Medicines Evaluation Board

Central Committee on Human Research

Regulatory Science at the MEB and CCMO

Marjon Pasmooij and Frits Rosendaal

20 May 2026

RegulatoryScience

Regulatory Science is an **applied science** which, via various scientific disciplines, assesses internal regulations and policy in relation to the assessment of the entire life cycle of medicines.

New insights contribute to 'evidence based regulatory practice': It involves answering questions such as: ***are we doing things properly, do adjustments need to be made on the basis of new knowledge and are prepared, based on our current knowledge and expertise, for change and innovation?'***

Regulatory Science also aims to **develop and improve instruments, standards and methods** used to assess medicines in terms of efficacy, risks and quality and **improve and innovate of the system** as a whole.

MEB Science Policy 2025-2029

Replacement, reduction & refinement of animal studies

Data-driven assessment

Personalised medicine

New pharmaceutical legislation

PhDstudents (internal + external)

Naam
Audrey Hermans

Naam
Bram Storosum

Naam
Britt Duijndam

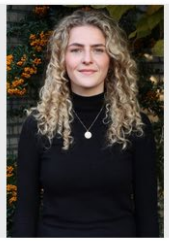
Naam
Cedrine Steinz

Naam
Christine van Hattem

Naam
Doerine Postma

Naam
Donya Moslemzadeh

Naam
Emma van Dijk



Naam
Esther Lubberts

Naam
Fabian Windführ

Naam
Geeske Grit

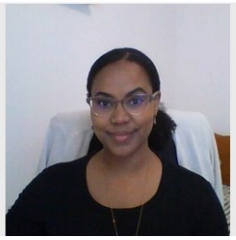
Naam
Jose Gepanaga

Naam
Judit Sebares Huerta

Naam
Loes den Otter

Naam
Loes Maton

Naam
Lucina-May Nollen



Naam
Njeri Kamau

Naam
Pieter Annema

Naam
Puck Roos

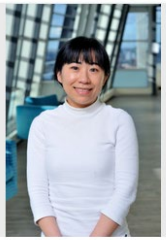
Naam
Rafaella Buzatu

Naam
Renske Grupstra

Naam
Sem Cohen

Naam
Sharon Essink

Naam
Stefan Verweij



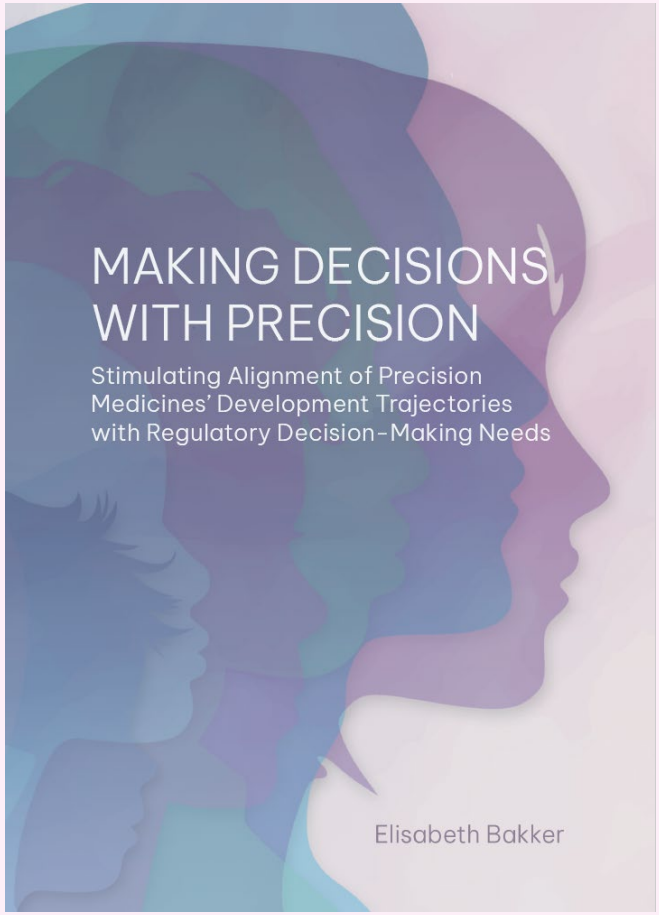
Naam
Tzu Chien

Naam
Vasiliki Tassopoulou

26 PhDstudents

PhDdefenses

7 April 2026



13 May 2026

MSCA Doctoral Networks

POLARIS: Progress in Leukodystrophies: Advance, Rate and Implement new treatment Strategies

Prof. Nicole Wolf, Amsterdam UMC

15 PhDs

1 PhD involvement supervisory role:

- Regulatory and access pathways for leukodystrophy therapies

REGOLUTION: REGolution: A training program on novel quantitative methods in regulatory decision making

Prof. Helga Gardarsdottir, Utrecht University

14 PhDs

5 PhDs involvement supervisory role:

- Bayesian and frequentist error metrics
- Registry-augmented hybrid controls for ALS Trials
- Vaccine evaluation in dynamic disease contexts
- Indirect comparisons for significant benefit: Assessing efficacy and non-inferiority
- AI in regulatory decision-making: bias and explainability

European Platform forRegulatoryScience Research

Amechanism for dialogue and collaboration between **academic, public and non-for-profit regulatory science researchers and regulators**

- To systematically advance and accelerate research addressing regulatory needs
- To refine and enrich regulatory topics with research interests and methods expertise
- To progress methodological standards and to increase the quality and relevance of research outputs for regulatory implementation
- To accelerate translation of outputs into improved R&D and regulatory practices
- To support growth of academic researcher community engaging on regulatory issues

Platform topics

Starting point: EMA's Regulatory Science Research Needs

First platform meeting (June2025)

- Pharmacological modelling research – e.g. for optimising PK (and PD) designs for extrapolation
- European assessment report as research tool

Second platform meeting (September2025)

- Biomarkers
- Clinical data publication as research tool
- Funding opportunities and regulatory involvement

Third platform meeting (April 2026)

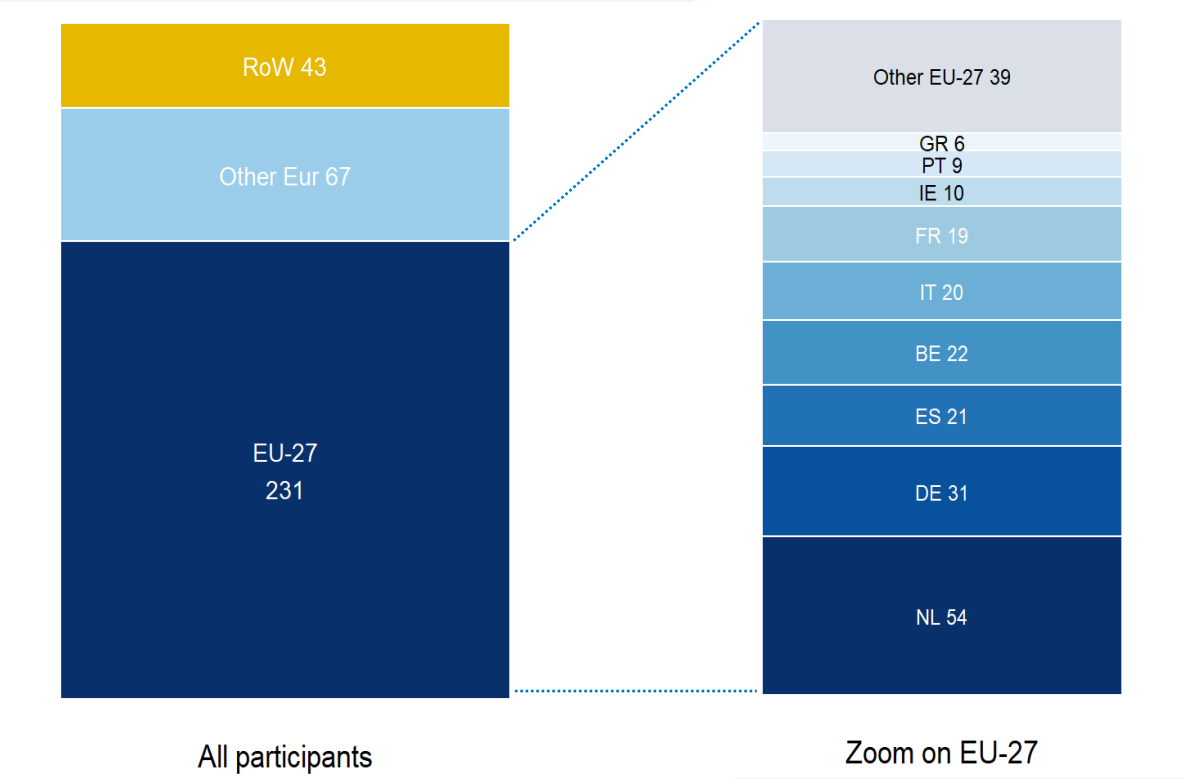
- Clinical trial registers and use by researchers
- Research and evidence generation for medicines including new uses
- RWD research: EMA/HMA Catalogues of real-world data sources and studies

Reports and outputs
https://www.ema.europa.eu/en/about-us/what-we-do/regulatory-science-research/european-platform-regulatory-science-research

Fourth platform meeting (16 June 2026)

The Platform’s growing community

Over 300 researchers and scientists and counting



Pharmacometrics
Regulatory – academic collaboration
Platform trials
Regulatory sandbox
Funding opportunities
Medical devices
Digital technologies
Modelling
Patient experience data
ATMPs
Rare diseases
Real world data
Accelerated pathways
Clinical trial methodology
New approach methodologies
Nanomedicines
Academic drug development
Regulatory – HTA interface
AI & machine learning
Uncertainty communication
Drug repurposing
Pharmacovigilance
Benefit risk methodologies
Antimicrobial resistance
Vaccines
Data availability and sharing
...
Biomarker validation

Opportunities and invitation to get involved

- Researchers from academic, public and not-for-profit institutions, as well as regulators, can participate in the platform at this time
- The platform is open to both EU and non-EU nationals
- EMA and HMA invite researchers and regulators to express their interest in participating in the platform and its meetings by completing the form available here: EUSurvey - Survey
- Platform meetings, reports and outputs available here: European Platform for Regulatory Science Research | European Medicines Agency (EMA)

- Join the growing academic researcher community working on regulatory science topics
- Suggest topics and ideas for the Platform
- Participate and collaborate on discussion sessions and working groups

Sciencæat the CCMO

- **Science**lies at the heart of the CCMO. Medical Research Ethics Committees are often the first to assess new developments in medicines, medical devices, diagnostics, and innovative treatments

- Keeping scientific knowledge up to date is therefore essential

- The scope of the CCMO is broad, e.g.:
  - medicines, medical devices and diagnostics
  - new surgical methods
  - comparison of treatments
  - psychological research (e.g., questionnaires)

Mandate and expertise of the CCMO

Founded in 1999, art. 14 "Wet medisch-wetenschappelijk onderzoek met mensen" (WMO)

Mandate

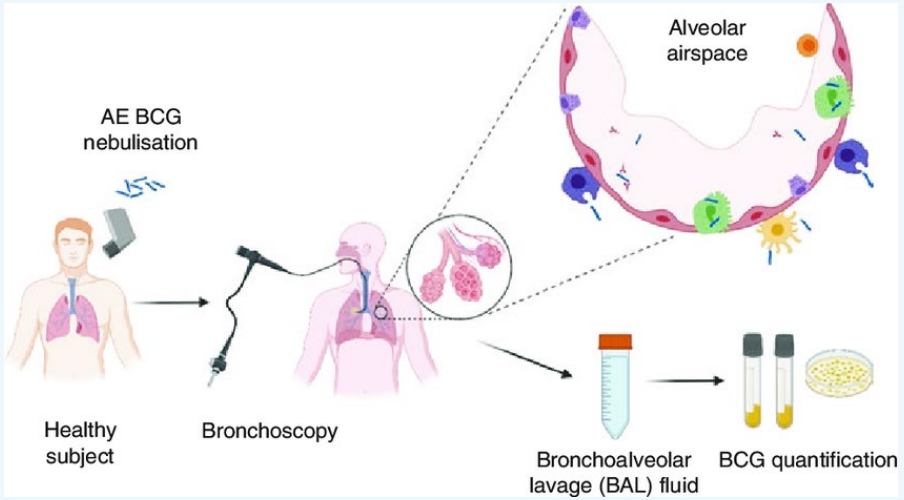
- Acts as primary ethical board for specific research protocols (minors, cell therapy, embryo research, gene therapy, heroin studies
- Oversees local medical ethics committees
- Adjudicates appeals
- Develops policies (e.g., minor intervention, N-of-1 studies)

Expertise and disciplines

- Includes expertise on ethical, clinical, methodological, pharmacological, and patients' perspective (and more)

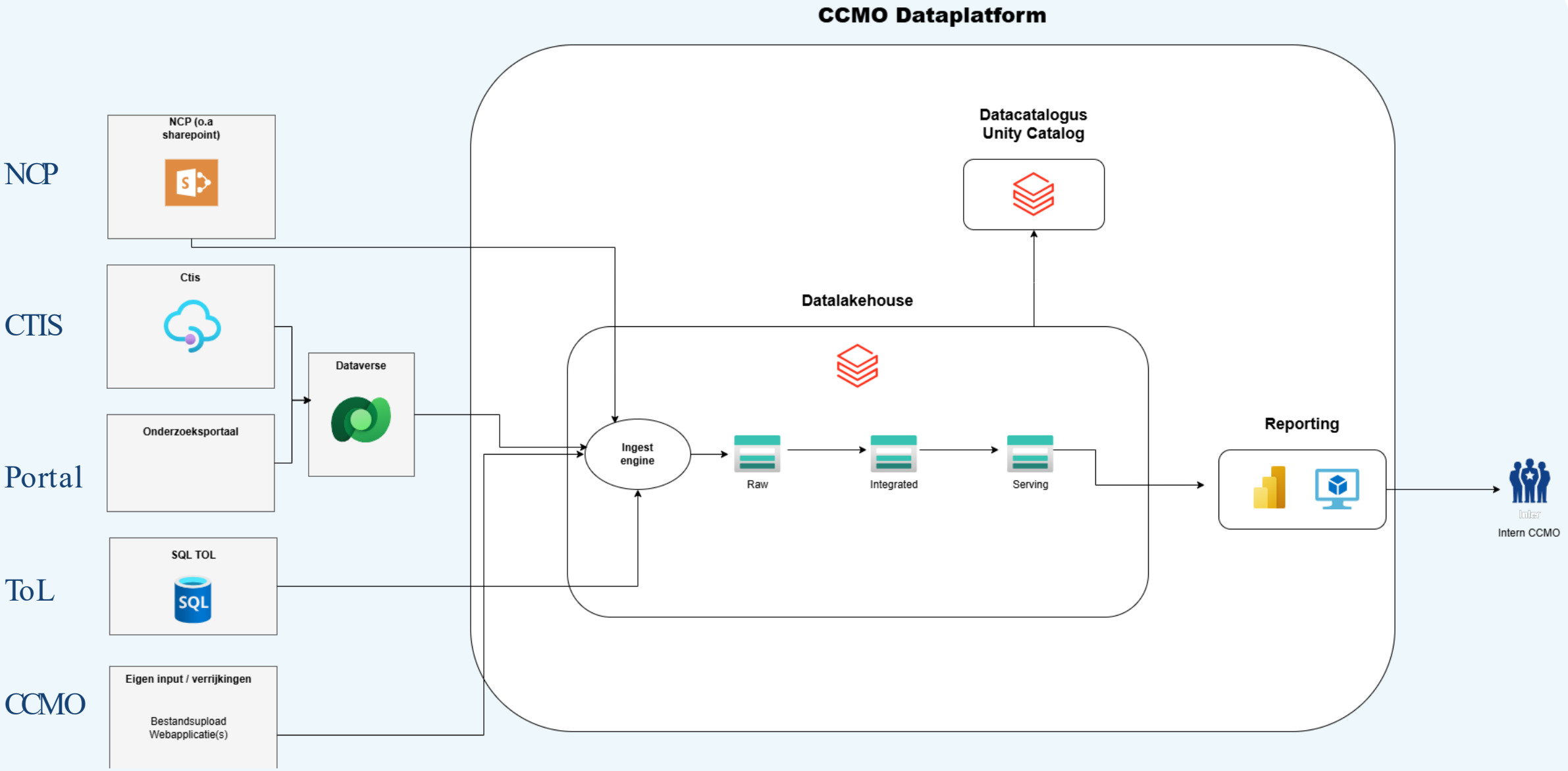
Topicsinitial projects 2025

1. Regulatory roadmap for the development of quality control of pluripotent stem cell-derived cell therapy products
2. Development of framework for research protocols with Controlled Human Infection Models (CHIM)
3. Quality concerns ATMPs
4. Premature ending of clinical trials in the Netherlands
5. Data-infrastructure: precondition of regulatory science at the CCMO (and MRECs)

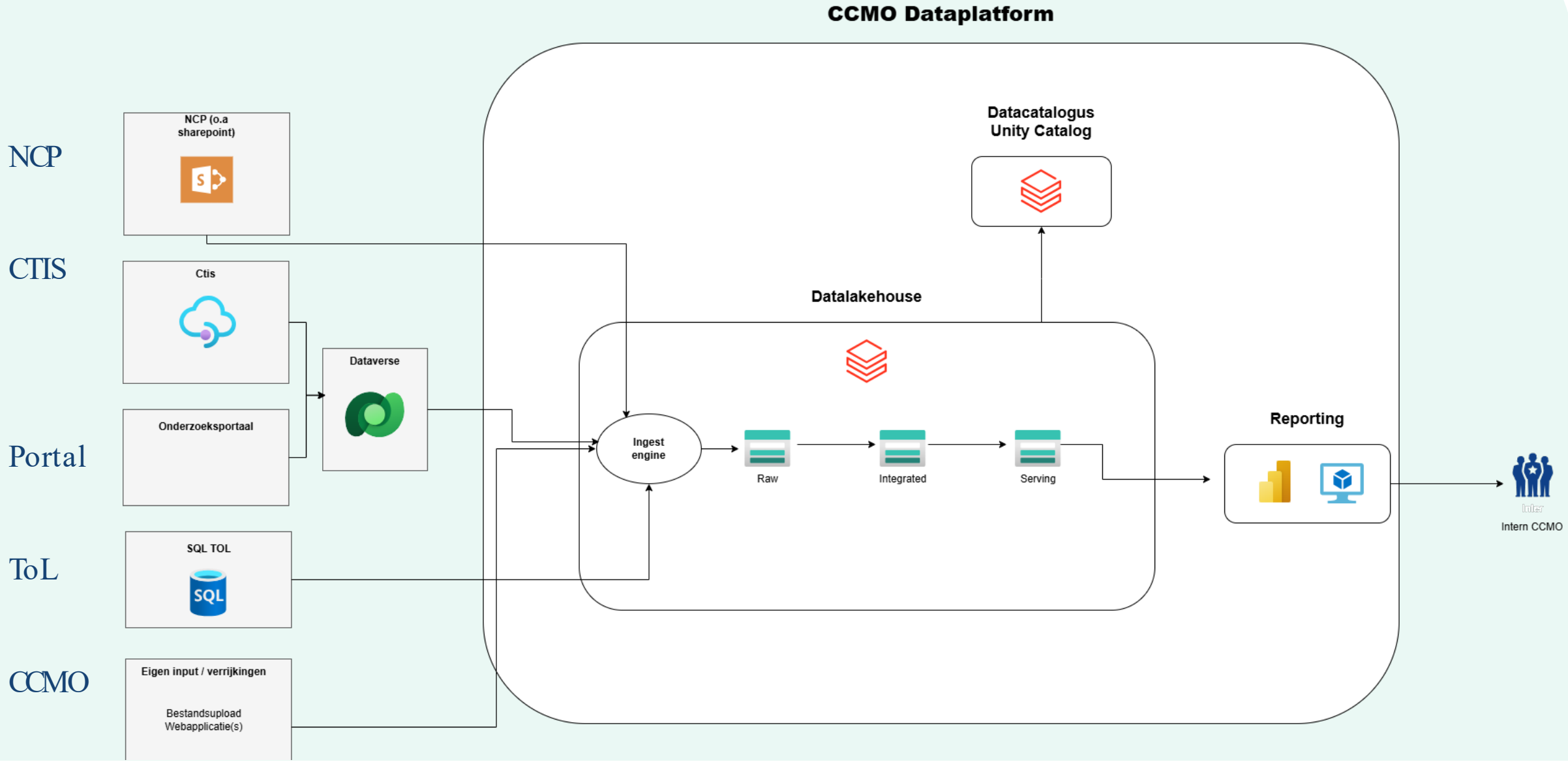


Peralta Alvarez et al., *Vaccines for Neglected Pathogens: Strategies, Achievements and Challenges*, 2023

Data-infrastructure



Data-infrastructure



Next steps at CCMO

- Further development data platform (3-year project)
- Evaluation initial research projects
- Evaluation science policy & processes, incl. further discussion with the MEB on collaboration
- New programme 2026-2027: small size science projects

Questions?

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ccmo@ccmo.nl