.

Innovative Medicines Initiative
Call No. 6:
Strengthening the monitoring of Benefit and Risk

PROTECT

Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium

PROTECT

- **Led by the EMEA**
- **Five year research programme**
- **20 million Euros**
- **29 Partners**
  - 17 Public
  - 12 Pharmaceutical Companies
- **7 work packages**
  - Project Management and Administration
  - Framework for PhV & PhEpi studies
  - Methods for SD & SE using spontaneous report databases
  - New tools for data collection from consumers
  - Benefit/risk integration and representation
  - Proof of concept studies
  - Training and communication

Conclusions

- Registries of biologic treatment serve as a successful example for other registries
- Risk management is moving towards benefit-risk management, registries may be expected to collect both safety and efficacy data
- Move towards more active pharmacovigilance includes capacity building via EPITT, and methodologies development via IMI, both of which may have impact on both existing and new registries