



## **DEPARTMENT OF COMMERCE**

### **National Institute of Standards and Technology**

#### **Intent to Establish Isotope Metallomics Quality Assurance Consortium**

**AGENCY:** National Institute of Standards and Technology (NIST), Department of Commerce.

**ACTION:** Notice of research consortium.

**SUMMARY:** The National Institute of Standards and Technology (NIST), an agency of the United States Department of Commerce, in support of efforts to develop and evaluate measurement methods and reference standards, including reference materials, to support measurement quality and comparability for the isotope metallomics measurement community, is establishing the Isotope Metallomics Quality Assurance Program (IMQAP) Consortium (“Consortium”). The Consortium will bring together stakeholders to identify and address measurement and standards needs related to isotopic measurements of clinical/biological materials and products. The Consortium efforts are intended to advance measurement capabilities, provide measurement quality assurance strategies, support the development of clinical/biological matrix reference materials, and collect data to support the development of best practices and standard methods. Participants will be required to sign a Cooperative Research and Development Agreement (CRADA). At NIST’s discretion, entities that are legally prohibited or not legally authorized to enter into a CRADA may be allowed to participate in the Consortium under an agreement other than a CRADA with terms that may differ, as necessary, from the CRADA terms.

**DATES:** The Consortium’s activities will commence on September 1, 2025 (“Commencement Date”). NIST will accept letters of interest to participate in this Consortium on an ongoing basis.

**ADDRESSES:** Completed letters of interest must be submitted via the letter of interest webform at <https://forms.gle/BFUIDXuAqSxa2XZUA>, by email to [jacqueline.mann@nist.gov](mailto:jacqueline.mann@nist.gov), or via hardcopy to the Consortium Manager, Dr. Jacqueline Mann, Chemical Sciences Division of NIST's Material Measurement Laboratory, 100 Bureau Drive, Mail Stop 8391, Gaithersburg, Maryland 20899. Organizations whose letters of interest are accepted in accordance with the process set forth in the **SUPPLEMENTARY INFORMATION** section of this notice will be asked to sign a consortium CRADA with NIST. A consortium CRADA template will be made available to qualifying applicants.

**FOR FURTHER INFORMATION CONTACT:** Jaime Maynard, Technology Transfer Agreements Specialist, Consortia Agreements Specialist, National Institute of Standards and Technology's Technology Partnerships Office, by mail to 100 Bureau Drive, Mail Stop 2200, Gaithersburg, Maryland 20899, by electronic mail to [Jaime.Maynard@nist.gov](mailto:Jaime.Maynard@nist.gov) or by phone (301) 975-8408.

**SUPPLEMENTARY INFORMATION:** The objective of the IMQAP is to develop and evaluate measurement methods and standards to support quality and comparability of metal isotope measurements for the isotope metallomics community with the aim of facilitating the adoption of isotope analytics by clinical laboratories and practitioners. Naturally occurring stable metal isotope analytics in the health and medical sciences (Isotope Metallomics) has demonstrated high potential for clinical biomarker development, diagnostics and prognostics. Isotopic biomarkers demonstrate higher sensitivity and specificity for some pathologies compared to standard biochemical markers as they are less susceptible to complex biochemical processes than traditional molecular-based biomarkers. For instance, Copper (Cu) isotope ratios can detect breast and colorectal cancers several months earlier than traditional biomarkers and Calcium (Ca) isotopes in blood and urine are able to detect musculoskeletal diseases such as osteoporosis years before the standard method of Dual X-ray absorptiometry (DXA). Chronic diseases like diabetes, cardio-vascular diseases, and cancers are the leading cause of death worldwide. It is

estimated that by 2030 the cost of these diseases will reach \$47 trillion worldwide. The yearly cost of these diseases to the American medical system is more than \$1 trillion and only growing larger. In response to the ever-rising costs, there is a clear movement away from the current reactive intervention-based healthcare model toward predictive, preventive, and personalized medicine (PPPM) for optimal and cost-effective healthcare. This new model will demand a new generation of biomarkers that are capable of early detection and provide for effective monitoring of targeted therapies. Isotope analytics are emerging as powerful tools for addressing this need. The focus of this Consortium is to evaluate, develop, and standardize methods of characterization for metal isotopes in clinical/biological materials improving the metal isotope measurement methodologies and capabilities employed by the isotope metallomics community and the overall measurement comparability within the community enabling organizations that join the Consortium (“Consortium Members”) to improve the accuracy and precision of their measurements and build the quality and confidence needed for adoption of metal isotopes as a tool in the clinical setting. The IMQAP Consortium will work together to address the following goals:

- Evaluate the applicability of current reference materials to meet the needs of the isotope metallomics community. If needed, develop new reference materials to support advancement of the isotope metallomics measurement community.
- Evaluate the suitability of current measurement approaches (e.g., repeatability and comparability) to measure the suite of relevant metal isotopes using interlaboratory exercises based on candidate reference materials and/or commercial products.
- Utilize common clinical/biological materials to collect reproducibility data in support of measurement assurance and standards development.
- Propose tests(s) that can be standardized through the clinical lab standards organization or similar consensus process, using outcomes from Consortium efforts as a foundation.

- No proprietary information will be shared as part of the Consortium. Contributions of materials to be used as interlaboratory study samples, such as chemical/biological materials, are highly encouraged

## **Participation Process**

NIST is soliciting responses from all sources, including other Federal Government agencies, foreign government agencies, industrial organizations (including corporations, partnerships, and limited partnerships, and industrial development organizations), public and private foundations, and nonprofit organizations (including universities). Eligibility to participate in the Consortium will be determined by NIST based on the information provided by prospective participants in response to this notice. Prospective participants can submit a letter of interest by completing the letter of interest webform at <https://forms.gle/BFU1DXuAqSxa2XZUA> alternatively, parties can answer the questions detailed in LETTER OF INTEREST, below, and send via email or hardcopy (for reference, see **ADDRESSES** section above). NIST will contact interested parties if there are questions regarding the responsiveness of the letters of interest to the project objective or requirements identified below.

Each responding organization's letter of interest should include the address, point of contact, and following information:

(1) The contribution(s) the organization will make to the Consortium efforts. All Consortium members must contribute one or more of the following:

- a. Analytical Testing: Narrative of interest and experience in the measurement of stable metal isotopes of biological materials and description of the services and/or technical capabilities (*e.g.*, available instrumentation, published methods, relevant accreditations) they will contribute to Consortium activities.
- b. Materials: Narrative of interest and description of the biological materials and products they will contribute to Consortium activities.

c. Unique Industry or Community Perspective: Narrative of interest and description of other relevant expertise (*e.g.*, standards development, measurement methods development) they will contribute to Consortium activities.

(2) List of interested party's anticipated participants.

Letters of interest must not include proprietary information, including proprietary business information. NIST will not treat any information provided in response to this notice as proprietary information. NIST will notify each organization of its eligibility to join the Consortium. In order to participate in this Consortium, each eligible organization must sign a CRADA. Entities that are legally prohibited or not legally authorized to enter into a CRADA may be allowed to participate in the Consortium, at NIST's discretion, under an agreement other than a CRADA with terms that may differ, as necessary, from the Consortium CRADA terms. Foreign governmental entities may, at NIST's discretion, be permitted to participate in the Consortium under an appropriate international agreement. NIST does not guarantee participation in the Consortium to any organization submitting a letter of interest.

(Authority: 15 U.S.C. 3710a)

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