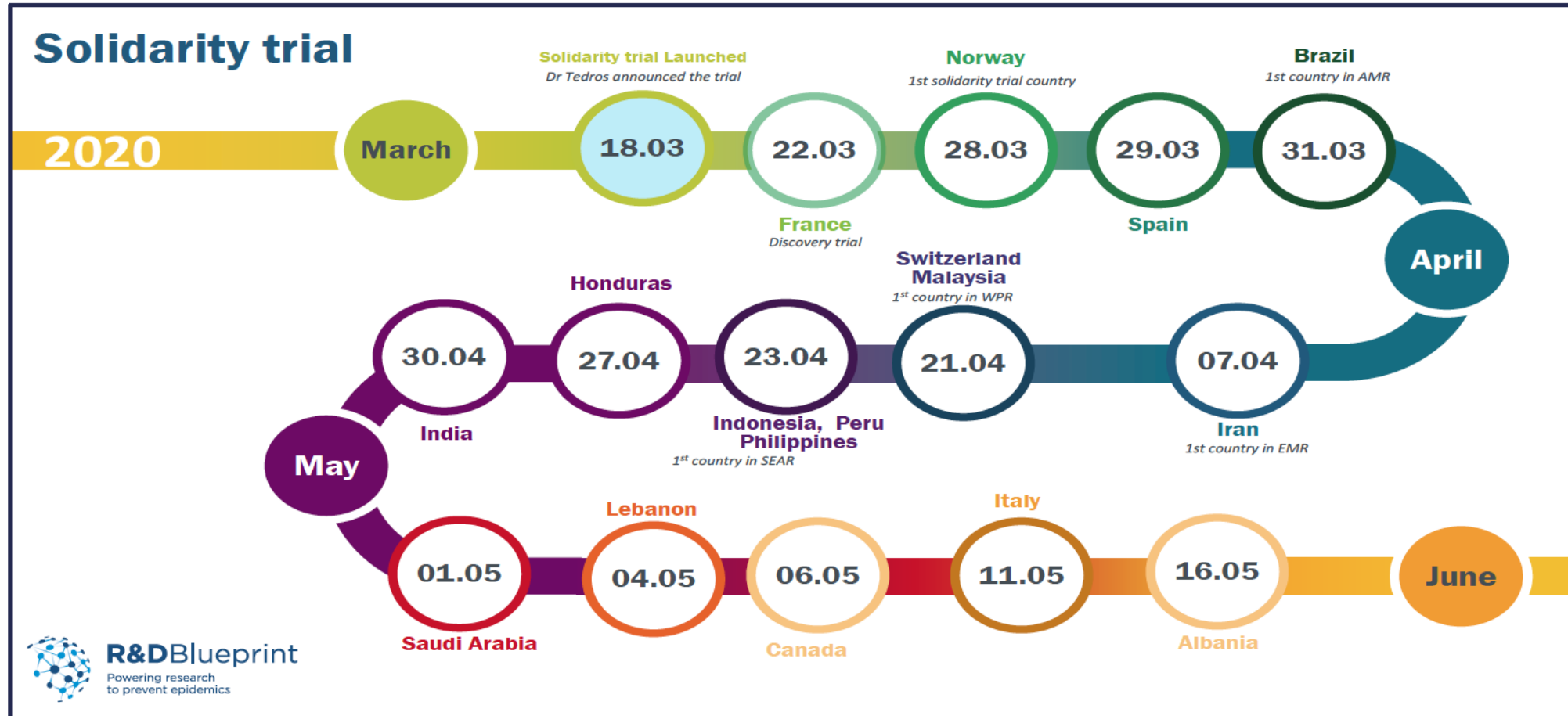


COVID-19 pandemic

- Declared Public Health Emergency of International Concern 30 January 2020, declared pandemic 11 March 2020
- 9 March first contact from the OUH clinicians, eCRF (two pages) and protocol
- National lockdown in Norway 12 March 2020
- NOR-Solidarity Protocol submitted to ethics 19 March 2020, approval 20 March 2020
- Submitted to regulatory 23 March 2020, 42 comments to application on the 25th, replied 26th, approval 26th (22:34).
- 1st patient randomised 28th of March



NOR-Solidarity Trial



The role of CTU

- Protocol input
- Regulatory (EudraCT form)
- eCRF/Data Management
- Drug logistics
- Risk assessment, monitoring plan, initiation/Green light 27th 22:33 (Bjørn)
- Reply to regulators
- Coordination
- Statistics



EU-RESPONSE

- May 1st, contacted by John-Arne Røttingen to draft a pan-european platform trial.
- Delivered 4th of May
- Funding received from EU commission in August (16.7 mill€)
- OUH selected sponsor of EU-SolidAct platform trial, 1st patient June 2021 testing baricitinib
- 2022 new arm testing bemcentinib
- Totally 17 countries, ca 100 sites



MPX-RESPONSE

- Mpox (formerly monkeypox) declared Public Health emergency of international concern July 2022
- EU-RESPONSE consortium responded with an application to the EU commission
- MPX-RESPONSE funded with 12 mill€ to run trials in Europe, South America and Africa
- OUH/CTU asked to provide Data management/eCRF and lead the operational aspects.
- OUH/CTU also provides data sharing platform through the UiO TSD



Experiences

- 1) The importance of collaboration between clinical and operational teams
- 2) The importance of legal expertise (agreements)
- 3) The importance of regulatory expertise (SLV -> VHP -> CTIS)
- 4) The importance of data management
- 5) The importance of monitoring/Clinical Research Associates
- 6) The importance of grants expertise
- 7) The importance of risk



Ultimately

- The importance of having the experience, procedures, competence and capacity to move fast while maintaining the safety and well-being of the participants
- The OUH research support services is as good or better than any mainland Europe CTU



Conclusion

- Doing high quality confirmatory research in a pandemic setting is extremely demanding
- May not be as sexy as hypothesis generating research
- Depending on dedicated clinical personnel and funding
- But equally important, to have operational structures in place which quickly can pivot into a pandemic mode when needed
- The research support services for clinical trials is a very important such structure!

