We need a sandbox

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2 main ideas

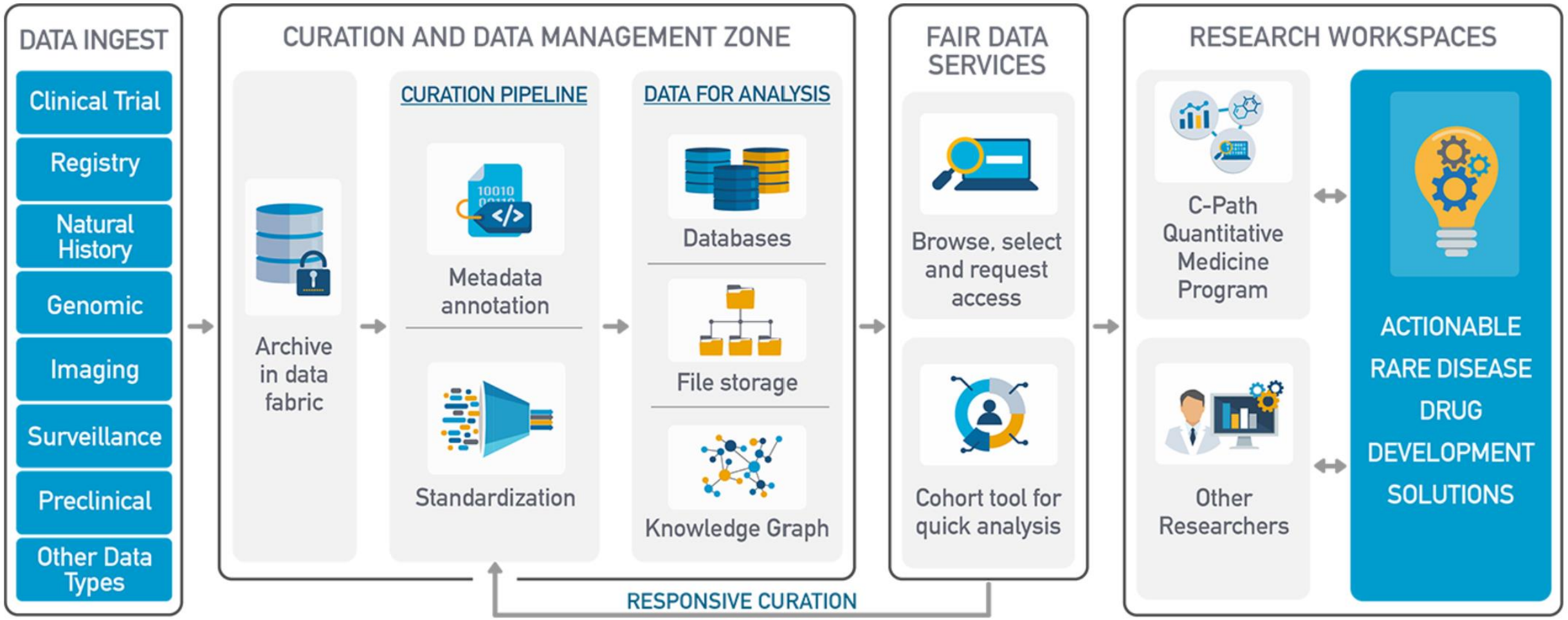
A sandbox with data from clinical trials

Create real-world data datasets by linking and analyzing patient registry data with clinical trials data

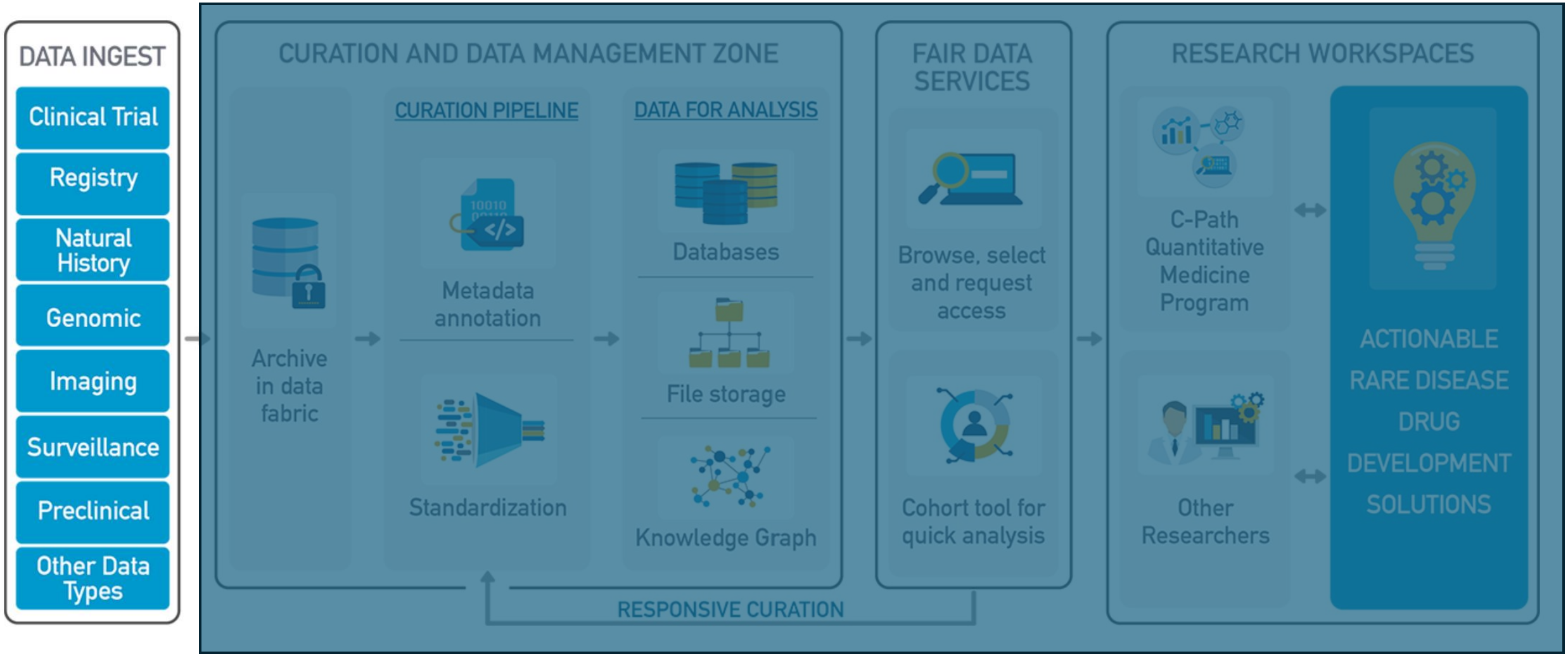
A sandbox with data from clinical trials

- The idea is to provide the data we already have from clinical trials in a research sandbox as an open analytics platform.
- Don’t reinvent the wheel. Just copy one RDCA-DAP | Critical Path Institute (c-path.org)
- RDCA-DAP is an FDA-funded initiative that provides infrastructure to support rare disease characterization and accelerate therapy development. It facilitates data sharing and analysis to better understand disease progression, biomarkers, and support innovative trial designs.

Sandbox architecture



Where is the problem?



Asking patients organization to build their own registries is not fair





EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Executive Director

Letter of support for Patient Data Platform for capturing patient-reported outcome measures for Dravet syndrome

On 09 December 2015 the applicant Dravet Syndrome Foundation Spain requested qualification opinion for Patient Data Platform as an electronic tool for capturing patient reported outcomes in paediatric epilepsies, pursuant to article 57(1)(n) of regulation (EC) 726/2004 of the European Parliament and of the Council.

During its meeting held on 11-14 April 2016, the SAWP agreed on the qualification advice to be given to the applicant. During its meeting held on 25-28 April 2016, the CHMP adopted the advice to be given to the Applicant.

The sponsor seeks qualification opinion for their proposed "Patient Data Platform" (PDP) as a patient-reported outcome measure (PROM) to be used within drug development for paediatric epilepsies.


Thank you!