

The background of the slide features a close-up, shallow depth-of-field photograph of several glass beakers and test tubes. The glassware is arranged in a cluster, with some in sharp focus and others blurred. The lighting is soft and even, highlighting the transparency and reflections on the glass surfaces. The overall color palette is a range of blues, from light sky blue to deep navy blue, which is consistent with the FDA's branding.

FDA

**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DRUG EVALUATION & RESEARCH



**FDA'S BIOMARKER QUALIFICATION PROGRAM
EDUCATIONAL MODULE SERIES—MODULE 7**

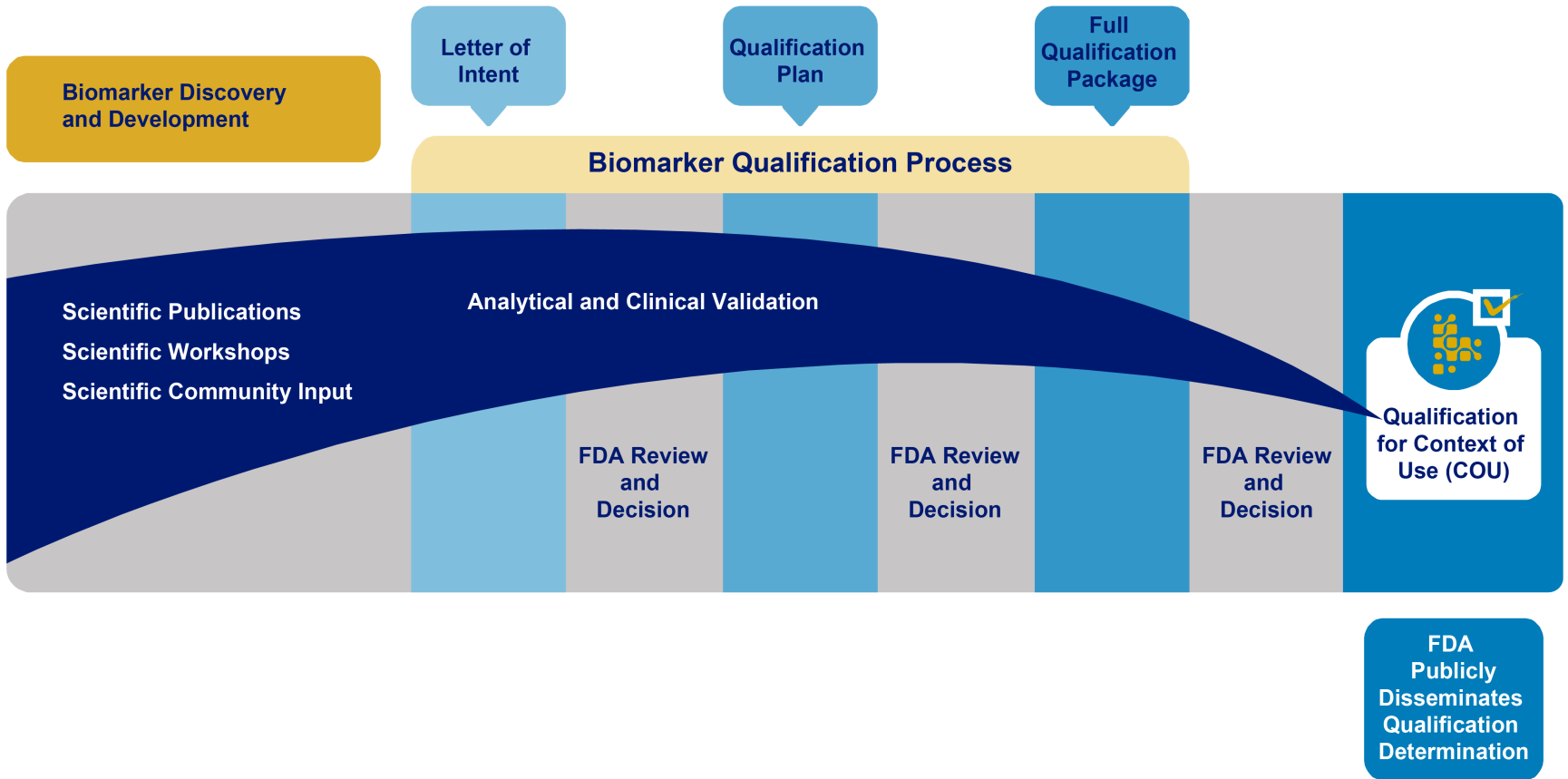
THE ROLE OF CONSORTIA IN BIOMARKER DEVELOPMENT AND QUALIFICATION

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DEVELOPMENT OF QUALIFIED BIOMARKERS





BIOMARKER QUALIFICATION IS A MULTI-STEP PROCESS

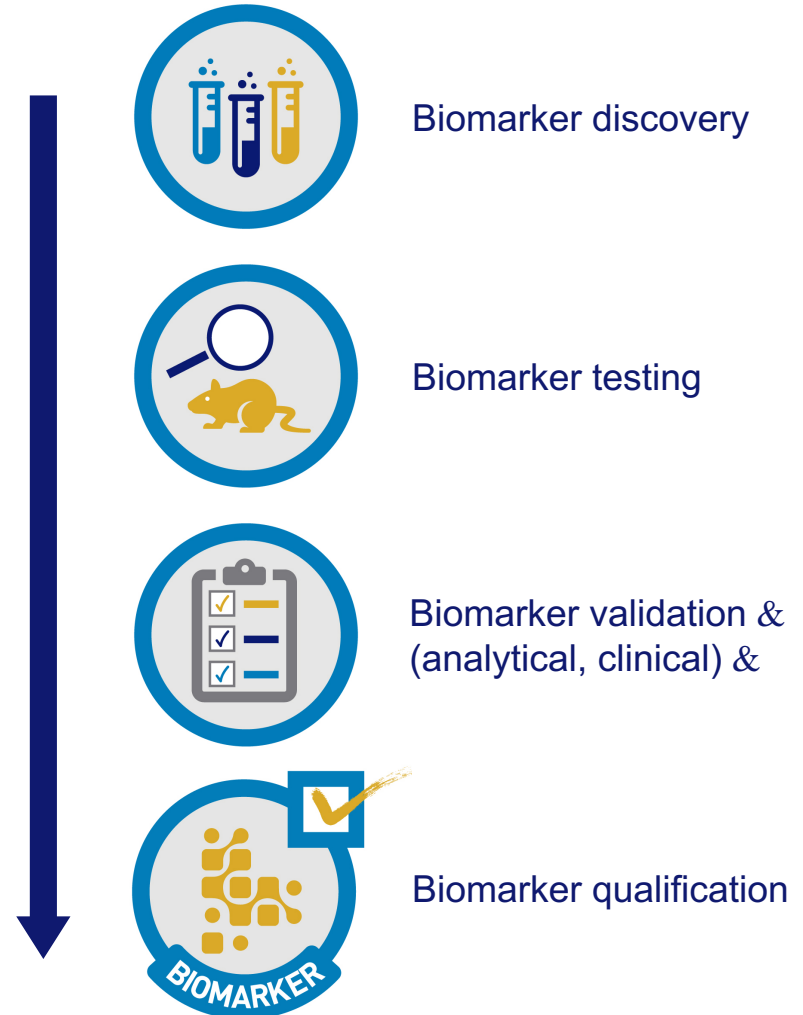


Several steps of evidence generation

Requires resources and expertise

Collaborative efforts can facilitate sharing of resources

- Biological samples
- Data
- Scientific knowledge and expertise &
- Leverage costs

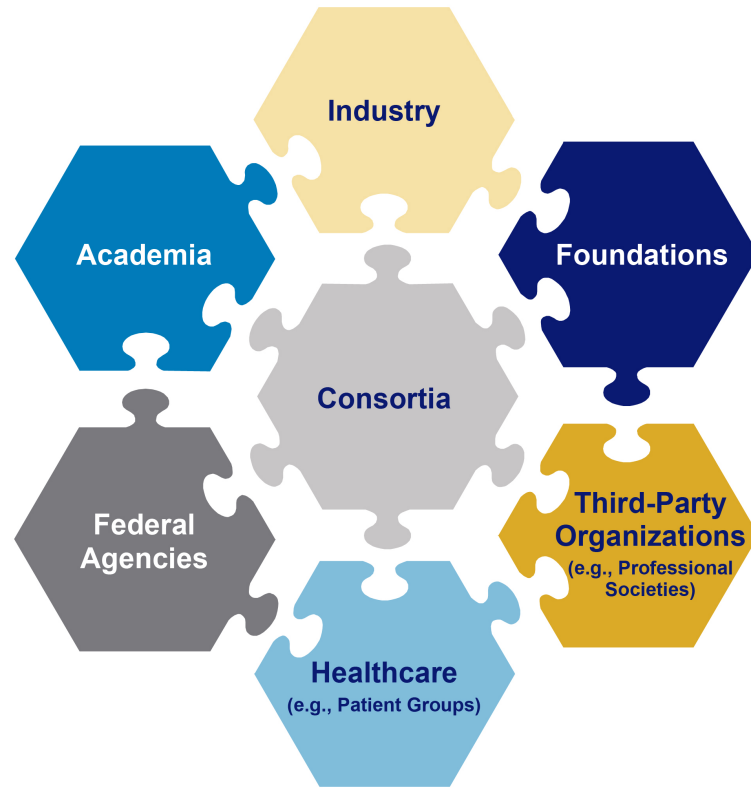




WHAT ARE CONSORTIA? &



A consortium is a & collaborative group & managed by a convening or & coordinating organization & involving multiple & stakeholder organizations including at least one non-profit or 501(c)(3) & organization and at least & one for profit organization. &



[MAPP 4100.2 CDER Staff Participation in PPPs and Consortia](https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM532571.pdf)

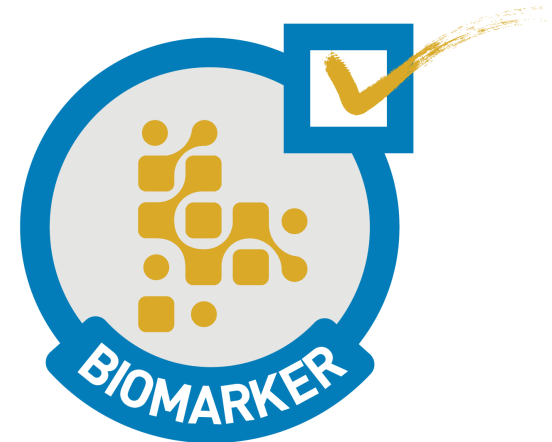
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ROLE OF CONSORTIA IN THE DEVELOPMENT AND QUALIFICATION OF BIOMARKERS

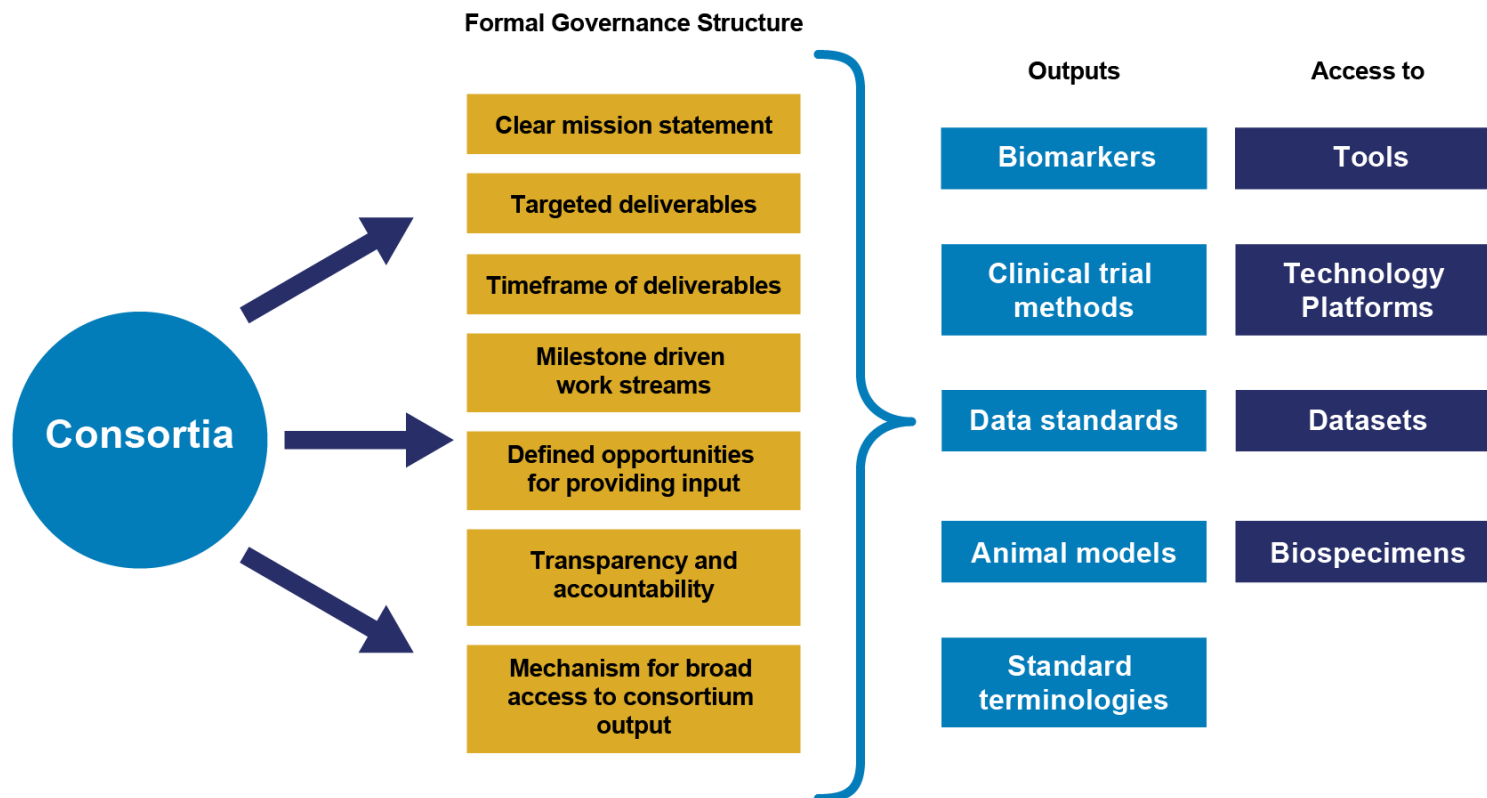
FDA

- Provide a neutral collaborative environment for partnering, sharing, and leveraging the resources for biomarker development and qualification
- Facilitate workshops, scientific discussions, gather input from scientific community, and to streamline advances in regulatory science
- Provide an opportunity for scientific staff engagement to discuss current thinking on biomarkers and other regulatory science efforts.

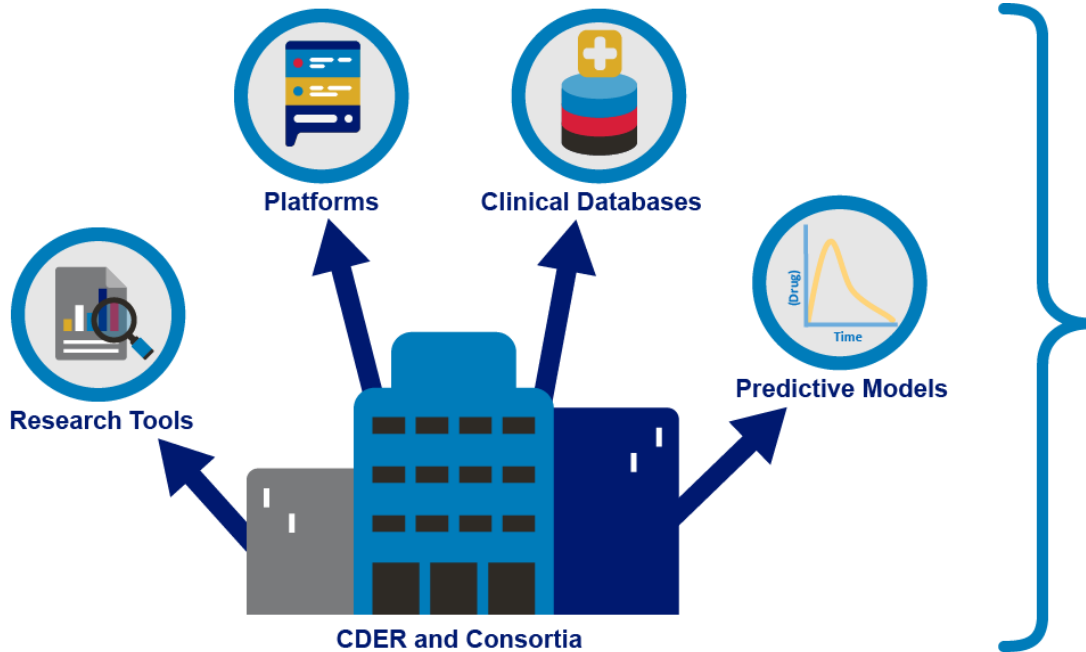




VALUE OF CONSORTIA &



CDER ENGAGEMENT WITH CONSORTIA EFFORTS



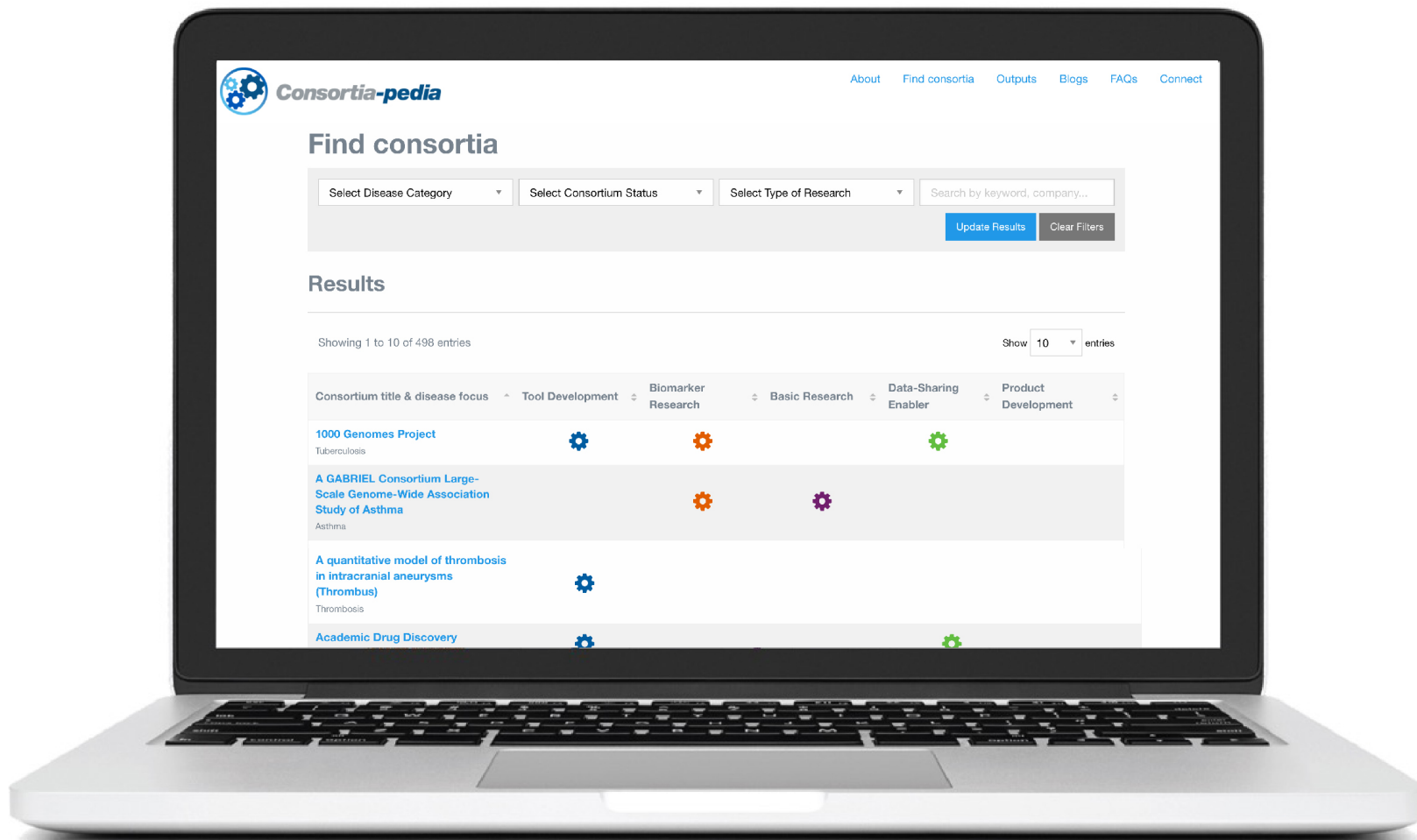
Project results are made publicly available to benefit public health



For more information: &

[MAPP 4100.2 CDER Staff Participation in PPPs and Consortia &](#)

<https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM532571>





LEARN MORE &

FDA

www.fda.gov/BiomarkerQualificationProgram

Learn more about CDER's engagement with consortia efforts:

<https://www.fda.gov/Drugs/ScienceResearch/UCM575772.htm> &