EMA strategy 2025: regulatory framework for emerging clinical data generation

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Norwegian Medicines Agency

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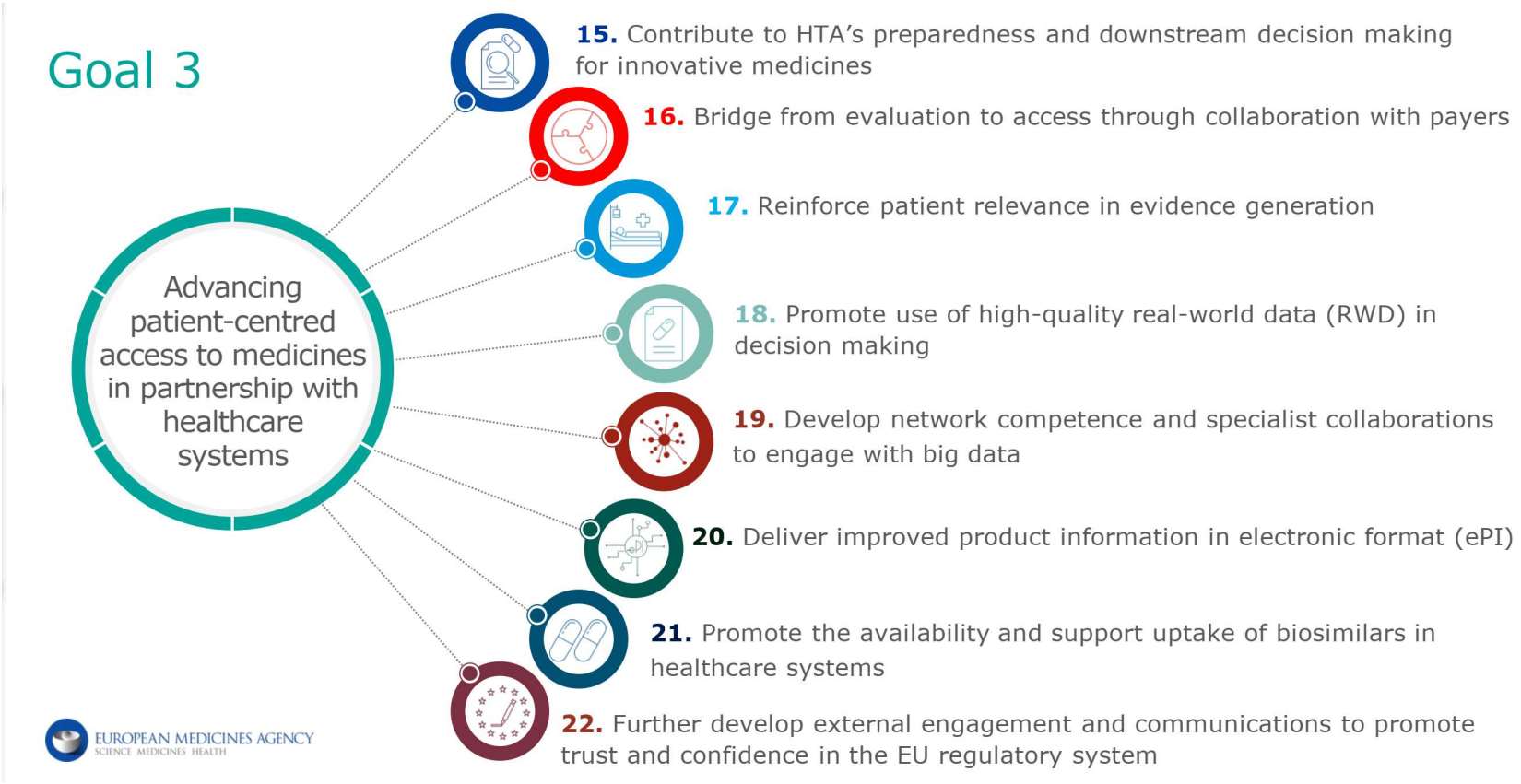
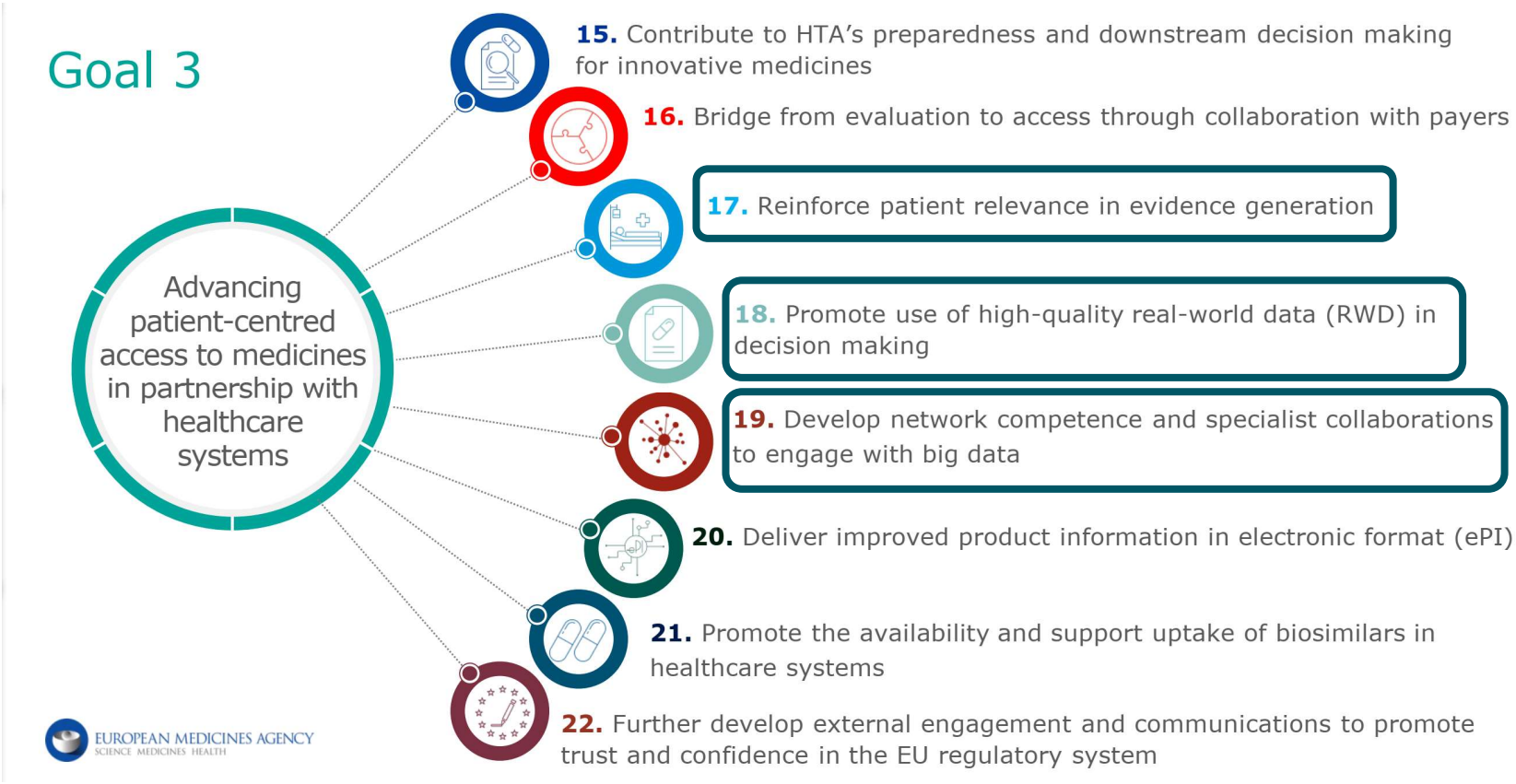
EMA‘s Regulatory Science Strategy to 2025

- This strategy has been developed between 2018 and 2019
- Two workshops were the basis for this strategy, involving all relevant stakeholders
- Five goals for human medicines regulation
    1. Catalysing the integration of science and technology in medicines development
    2. Driving collaborative evidence generation – improving the scientific quality of evaluations
    3. Advancing patient-centre access to medicines in partnership with healthcare systems
    4. Addressing emerging health threats and availability/therapeutic challenges
    5. Enabling and leveraging research and innovation in regulatory science

Advancing patient-centre access to medicines in partnership with healthcare systems



Advancing patient-centred access to medicines in partnership with healthcare systems



HMA European Medicines Agencies Network Strategy to 2025


HMA

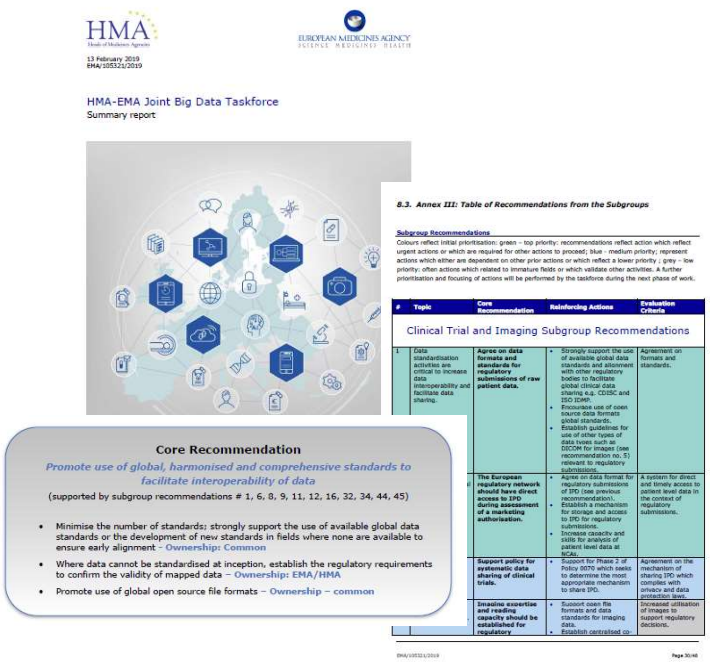
EUROPEAN MEDICINES AGENCY

3 July 2020
EMA/321483/2020

European medicines agencies network strategy to 2025
Protecting public health at a time of rapid change

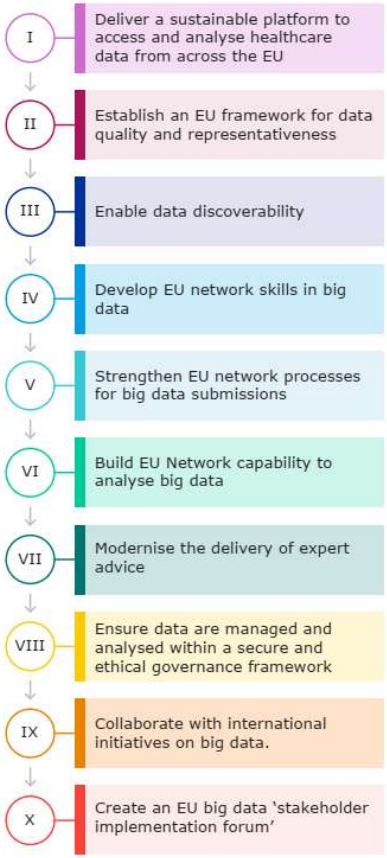
Strategy outline

Big Data Task force -> finished end 2019



- Characterisation of data sources
- Synopsis of the survey of NCAs and industry
- Set of core recommendations
- Annexes:
  - Recommendations from 6 subgroups which underpin the core recommendations
- Summary report endorsed by HMA and EMA management board.
- Phase I defined the ‘what’ but not the ‘how’ or the ‘when’
- Agreement for the extension of taskforce mandate until end of 2019
- Phase II – Regulatory prioritisation of recommendations

Big Data Steering group Workplan



Data Analysis and Real World Interrogation Network - DARWIN.
Build the business case with stakeholders and secure funding to establish and maintain a secure EU data platform that supports better decision-making on medicines by informing those decisions with robust evidence from healthcare.

Establish an EU framework for data quality and representativeness. Develop guidelines, a strengthened process for data qualification through scientific advice, and promote across Member States the uptake of electronic health records, registries, genomics data, and secure data availability.

Identify key metadata for regulatory decision-making on the choice of data source, strengthen the current ENCePP resources database to signpost to the most appropriate data, and promote the use of the FAIR principles (Findable, Accessible, Interoperable and Reusable).

Develop a big data training curriculum and strategy based on a skills analysis across the network, collaborate with external experts including academia, and target recruitment of data scientists, omics specialists, biostatisticians, epidemiologists, and experts in advanced analytics and AI.

Launch a 'big data learnings initiative' where submissions that include big data are tracked and outcomes reviewed, with learnings fed into reflection papers and guidelines. Enhance the existing EU PAS register to increase transparency on study methods.

Build computing capacity to receive, store, manage and analyse large data sets including patient level data (PLD), establish a network of analytics centres linked to regulatory agencies, and strengthen the network's ability to validate AI algorithms.

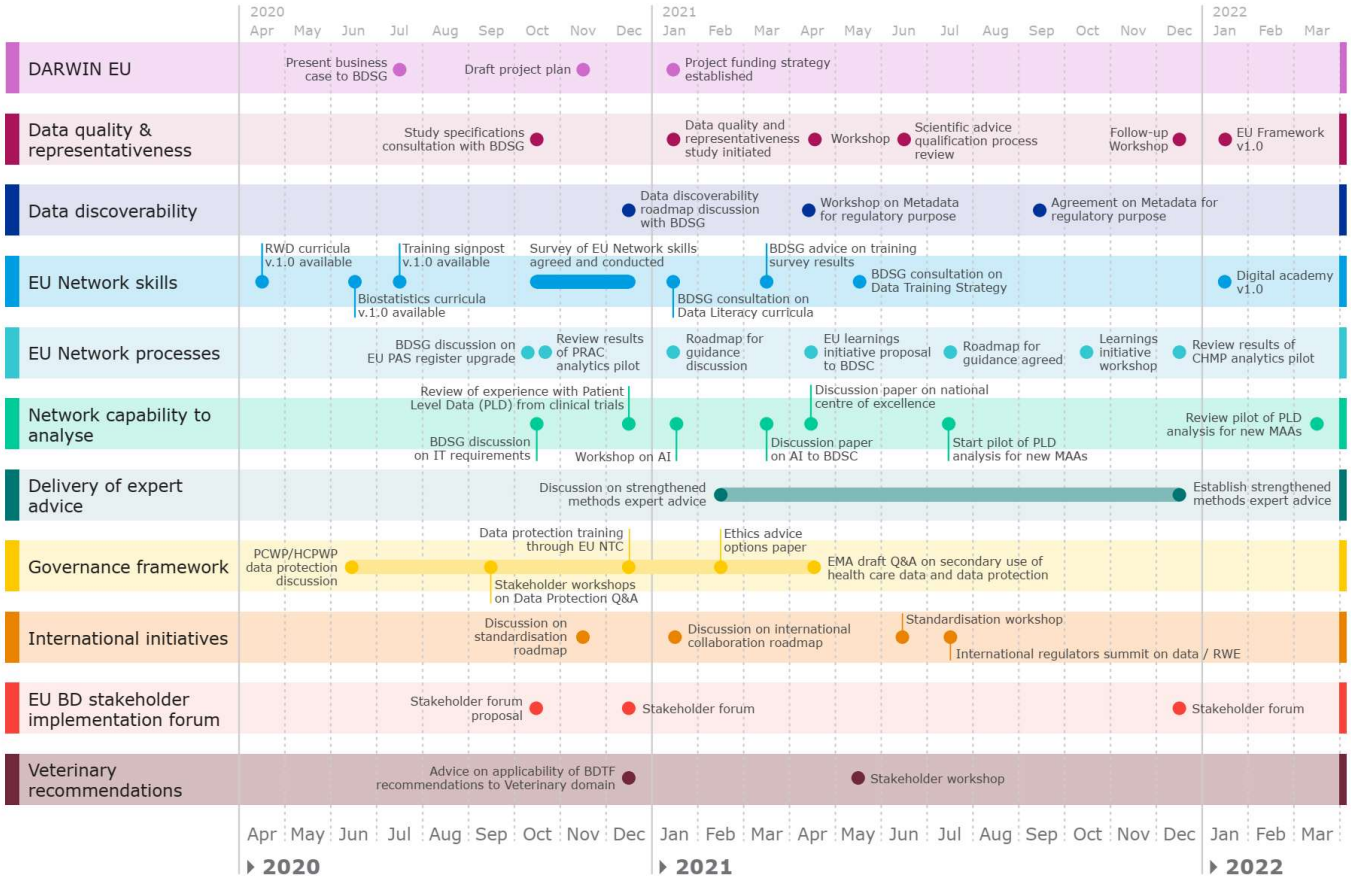
Build on the existing working party structure to establish a Methodologies Working Party that encompasses biostatistics, modelling and simulation, extrapolation, pharmacokinetics, real world data, epidemiology and advanced analytics, and establish an Omics Working Party that builds on and reinforces the existing pharmacogenomics group.

Engage with initiatives on the implementation of EU data protection regulations to deliver data protection by design, engage with patients and healthcare professionals on data governance, and establish an Ethics Advisory Committee.

Support the development of guidelines at international multilateral fora, a data standardisation strategy delivered through standards bodies, and bilateral collaboration and sharing of best practice with international partners.

Dialogue actively with key EU stakeholders, including patients, healthcare professionals, industry, HTA bodies, payers, device regulators and technology companies. Establish key communication points in each agency and build a resource of key messages and communication materials on regulation and big data.

Timelines and deliverables



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