Request for Information Viral Vectors Interlaboratory Evaluation Study for an SV-AUC Method Harmonization (Viral Vectors RFI 2025.01)

RFI Release Date: September 9, 2025

Submission Due: October 1, 2025 (5 pm ET)

1. Overview

The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is dedicated to advancing biopharmaceutical manufacturing innovation, developing standards to enhance manufacturing efficiencies and speed, and cultivating a leading biopharmaceutical manufacturing workforce. This Request for Information (RFI) seeks to gather community engagement for a future interlaboratory study into SV-AUC Method Harmonization. This initiative aims to support NIIMBL's Viral Vector program in biomanufacturing. This RFI does not constitute a funding opportunity and is not a solicitation of proposals for funding.

2. Background

NIIMBL invites submissions from NIMBL members interested in or experienced with Sedimentation Velocity Analytical Ultracentrifugation (SV-AUC) Methods used for of Adeno-Associated Virus (AAV) Analysis.

NIIMBL's Viral Vector program is driving innovation in AAV gene therapy to bring transformative treatments to the rare disease community. By addressing specific challenges in the quality control of AAV therapies, NIIMBL aims to improve the confidence of sponsors and manufacturers in the quality and safety of their novel therapeutics. Through the leveraged scientific expertise within NIIMBL member organizations, the future study aims to bring clarity in best practices for measuring AAV capsid content, a critical quality attribute, as measured through SV-AUC. The future RFA will seek collaborators, and study participants who will have the opportunity to anonymously benchmark capabilities for ensuing product quality while directly contributing to advancing cutting-edge analytical solutions that will accelerate the development and accessibility of life-changing therapies. It is NIIMBLs intent to make the methods, data, and findings resulting from this proposed RFA publicly available (i.e., fully open-access) for use by any 3rd party for any purpose whatsoever.

Purpose of this RFI:

- To identify and engage capable parties for participation in a future interlaboratory study focused on the harmonization of AAV analysis by SV-AUC. This initiative aims to bring together laboratories with relevant expertise to collaboratively evaluate and align on SV-AUC best practices, specifically, sample preparation, data collection, analysis, and reporting across the field.
- Compile community stakeholder input on the utility of SV-AUC for AAV analysis in the context of therapeutic characterization and/or batch release.

Note: This RFI does not constitute a solicitation for funding proposals.

3. Detailed Request

Your Input Matters

A previous interlaboratory study [https://pubmed.ncbi.nlm.nih.gov/39723438/] showed variability of AAV species quantitation by SV-AUC between different laboratories, highlighting the need for a robust, standardized SV-AUC workflow available to the gene therapy and broader scientific communities. The NIIMBL Viral Vector Program is planning a future project to support the harmonization of SV-AUC protocols for AAV analysis. This RFI is soliciting the community for interest in, and capability for a prospective interlab study as described below. The full scope of the interlab study will be scaled to the NIIMBL community's indicated capability to support.

Interlab Study Goals:

This planned study aims to:

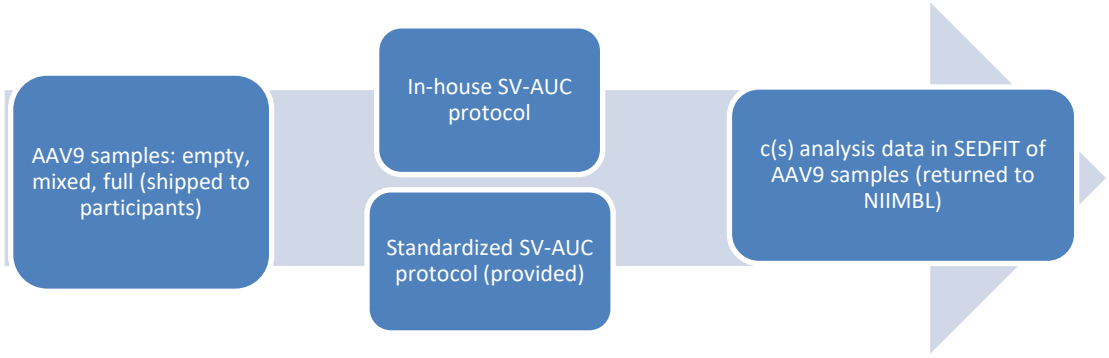
- Develop a set of best practices / recommendations along with a standardized platform protocol

for AAV analysis by SV-AUC, including experimental setup, execution, and data analysis.

- Evaluate performance of the proposed platform method through an interlaboratory study using a NIIMBL provided set of AAV samples covering representative ranges of full and empty capsids, as well as other AAV capsid species.
- Publish and make broadly available the materials and methods for the proposed platform SV-AUC, as well as study generated supportive data.

Interlab Study Design:

To achieve these goals, the project team will distribute the proposed NIIMBL platform SV-AUC protocol and a panel of AAV9 samples (representing full, empty, and other capsid species) to participating laboratories. Participants will analyze the samples using both their in-house SV-AUC method and using the NIIMBL provided platform protocol and outlined below. The data from both methods will be anonymized, blinded, and aggregated by NIIMBL. The data will be used to evaluate the performance of the NIIMBL platform SV-AUC protocol. Further, an anonymized benchmarking report, with follow up consultation upon request, will be provided to each study participant.



The results of the future study are planned to be submitted for publication in a peer-reviewed journal. The NIIMBL Led Viral Vector Program believes that this initiative will drive further harmonization of SV-AUC measurements across the AAV and AUC communities.

4. Submission Details:

Submissions of a response to this RFI should be limited to 4 pages. Submitters are encouraged to include the following information.

A. **Experience or Position**: A brief summary of your experience or subjective position on the performance or utility of using SV-AUC for measuring capsid content of AAV vectors. This may include, but is not limited to, past or present challenges in the method as well as value for monitoring and controlling product quality in therapeutic applications.

B. **Organizational Capabilities**: An overview of an organization's capabilities, instrumentation, and facilities that could support the proposed interlaboratory SV-AUC study. Prior experience in using SV-AUC for analysis of AAV vectors, alternative delivery vectors, or other comparable analytes.

C. **Interest in Participation:** A non-funded interlab study will be conducted as previously described in section 3. An indication of motivation and willingness for participation in the study, as well as known constraints.

5. Submission Process

Submissions must be sent via the NIIMBL submission hub by the due date. Late submissions will not be considered.

6. Use of Information

The insights and information gathered from this RFI will be used to inform strategic planning for future solicitations. We discourage any sharing of proprietary information related to a respondent's in-house methods, as this is not required to participate in this study. Shared information, excluding organizational capabilities, may be used in future publications. Shared information regarding organizational capabilities may only be published with prior written approval of the referenced organization.

7. Encouragement for Broad Participation

We encourage submissions from a wide range of member stakeholders, including academic institutions, industry, technology providers, and other consortia members. Any submissions received from non-members of NIIMBL will only be considered if a Member Agreement has been submitted by the RFI submission deadline.

Regardless of comprehensive solutions, or insights into specific technical challenges with measuring AAV capsid content, your input is valuable. Feedback on this RFI's scope, requirements, and objectives is also welcome, as it will help refine our approach to addressing the needs of the biomanufacturing sector.

We look forward to engaging with the community to gather valuable information that will shape future initiatives. For more information, please contact projectcalls@niimbl.org.

8. Abbreviated List of Acronyms

RFI:	Request for Information
NIIMBL:	National Institute for Innovation in Manufacturing Biopharmaceuticals
SV-AUC:	Sedimentation Velocity Analytical Ultracentrifugation
AAV:	Adeno-Associated Virus