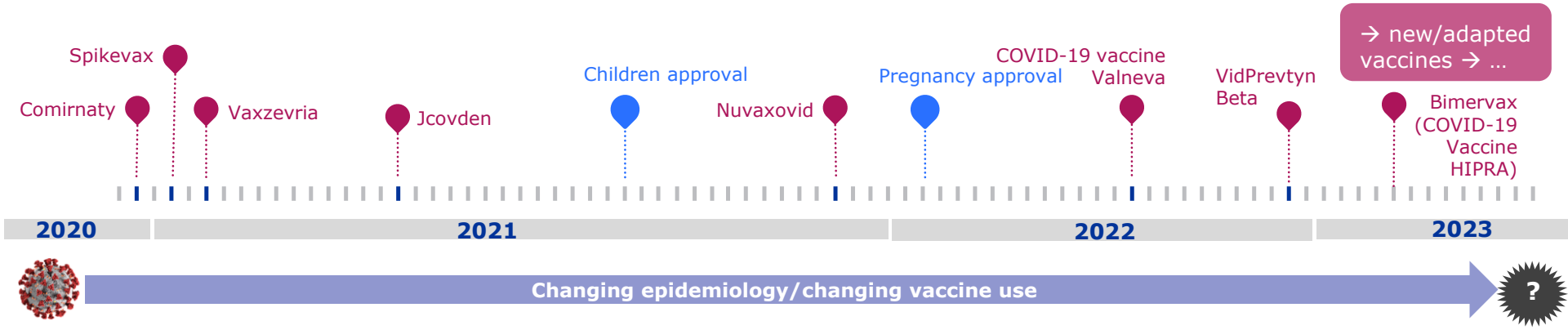
Measuring vaccine performance under emergency situations

Case studies and learnings for RWE generation

Multi-stakeholder workshop on Real World Data (RWD) quality and Real-World Evidence (RWE) use
Session 4: Using RWE to address public health emergencies – learnings and a view to the future

Mathijs Goossens
RWE Workstream
Data Analytics and Methods Task Force, EMA

Vaccination campaigns and the post-authorisation RWE needs



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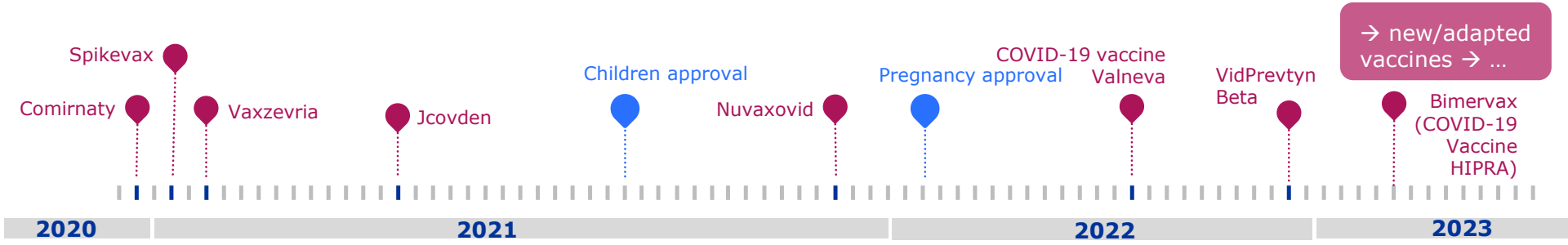


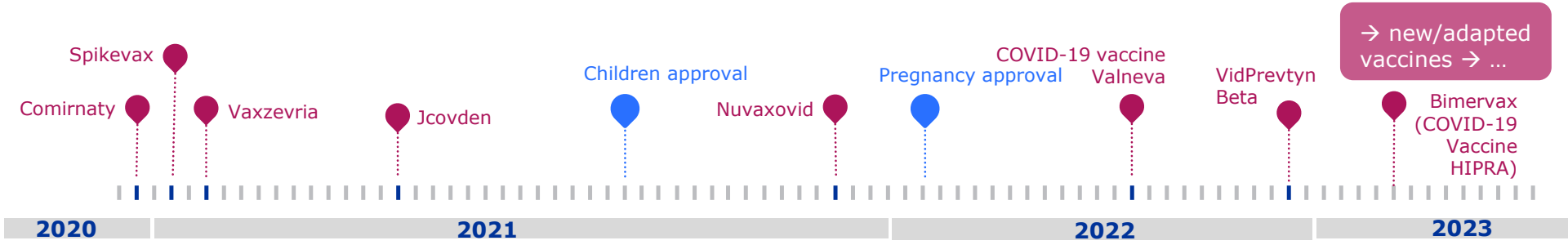
Changing epidemiology/changing vaccine use ?

Preparedness

Early & continued **safety** monitoring

Effectiveness studies

Vaccination campaigns and the post-authorisation RWE needs



Changing epidemiology/changing vaccine use → ?

Preparedness

Early & continued **safety** monitoring

Effectiveness studies

Safety: Anaphylaxis | TE/TTS | GBS | Myocarditis | Continuous monitoring →

Effectiveness: Variants, duration of protection/waning, transmission, immune imprinting, heterologous schedules

Pathways for generating RWE

EMA

- **Perform studies** using in-house databases
- **Procure studies** through EMA framework contracts
- **Conduct studies** via DARWIN EU

Industry

- PAES and PASS
- Submit RWE to support safety/ effectiveness claims

RWE generation

NCAs Member States

- Direct access to national data sources
- EHDS foresees that national Health Data Access Bodies will facilitate access to national datasets

Academia

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- Participate in large consortia
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ECDC/EMA Vaccine Monitoring Platform

Joint Vaccine Monitoring Platform (VMP)

EMA and ECDC **extended mandates** require to jointly study vaccine use, effectiveness and safety (EU 'Health Union') → **EMA-ECDC co-leadership and co-delivery**

- Main platform where post-authorisation vaccine studies are coordinated in the EU
- **Identification** of **evidence gaps** requiring studies and prioritisation of evidence needs
- **Independent studies** (using EMA in-house data sources, DARWIN EU®, and procured to framework contractors separately or jointly by the two Agencies)
- Synergies and exchange of scientific evidence, and facilitation of evidence **dissemination** to EU decision-makers*

An **Immunisation and Vaccine Monitoring Board** (IVMAB) provides advice to the VMP:

- **Strategic** identification, prioritisation and implementation of key research questions → "living" **research agenda**
- Leveraging and developing **methodologies**, infrastructures and networks, including advice on feasibility and study design
- **Interpretation** and **use** of results from observational/RWE studies
- **Dissemination** of the generated evidence
- **IVMAB meetings**: F2F at EMA on 6-7 Dec. 2022; virtual on 1st June 2023; F2F at ECDC on 18 September 2023

*EMA, ECDC, EC, national regulatory agencies and public health authorities, WHO, other supranational bodies and stakeholders

EMA-funded COVID-19 studies

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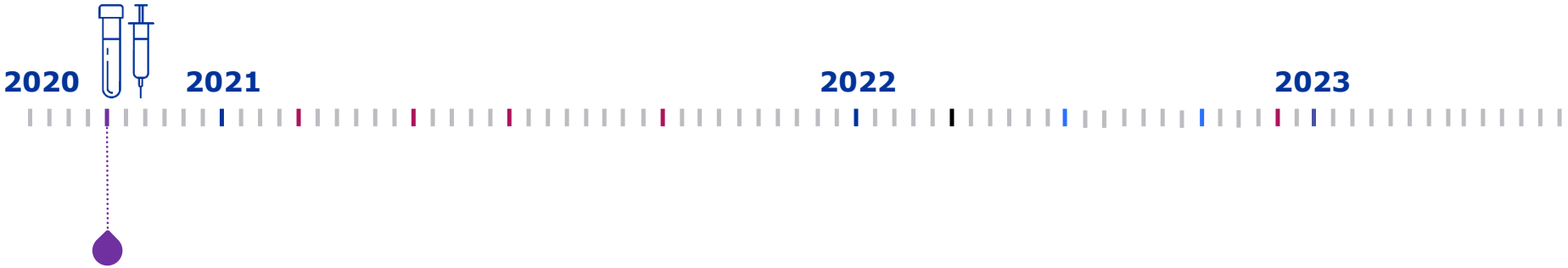
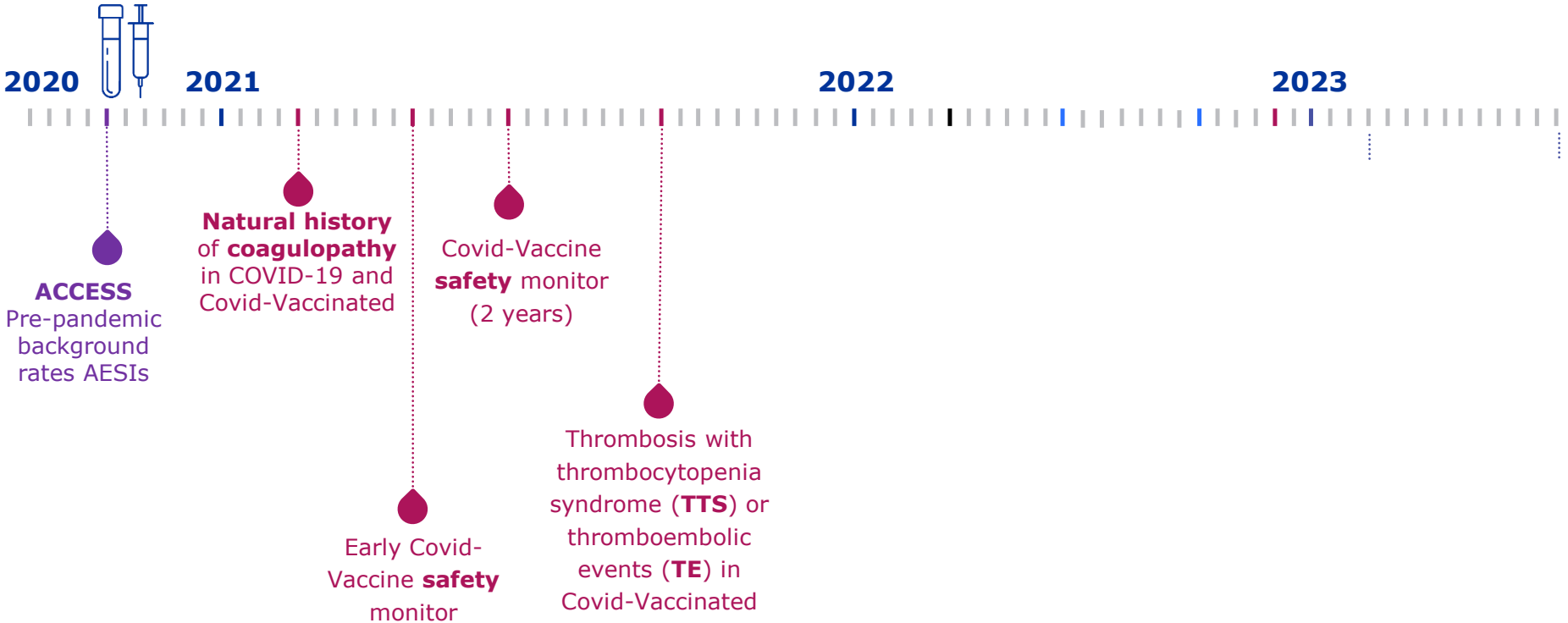
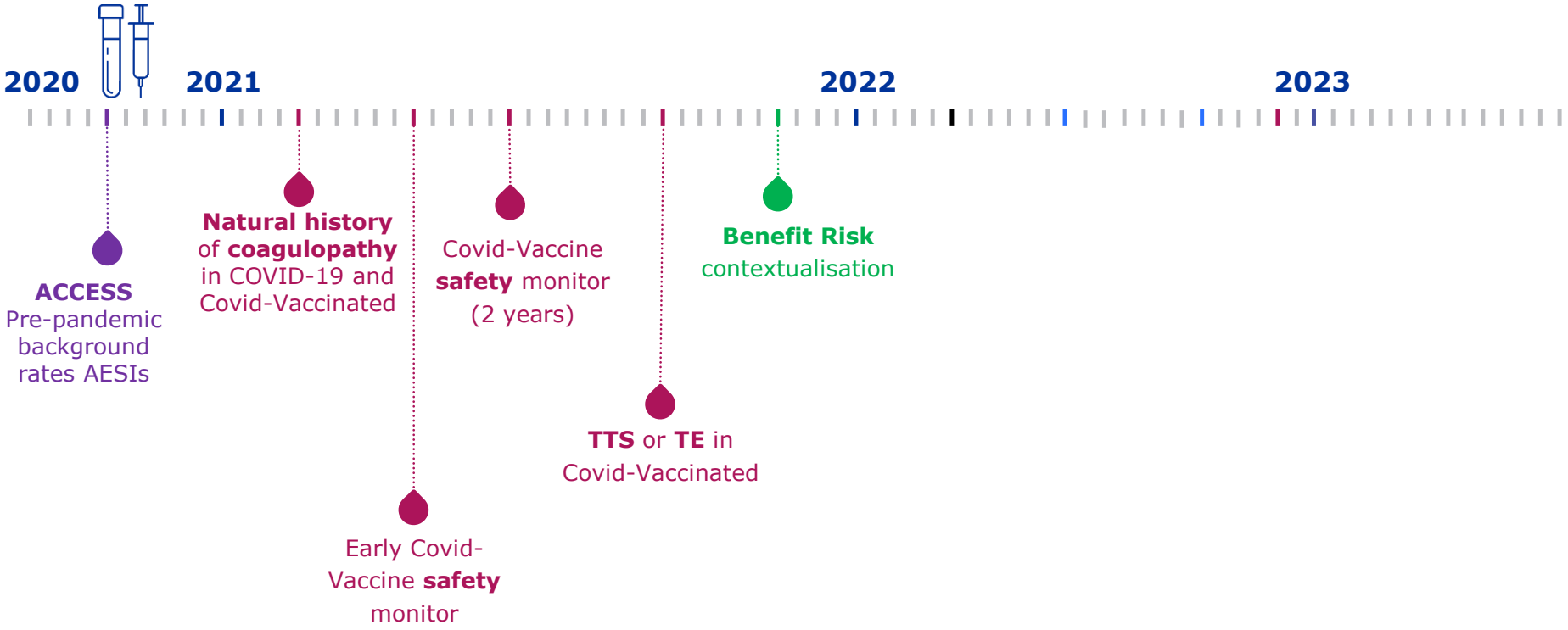


ACCESS
Pre-pandemic background rates AESIs

EMA-funded COVID-19 studies



EMA-funded COVID-19 studies



EMA-funded COVID-19 studies

2020 2021 2022 2023

ACCESS
Pre-pandemic background rates AESIs

Natural history of **coagulopathy** in COVID-19 and Covid-Vaccinated

Early Covid-Vaccine **safety** monitor

Covid-Vaccine **safety** monitor (2 years)

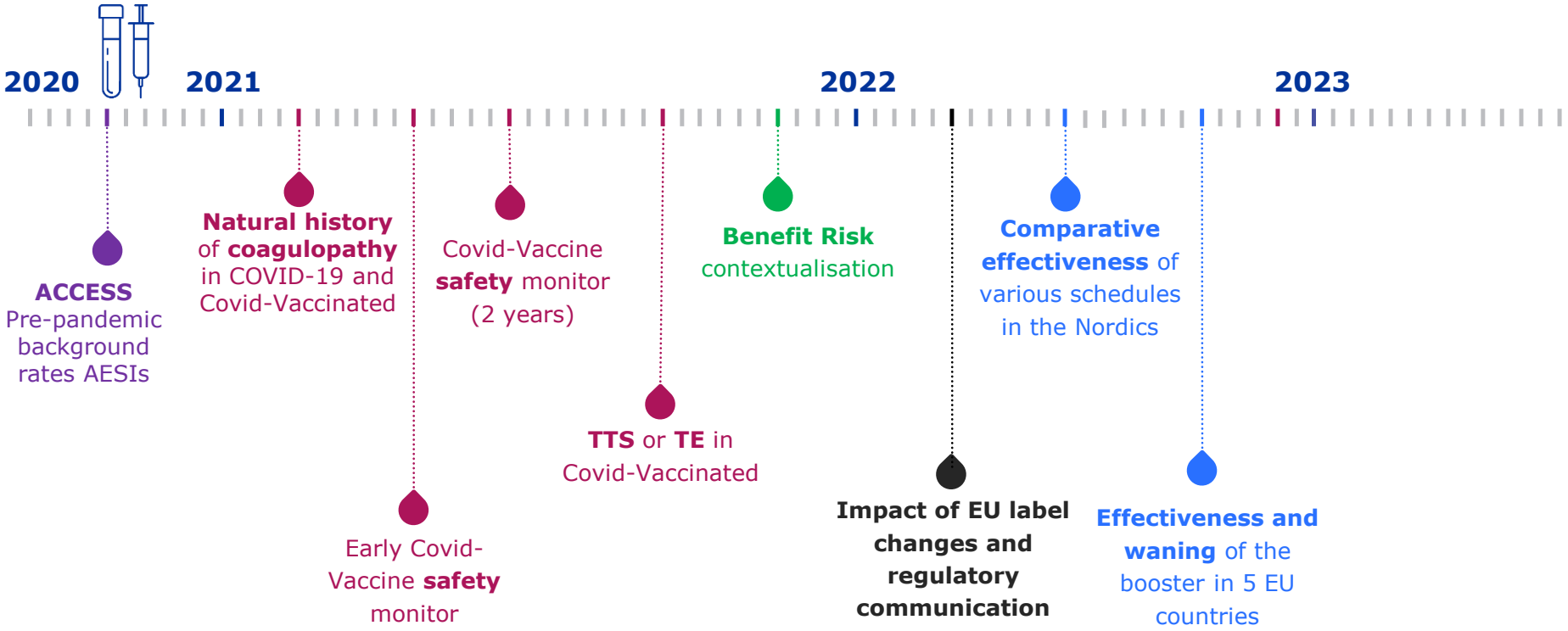
TTS or **TE** in Covid-Vaccinated

Benefit Risk contextualisation

Impact of EU label changes and regulatory communication on adenovirus vector vaccines in context of TTS

Safety
Effectiveness
Benefit/risk
Impact

EMA-funded COVID-19 studies



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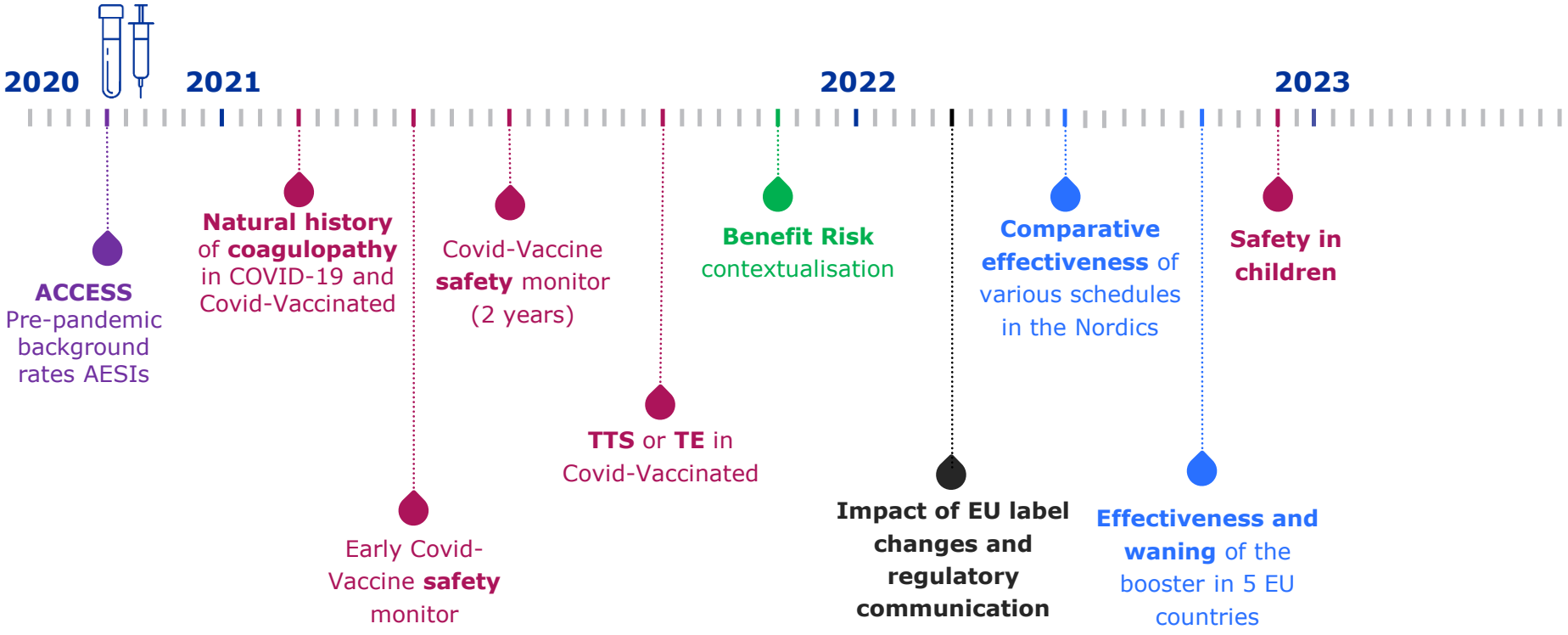

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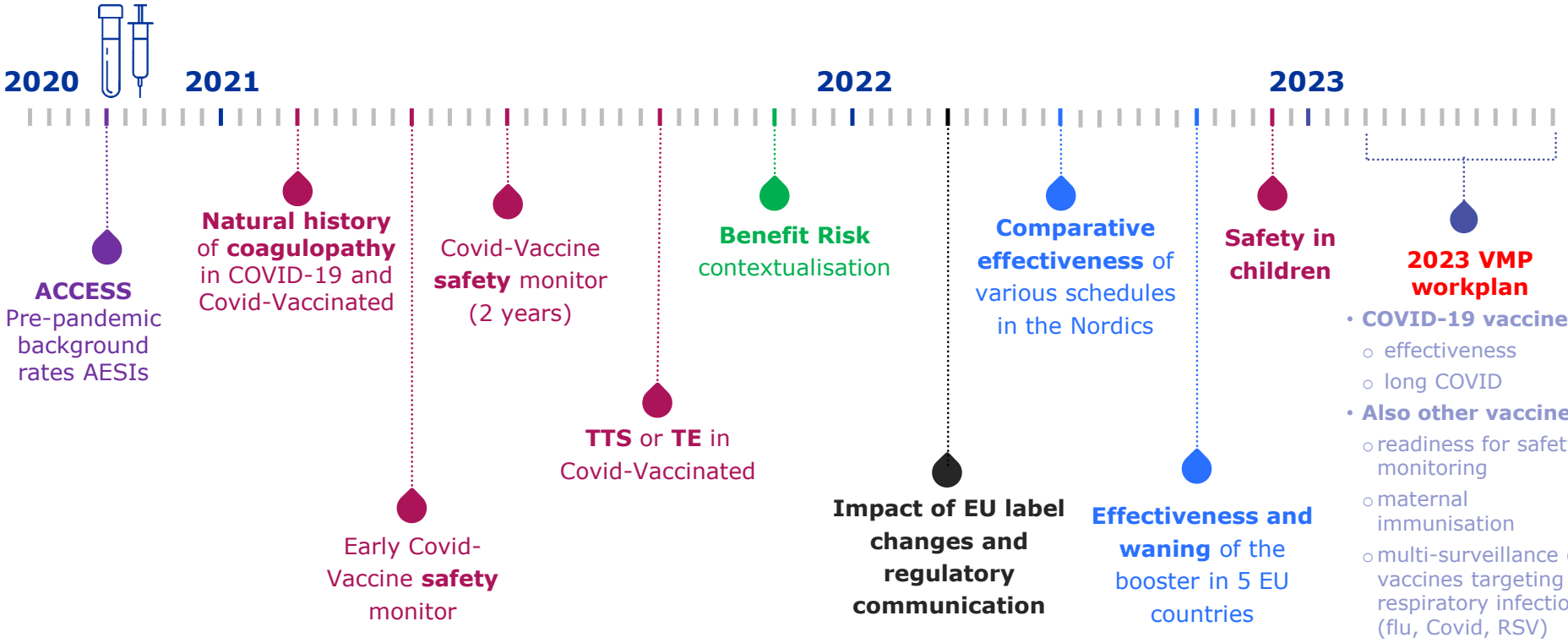

Lessons from the EMA perspective

Lessons from the EMA perspective

- Important lessons for future health threats… but still continuous need for coverage, safety and effectiveness data on **COVID-19 vaccines** (novel/adapted vaccines, long COVID, special populations)
- Preparedness (**ACCESS**): background rates used by EMA; protocol templates used by MAHs
- We now have improved knowledge of **data sources** and their characteristics
    - EHRs from several countries can be used (with limitations…)
    - Value of primary data collection to complement routine PV
    - Utility of federated networks (DARWIN EU expanding, EHDS, VAC4EU)
- **Multistakeholder/international** efforts can support response to public health emergencies: e.g., ICMRA technical subgroups and WGs on RWE; EU projects (e.g., Orchestra)
- Cross-fertilisation and **transparency** (EU PAS register)
- Enhanced **risk communication** to the public
- Rolling **appraisal** of emerging evidence can support regulatory decision-making

Future directions

- **Framework for RWE generation** to support continued preparedness:
  - Continuous update of background incidence rates of AESIs common to most (all) vaccines (≠ pathogens, platforms)
  - Adding research questions to ongoing studies if protocol allows for it
  - Recent (real-time) infection data are important (not available in all data sources)
- **Leverage RWE guidance**: ENCEPP Guide, EMA Data Quality Framework, catalogues of data sources, ICH M14 (using RWD in safety studies), ICH RP

Key messages

- **New ways of working** and generating/evaluating RWE
- Need for timely, high-quality, fit-for-purpose **RWE on vaccines** (from RWE generation to appraisal)
- **Preparedness** essential to develop a framework for agile vaccine monitoring
- Need to **balance** RWE generation feasibility / study design requirements / data quality and availability / public health urgency
- Pursue **collaborative**/multistakeholder efforts
- Expand COVID-19 learnings to also benefit the monitoring of **other vaccines**
- Future health crisis response will benefit from **DARWIN EU®** (in complement to other pathways)

Any questions?

Further information

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