Identifying centres/networks with the capacity and expertise to conduct PASS in children

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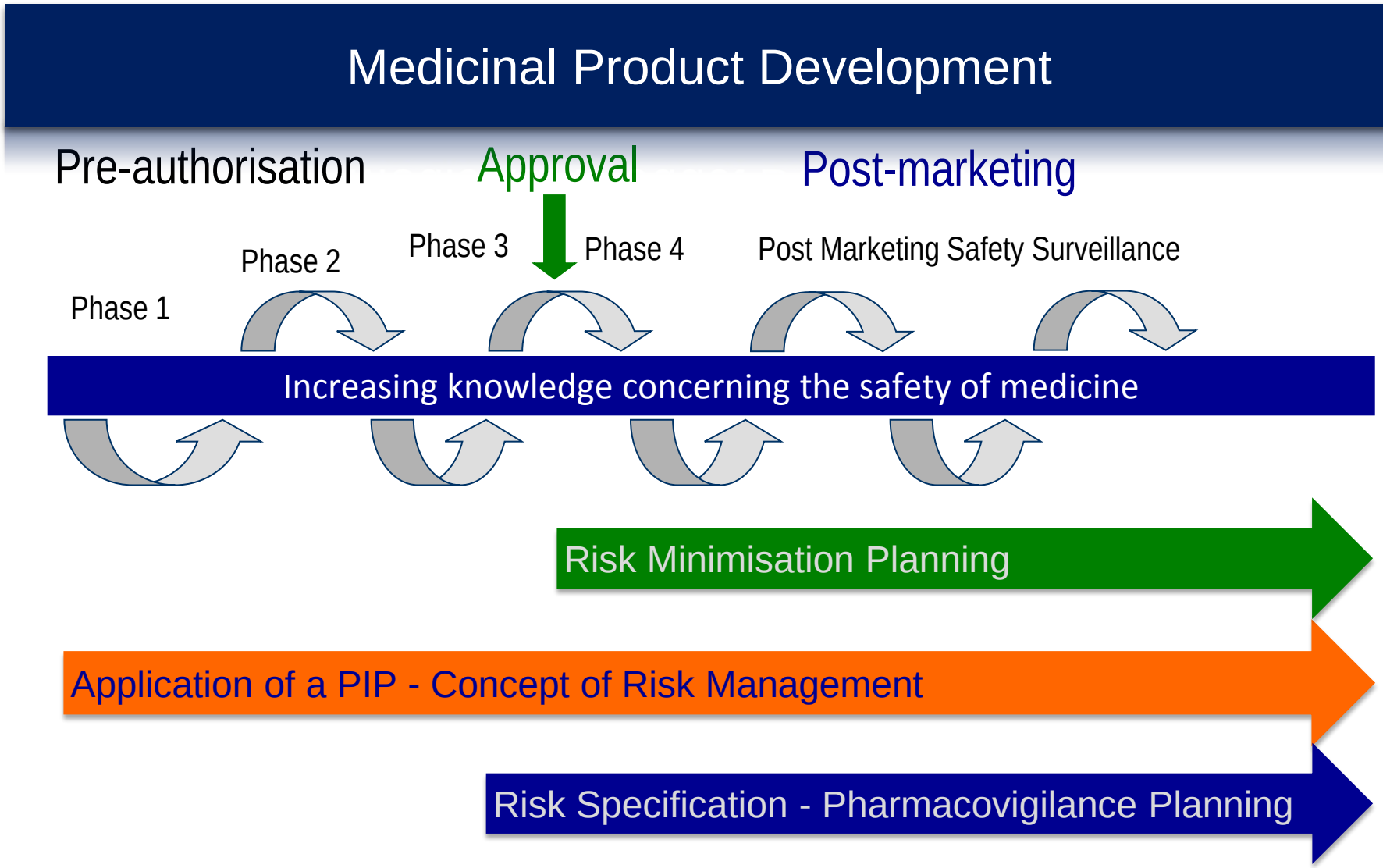
PASS in children



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Pharmacovigilance System Development

Module I	Pharmacovigilance systems and their quality systems
Module II	Pharmacovigilance system master file
Module III	Pharmacovigilance inspections
Module IV	Pharmacovigilance audits
Module V	Risk management systems
Module VI	Management and reporting of adverse reactions to medicinal products
Module VII	Periodic safety update report
Module VIII	**Post-authorisation safety studies (addendum I – non-interventional post-authorisation safety studies)**
Module IX	Signal management
Module X	Additional monitoring
Module XV	Safety communication
Module XVI	Risk minimisation measures – Selection of tools and effectiveness indicators

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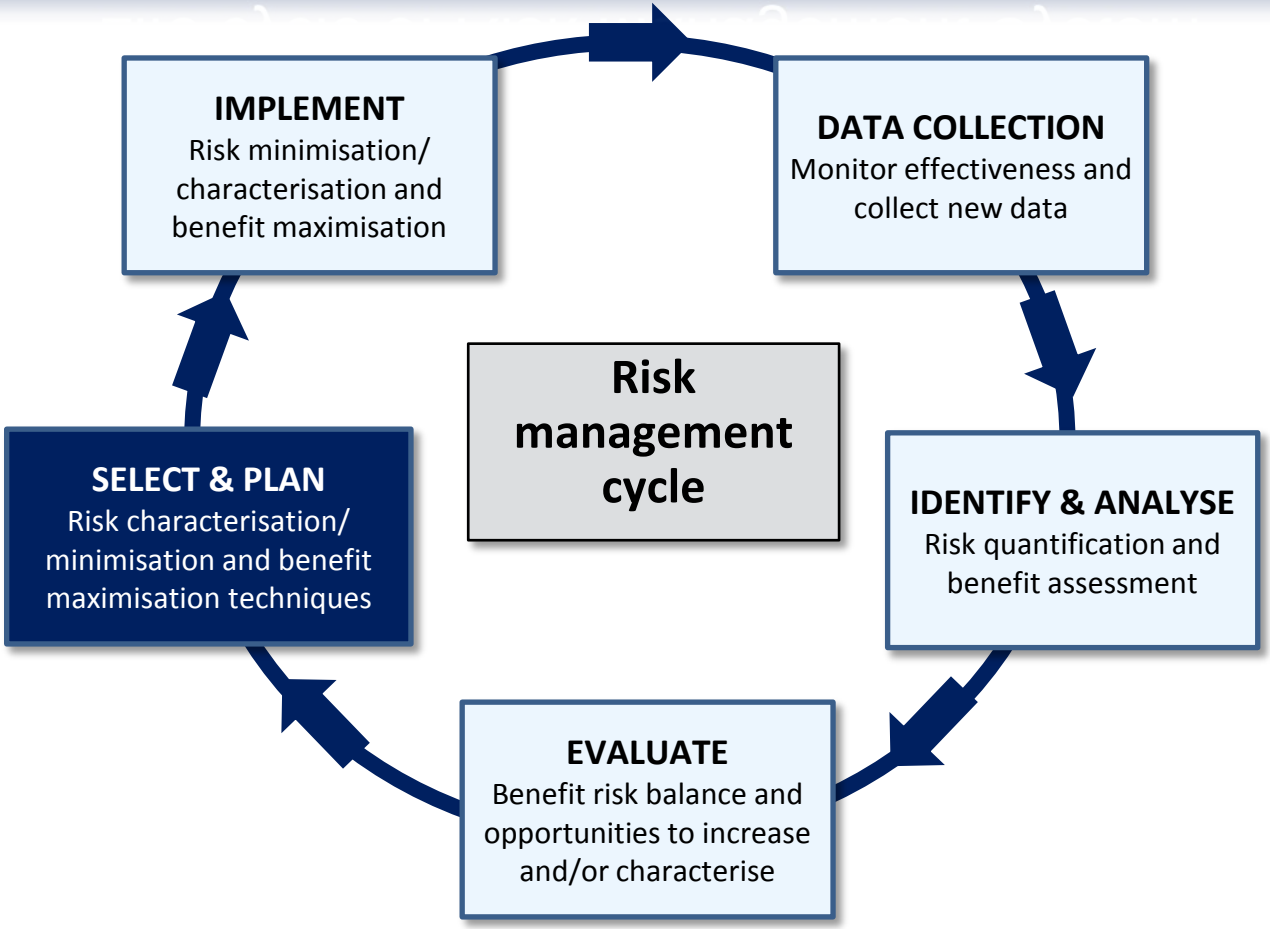
Life cycle of Risk Management System



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Pharmacovigilance planning

Structured plan to cover

- identification of new risks and characterisation of risk factors
- further investigation of identified potential risks including the planned approach how to collect these information

Routine pharmacovigilance (safety) activities

- description of Pharmacovigilance System Master File
- references to PSMF, SmPC, spontaneous reporting

Additional pharmacovigilance (safety) activities

- discussion of necessity for further action and measures
- requirements set by PRAC, CHMP, CMDh
- description of planned actions/measures for each safety concern
- Post-authorisation safety/efficacy studies (PASS/PAES)

PASS in children

Post Marketing Safety Studies (PASS)

Investigation with the authorised medicinal product

- identifying, characterising or quantifying a safety hazard
- confirming the safety profile of the medicinal product
- measuring the effectiveness of risk management measures
- PASS could be clinical trials or non-interventional studies
- initiated voluntarily by MAH or imposed as an obligation by NCA/ PRAC

The type of study design is not constraining a PASS, e.g. a systematic literature review or a meta-analysis may be considered as PASS depending on their aim.

PASS in children

Non-interventional (PASS)

Non-interventional studies are defined by the methodological approach used and not by its scientific objectives.

Requirements to be fulfilled cumulatively

- the medicinal product is prescribed in the usual manner according to the marketing authorisation
- the assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study
- no additional diagnostic or monitoring procedures are applied to the patients and epidemiological methods are used for the analysis of collected data

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Post Marketing Safety Studies (PASS)

Relevant scientific guidance to be considered by MAH/investigators for the planning, development of PASS and writing the report

- Pharmacovigilance Risk Assessment Committee (PRAC)
- National competent authorities (registration)
- Guide on Methodological Standards in Pharmacoepidemiology
- ENCePP Checklist for Study Protocols
- Guideline on conduct of pharmacovigilance for medicines used by the paediatric population
- Guidelines from the International Society of Pharmacoepidemiology (ISPE GPP)
- The final study report should be submitted as soon as possible within 12 months of the end of data collection

Post Marketing Safety Studies (PASS)

Potential grounds for conducting a PASS (PAES)

- enhancing safety data base due to small populations in clinical trials
- support of benefit/risk balance
- evaluation of safety in populations not studied
- supportive data to evaluate potential risks
- investigation of potential long-term effects
- effectiveness studies (vaccines)
- missing robust evidence of efficacy to be investigated post-marketing

Post Marketing Safety Studies (PASS)

Potential designs for PASS

Active surveillance

- Intensive monitoring schemes
- Prescription event monitoring
- Registries

Observational studies

- Cross-sectional study (survey)
- Cohort study
- Case-control studies
- Self-controlled case series
- Case-crossover study

Thanks for your attention

Any questions?