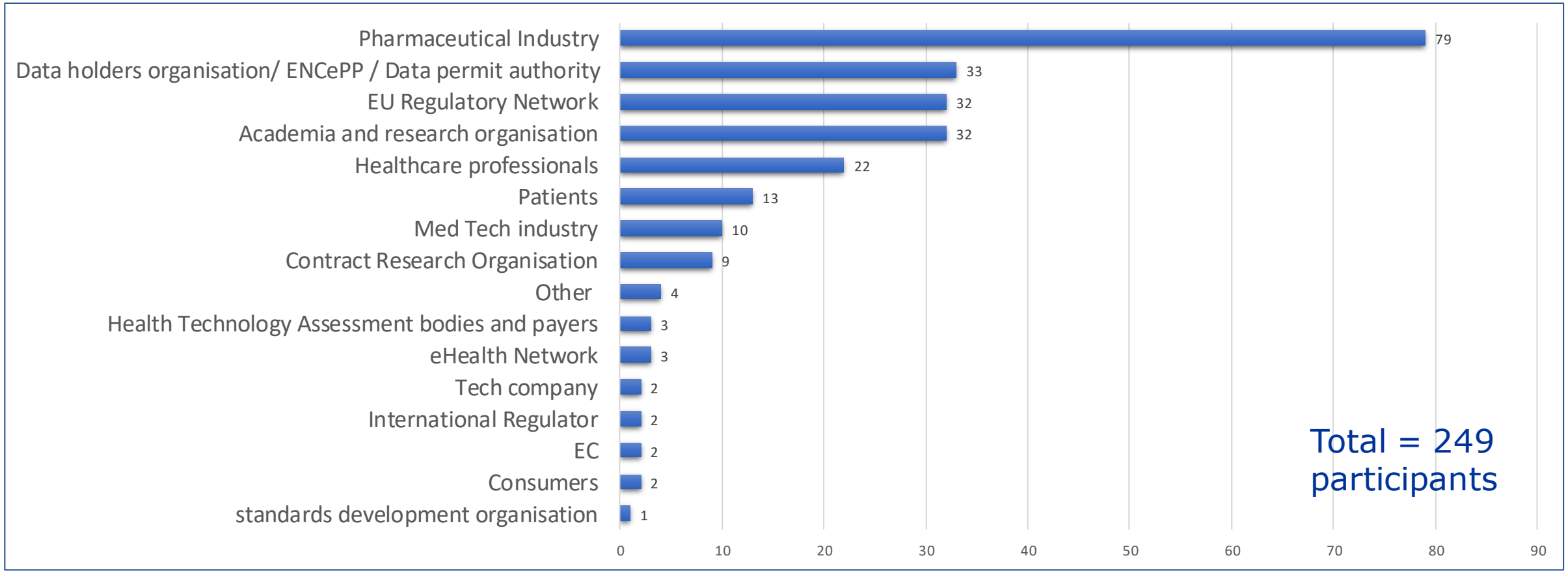
Aggregated feedback from pre-meeting survey

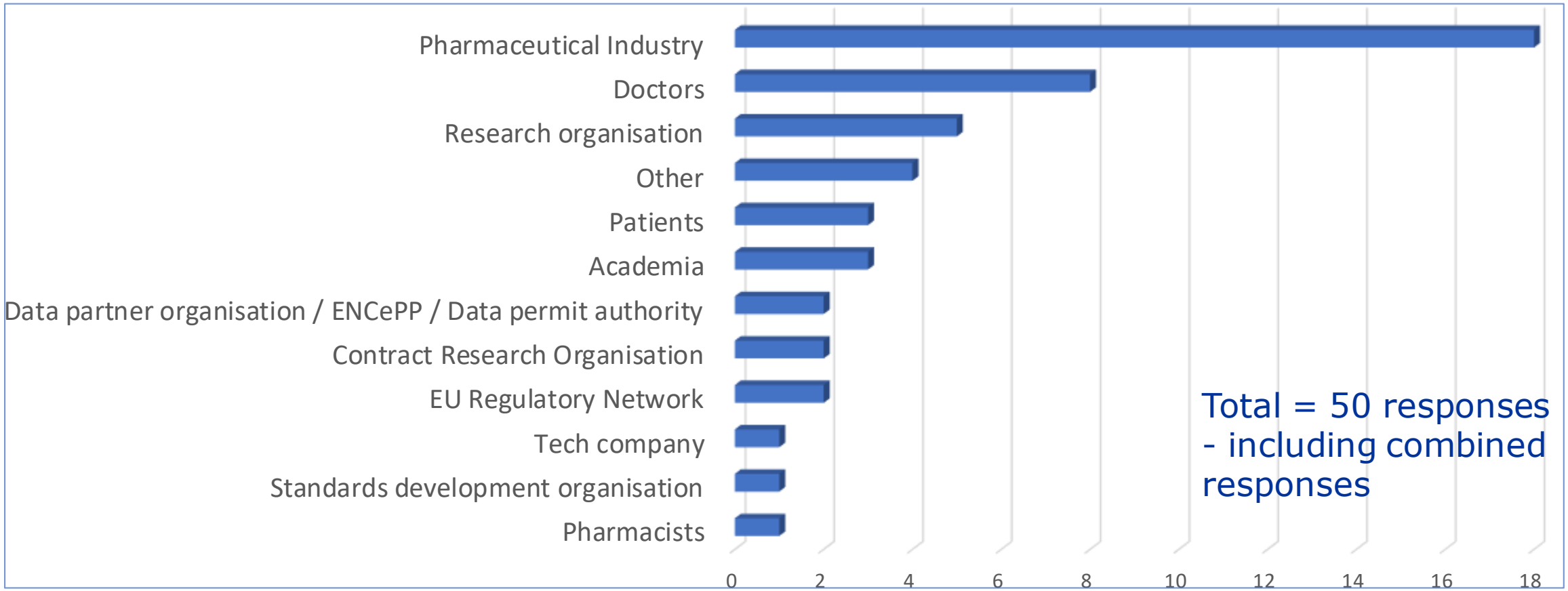
Session 2: Stakeholders' priorities

Francois Domergue,
Data Analytics and Methods Task Force (EMA)

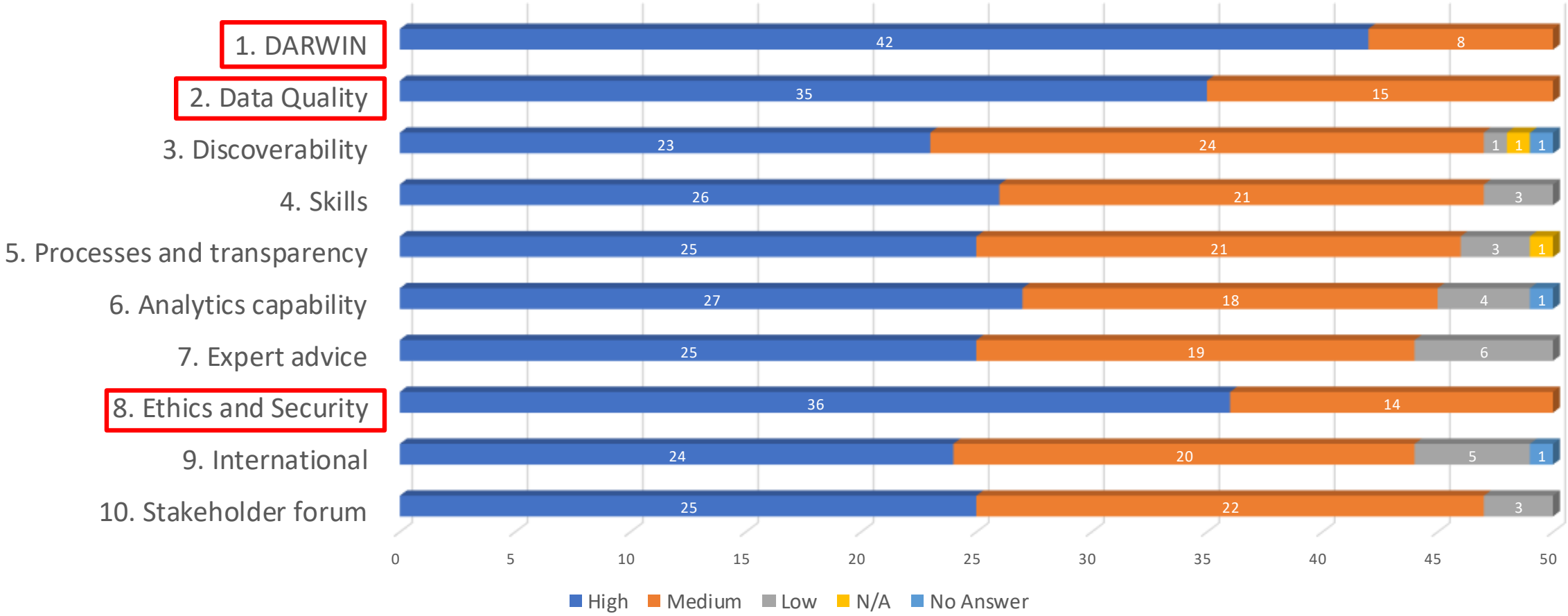
Registered participants for today's forum



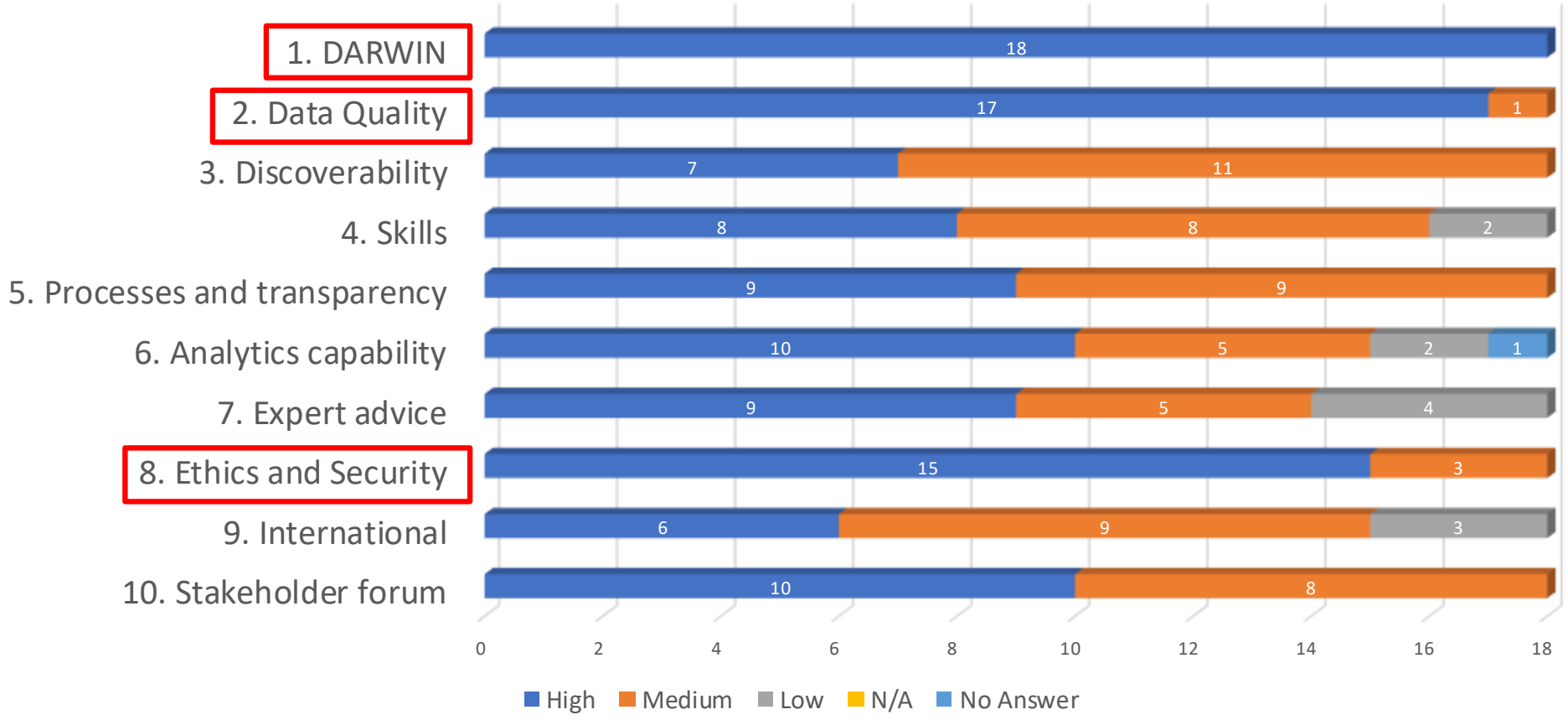
Number of response received



Priorities of each recommendations for all stakeholders



Feedback from Pharmaceutical Industry (1/2)

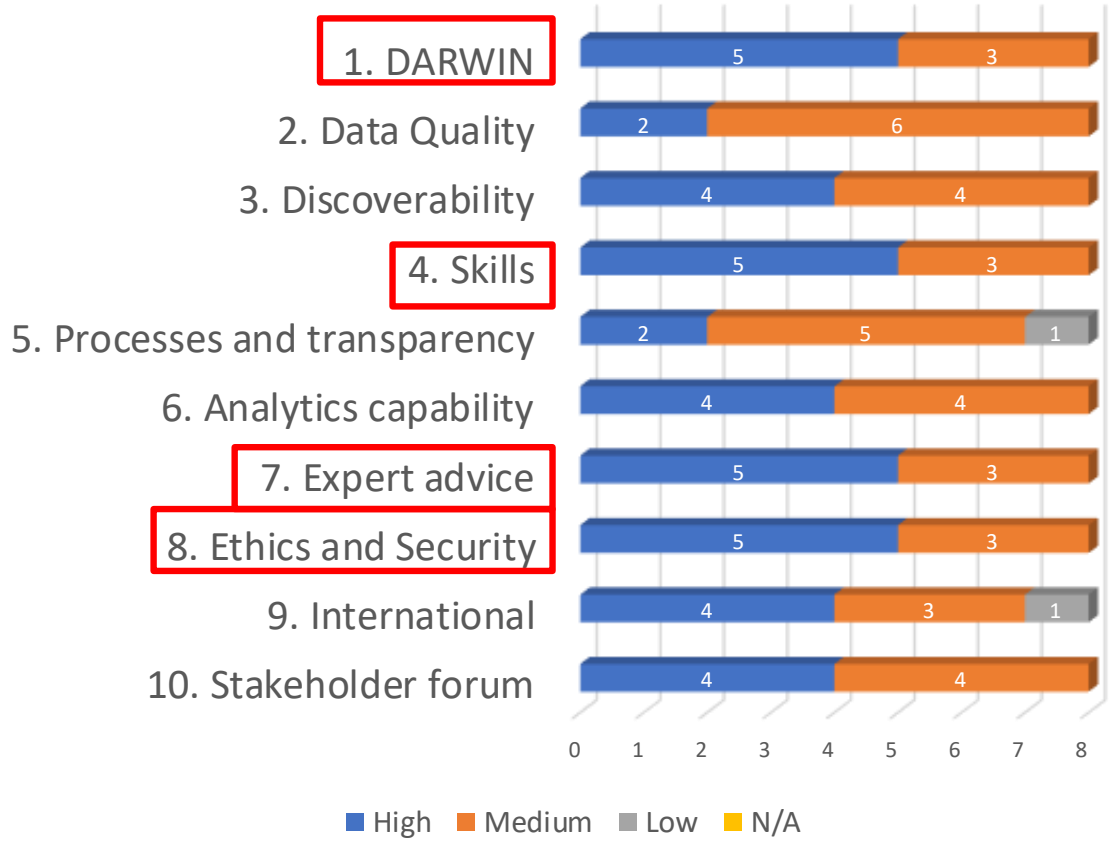


Feedback from Pharmaceutical Industry (2/2)

- Opportunity:
  - *Non-Rx medicines to be recorded in EMR/ pharmacy registries across the EU*
  - *RWD/RWE could be used to substantiate the benefit of older medicines, change of legal status like RX to OTC switch*
  - *reduce attrition rate and accelerate development by using advanced analytics and AI*
  - *elaborate new targets of new indications particularly for unmet medical need*
  - *Incentivize sharing of data/experiences*
  - *Development of sustainable platform, accessible by all stakeholders, incl. pharmaceutical industry*

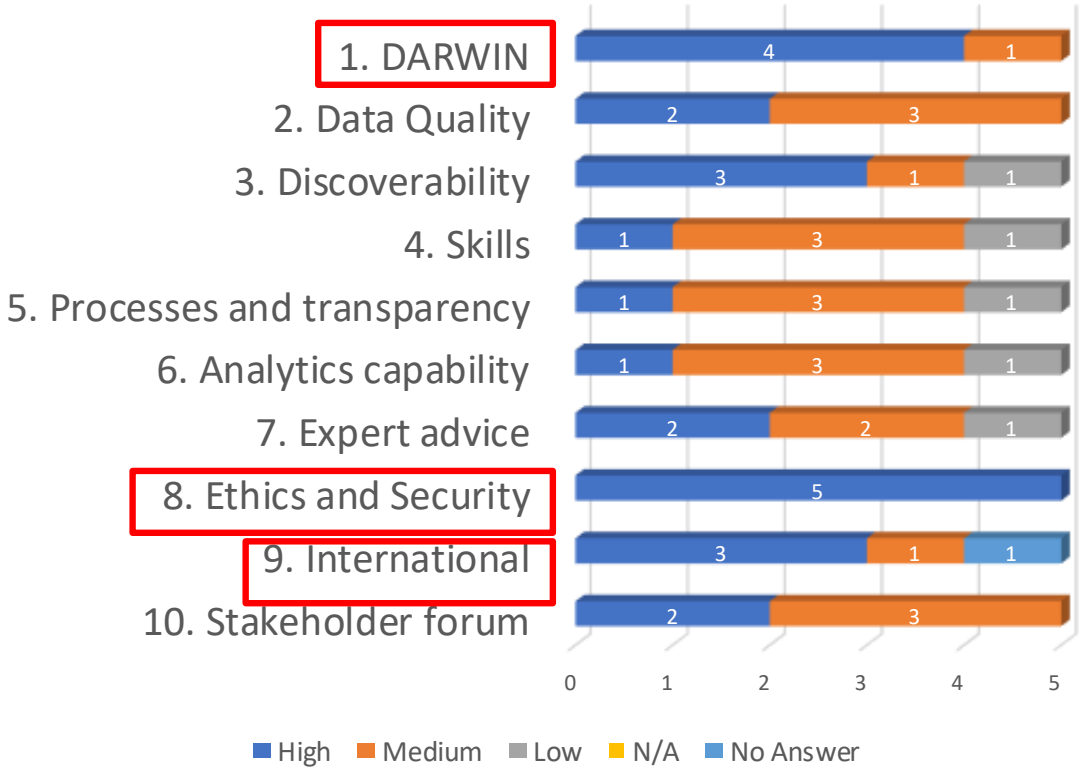
- Challenges:
  - *Operate within a secure and ethical governance framework in compliance with EU data protection regulations .*
  - *Integration of Big Data approaches in current regulatory processes*
  - *EU falling behind international developments with regards to BIG DATA use.*
  - *Industry needs to be regarded/involved as a true partner in the efforts -not being side-lined*
  - *Agreement and adoption of data standards, together with an optimal scientific advice process*
  - *Different perspectives & misalignment on data quality and representativeness,*
  - *Heterogeneity of data coming from different*
  - *Lack of consideration for equitable access across stakeholders and for leveraging experiences from other regulators in this field and harmonisation*
  - *Increase the hurdles in a way that will impact the feasibility of any RWD/RWE activities*

Feedback from Doctors



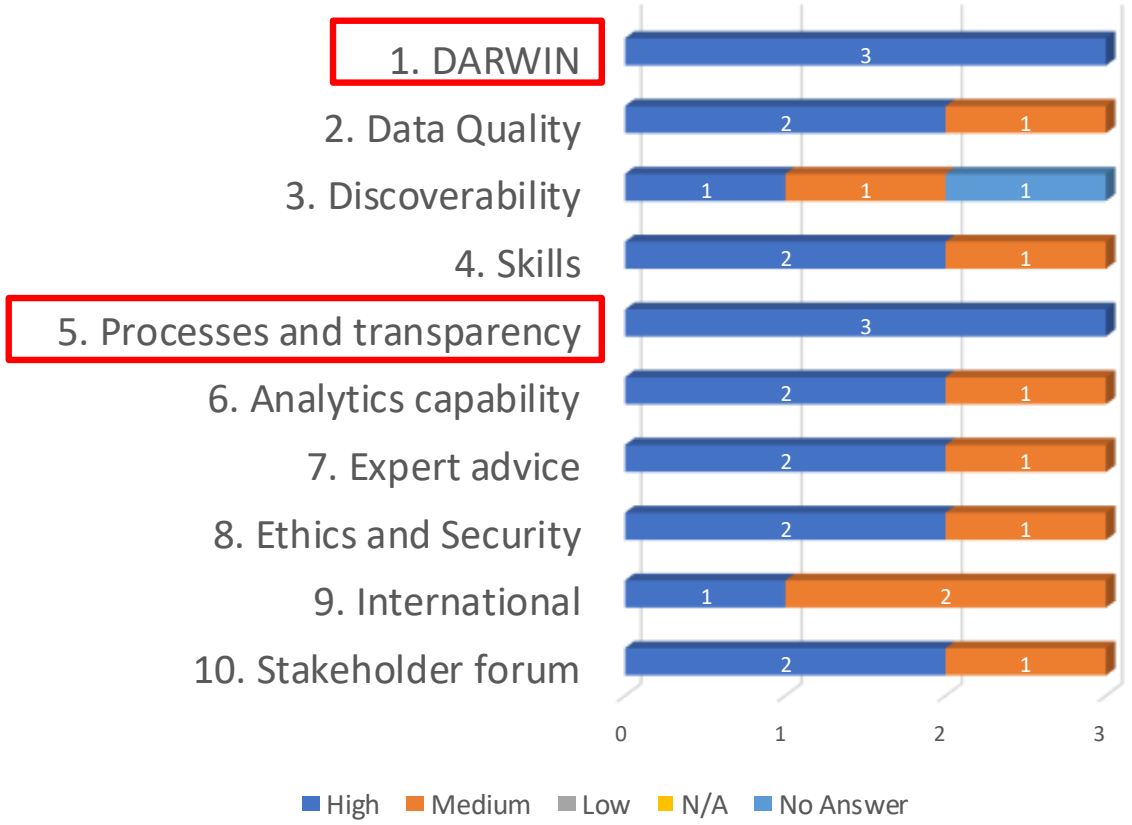
- Opportunity:
  - *Develop EU Network skills in Big Data: incorporation of cross-disciplinary*
  - *Implementation of results generated into clinical practice how to bridge the gap?*
  - *Ways to involve clinical pharmacologists and related expertise in strategy in joined up Big Data across the EU region and with external partners*
- Challenges:
  - *Ethical consideration regarding implementation of AI algorithms in the future, specifically what kind of "trial phases" should developed algorithms undergo before implementation in clinical practice*
  - *Sustainability of big data platforms beyond initial project funding, to allow for (costly) updates to HER*
  - *That increased regulatory complexity in obtaining patient consent may limit the quality/completeness of Big Data sets.*

Feedback from Research organisations



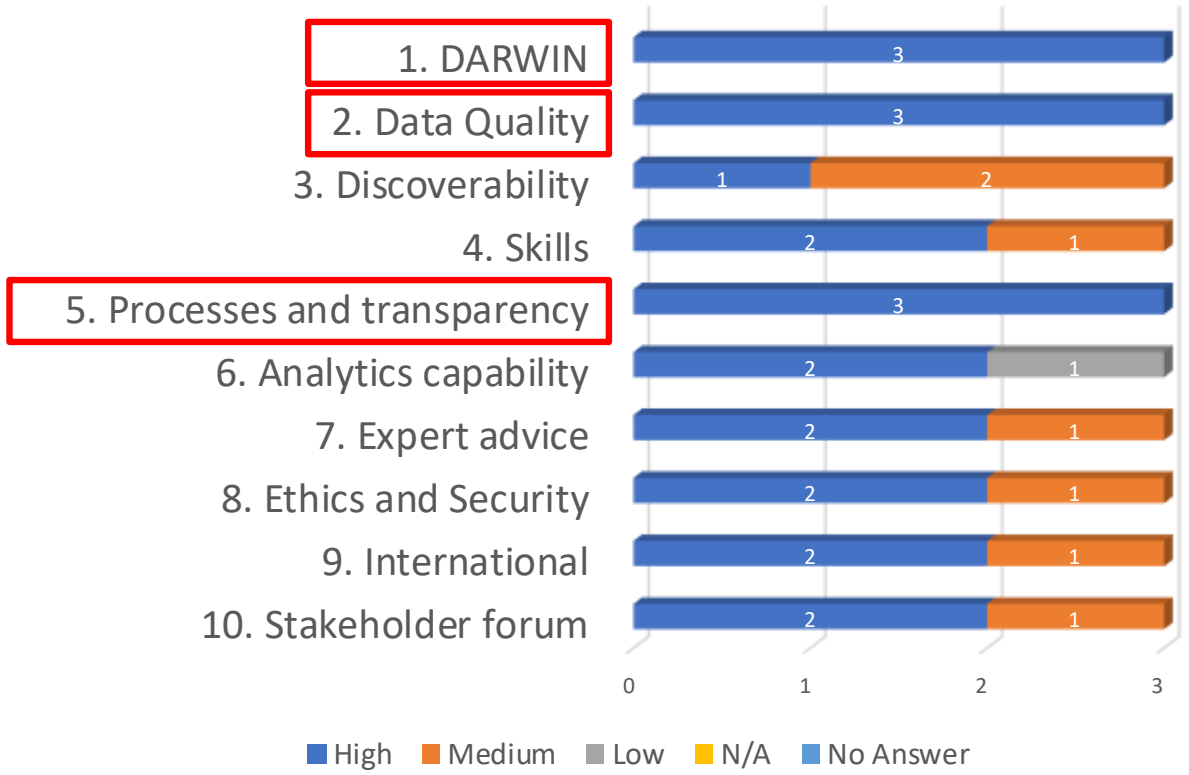
- Opportunity:
  - *The harmonisation of the big data framework and the setting up of guidelines for the use and re-use of big data.*
  - *Added value of our health database*
  - *A sustainable platform to access and analyse healthcare data from across the EU is not only an opportunity for decision making on medicine but also to promote reusing of the data for research*
  - *Pharmacoepidemiology / drug safety possibilities*
- Challenges:
  - *The biggest concerns/risks are those related to the protection of personal and special categories of data.*
  - *Building CDM*
  - *The risk to duplicate activities and platform at EU and National level - create confusion and lack of visibility*
  - *The main risk has been already occurred in COVID-19 pandemic. To not have verified and centralized high quality data to conduct proper research*
  - *Central control and limited access to big data for research*

Feedback from Patients



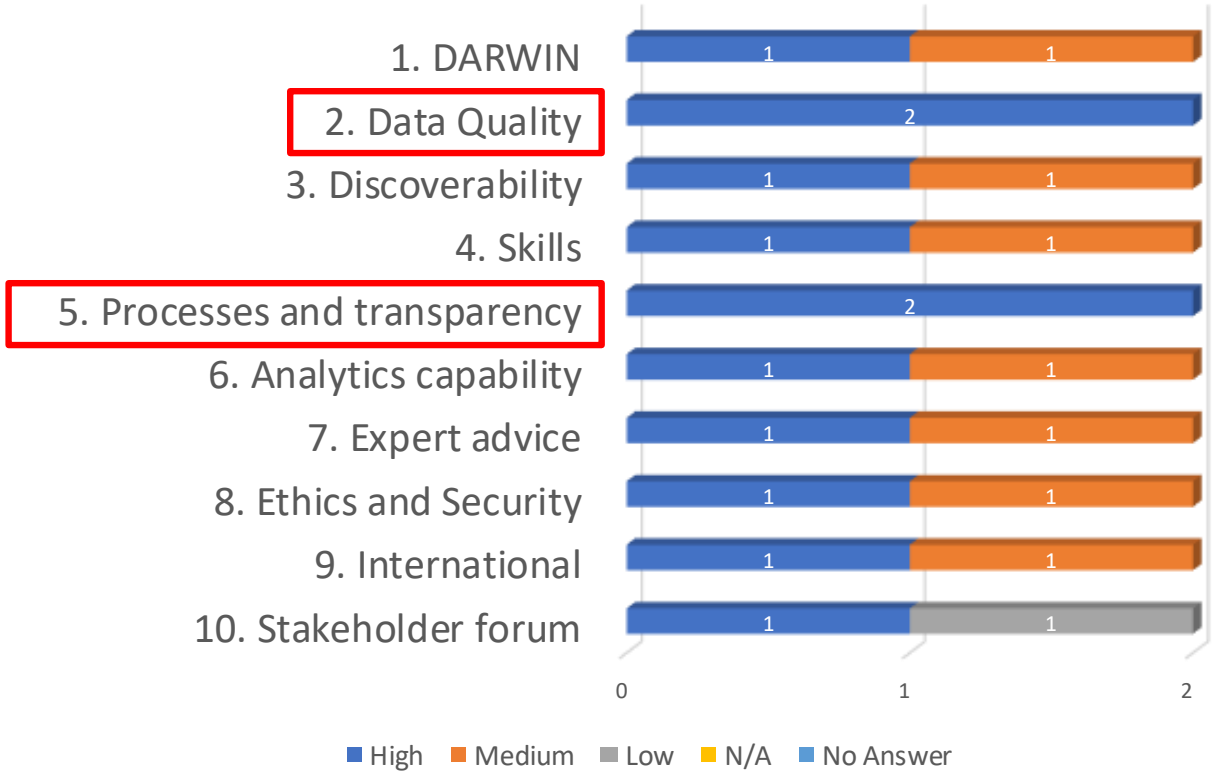
- Opportunity:
  - *To collaborate and move forward on sharing, storing, developing data and other information on health care, regulatory affairs and actually making a difference for the future, not just words!*
  - *healthcare data will help to flow and will let all citizens to receive faster diagnosis*
- Challenges:
  - *Protection of data and information across the entire spectrum of Big Data.*
  - *due to the fact that existing data are collected in different languages, formats and so on it will be difficult to analyze and compare them*

Feedback from Academia



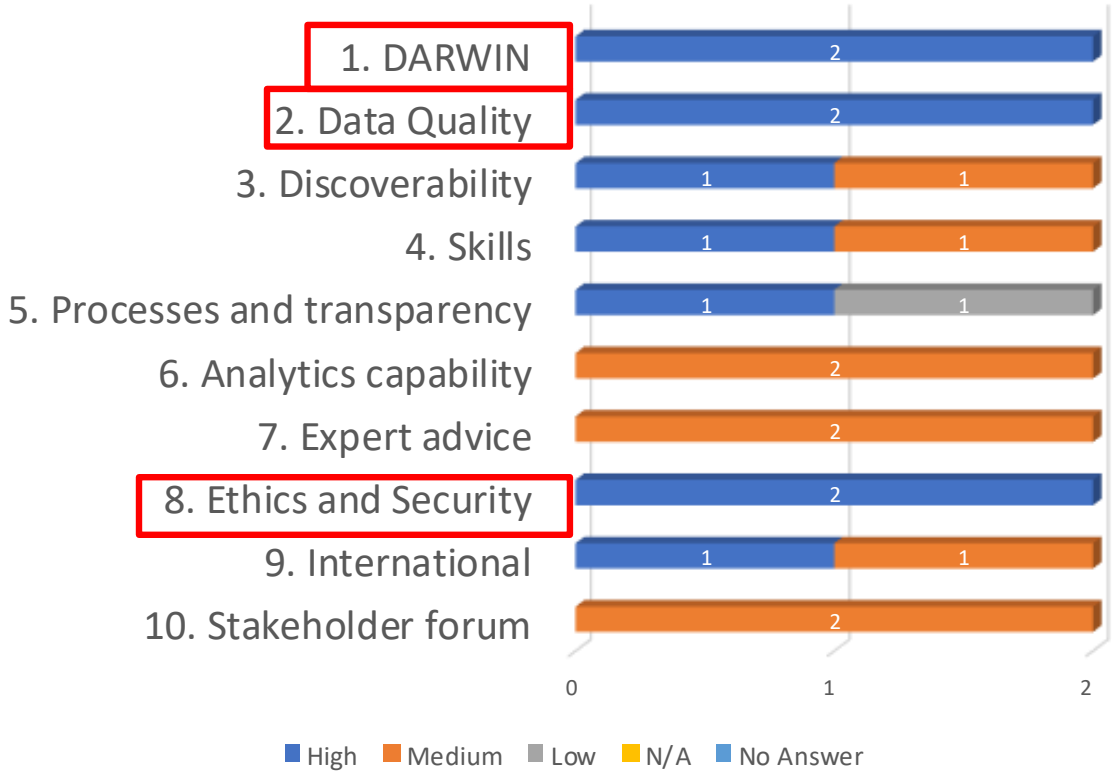
- Opportunity:
  - *It is a unique opportunity to analyse medical data from people all over Europe and to see many different consumptions, characteristics and the efficacy of various medicines.*
  - *Growing opportunities for the use of electronic health records and registries for both interventional and non-interventional studies + in general better access to big data for research purposes*
- Challenges:
  - *Data security*
  - *These data need to be connected with other genome data and various characteristics, which are different among the European Countries.*
  - *acceptability of use of big data for regulatory submissions; feasibility & acceptability of linkage of different big data sources; access to big data sources for research purposes*

Feedback from Data partner organisation / ENCePP / Data permit authority



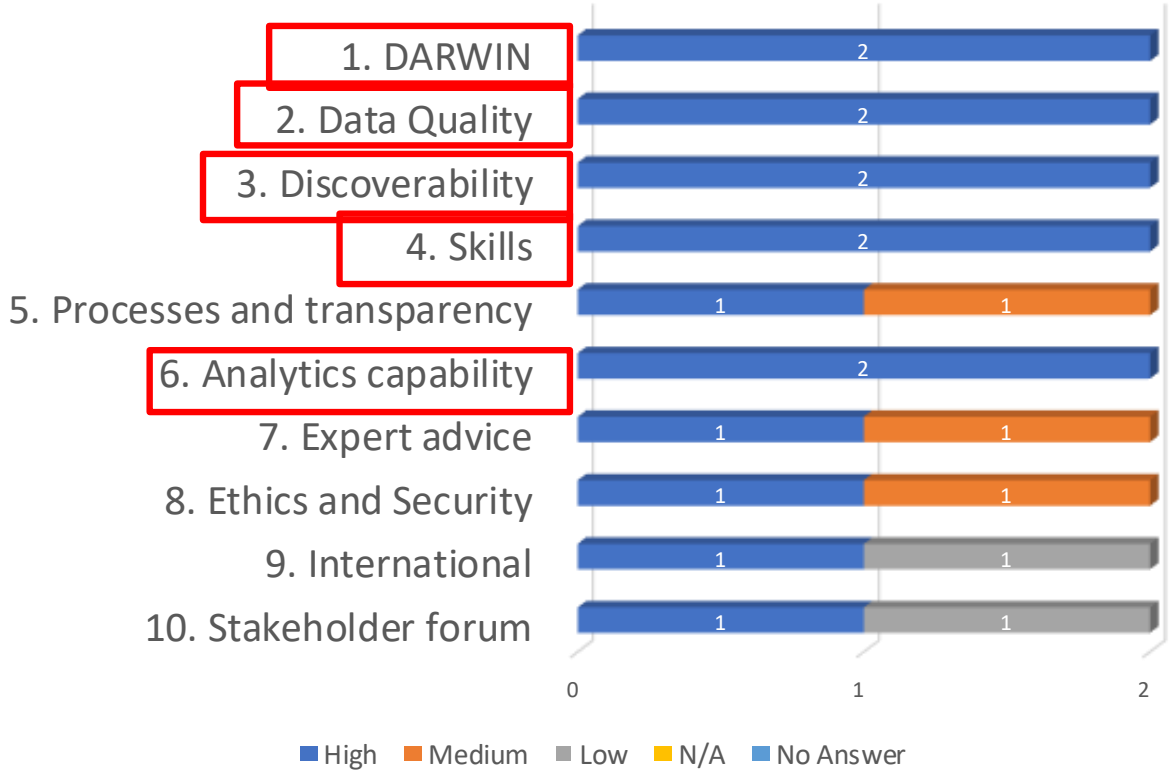
- Opportunity:
  - *Use the expertise e.g regarding pitfalls and strengths of EHR data, epidemiology, statistics, medicine and pharmacology that was acquired in the last years/decades to do valid studies with high impact*
  - *Opportunity to connect with other like-minded people as well as to finally be able to disrupt the status qua through regulatory decision making.*
- Challenges:
  - *It is very difficult to asses the quality of studies using EHR data. Badly conducted studies will be quicker and cheaper and might endanger patients but also trust in big data.*
  - *How does the initiatives incorporate the disease specific niche expertise and knowledge required to assess safety issues with subpopulations (like multiple sclerosis)?*

Feedback from Contract Research Organisation



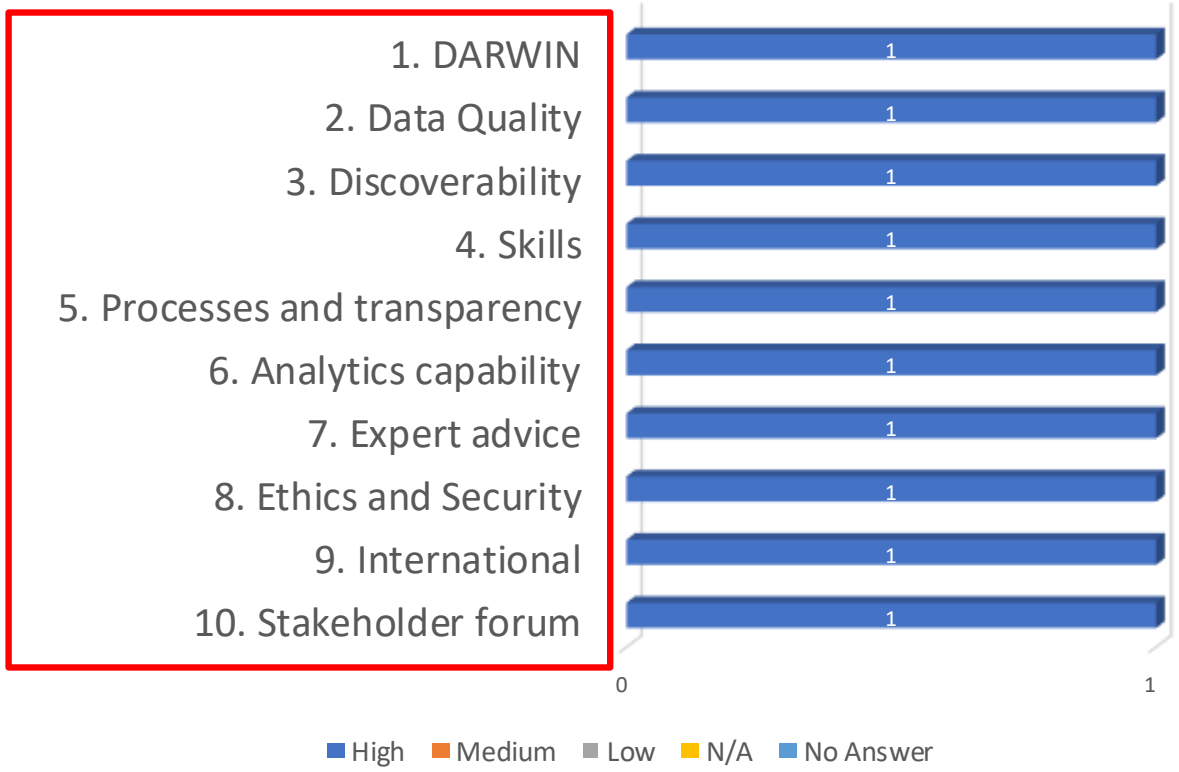
- Opportunity:
  - *DARWIN - the scope, the trade-offs, funding model, commercial access*
- Challenges:
  - *Risks of building inflexible data solutions which put off data partners and limit access for researchers (both academic and industry)*

Feedback from EU Regulatory Network



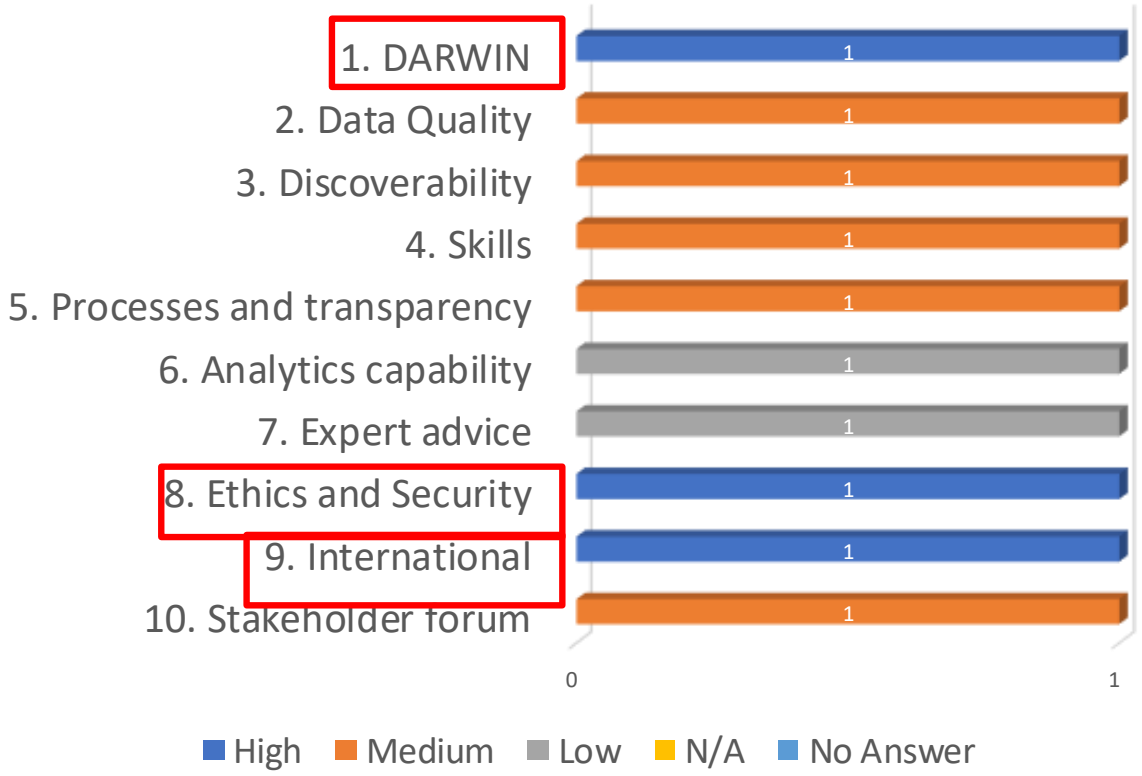
- Opportunity:
  - *representativeness: Enable across Member States the uptake of electronic health records, registries, genomics data, and secure data availability.*
- Challenges:
  - *representativeness, we measure impact only in small subgroup of MS and this can differ significantly*

Feedback from Tech company



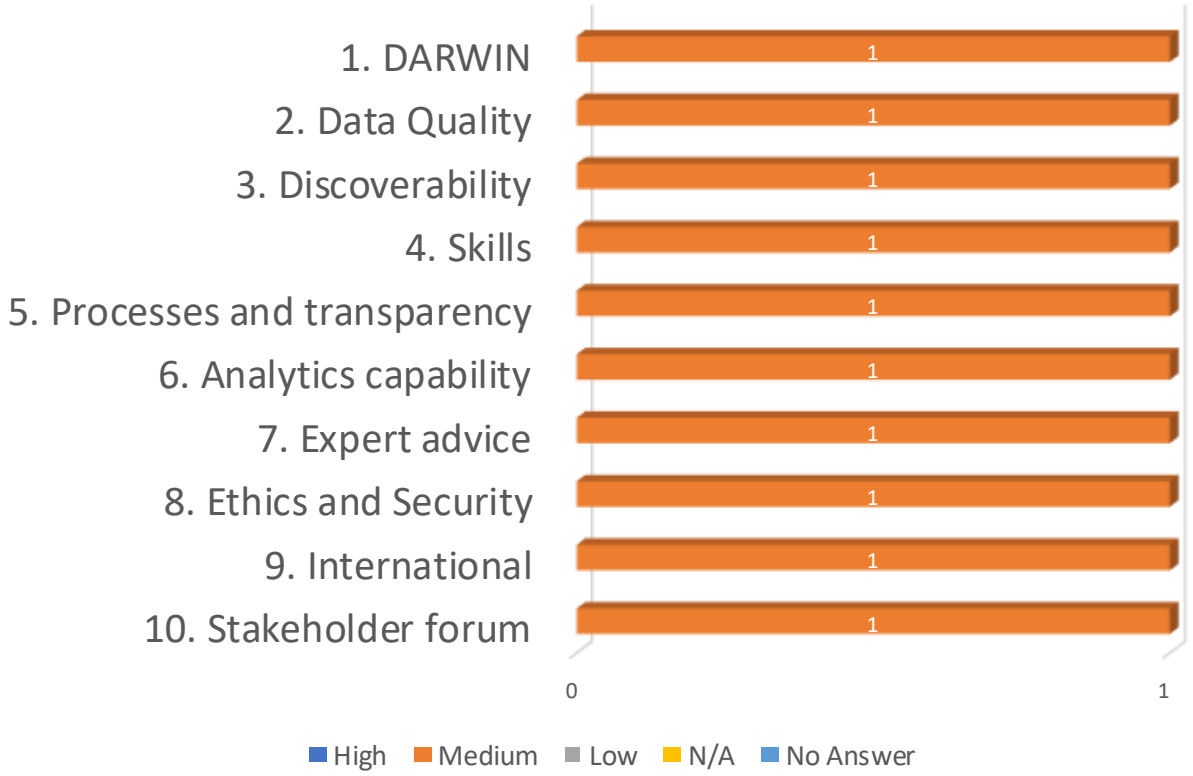
- Opportunity:
  - *Collecting better data on the appropriate (safe) use of medicines and stakeholder understanding of the benefit: risk profile of drugs is clearly beneficial to public health and ensure safe treatments.*
- Challenges:
  - *This could be inhibited by local NCA rules preventing the deployment of digital risk education designed for end user utility aligned with useful data collections. Some reviewers don't apply regs well.*

Feedback from Standards development organisation



- Opportunity:
  - *To advocate for collaborating with other countries toward a global path forward, involving standards such as OMOP and HL7 FHIR.*
- Challenges:
  - *Pursuing too ambitious a set of goals, which increases risk of failure and delays offering quick value to stakeholders. Hope to see a roadmap of incremental updates that prioritizes essential needs.*

Feedback from Pharmacists



- Opportunity:
  - *None*
- Challenges:
  - *None*

Initiatives shared via the survey (1/2)

- https://www.topra.org
- https://www.cdisc.org
- https://www.fda.gov/regulatory-information
- Danish Agency Centre of Excellence (DAC)
- Pilot project – establishing new platform for submission of data in CDISC format for new drug applications, FDA Sentinel
- Set up of EHR in Germany, IMI
- https://friendsofcancerresearch.org/covid19
- https://www.openehr.org
- https://ez.mu-sofia.bg
- https://www.harmony-alliance.eu
- https://prostate-pioneer.eu
- https://unstats.un.org/sdgs/hlg/Global-data-communitys-response-to-COVID-19
- https://www.big-data-europe.eu

Initiatives shared via the survey (2/2)

- HealthyCloud - CSA to be initiated
- PHIRI Population - Population Health Information Research Infrastructure - Project starting KOM was in November
- ERN
- www.msdataalliance.com
- www.covid19dataportal.org
- www.elixir-europe.org
- www.ec.europa.eu/health/ehealth/dataspace_en
- www.ehden.eu
- www.sentinel.esa.int
- www.pcornet.org
- https://www.hl7.org/fhir/overview.html
- OHDSI/OMOP, WHO and US ONC projects using a standard API.