Transgene's Bid Submission to Participate to Long-term Stability Studies
RFP 12.0

1. Global Amount of Ad5 WT Reference Material required

40 vials of Ad5 WT Reference

2. Commitment to monitor stability

We suggest to monitor the AdW5 reference stability only when stored at minus or equal to -55°C. Transgene will store the product at –70°C as –70°C freezers are available in the company. Testing the stability at – 20°C does not seem essential as –70°C freezers are available in most laboratories. Moreover, -70°C is generally recommended for the storage of live viruses.
Commitment to perform stability indicating tests; including sterility assessment and AdW5 materiel required is presented in the following table:

	Analysis				
Time-poin s (months)	Sterilit r	OD260/SDS	AE-HPLC	Infectious ti er	Detection f aggregate
0		2 vials	1 vial	1 vial	0 (see AE-HPLC)
6		2 vials	1 vial	1 vial	0 (see AE-HPLC)
12	2 vials	2 vials	1 vial	1 vial	0 (see AE-HPLC)
18	2 vials	2 vials	1 vial	1 vial	0 (see AE-HPLC)
24		2 vials	1 vial	1 vial	0 (see AE-HPLC)
36	2 vials	2 vials	1 vial	1 vial	0 (see AE-HPLC)
48	2 vials	2 vials	1 vial	1 vial	0 (see AE-HPLC)
60		2 vials	1 vial	1 vial	0 (see AE-HPLC)

3. Analytical Methods, personnel qualification and equipment

We propose the following analytical methods to test the stability of the AdW5 reference in long-term stability studies at each time point:

3.1 OD 260nm/SDS

Expertise, personnel qualification and equipment are described in Transgene's bid submission for RFP 8.0.

3.2 Anion exchange analytical HPLC

SOP, expertise, personnel qualification and equipment are described in Transgene's bid submission for RFP 8.0.

3.3 Infectious titer by TCDI50 assay

Expertise, personnel qualification and equipment are described in Transgene's bid submission for RFP 9.0.

3.4 Determination of aggregation by Photon Correlation Spectroscopy

SOP, expertise, personnel qualification and equipment are given in Transgene's bid submission for RFP 10.0.

4. Container integrity testing (sterility testing)

As proposed by the Working Group, test for sterility could be performed only at selected time-points over the five-year period. Moreover, we suggest that it could be perform in only one laboratory. More extensive studies will require too many vials from the reference lot.

If requested, these sterility tests could be performed in Transgene's QC lab by membrane filtration.

4. Plan for the beginning of the studies and for the data reporting

Transgene will be ready to begin testing in early to mid-September and to complete the analyses within 30 days of each time-point.

Stability data will be submitted to the Working group one month after each time-point.

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Please complete the following fields:

Contact Information – RFP 12.0

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***If laboratories are submitting a proposal as a group, a main contact should be provided along with contact information for each participating laboratory (attach additional copies of this form).**

Please indicate if your institution is also submitting proposals for the other activities:

- ☐X Determination of Particle Concentration
- ☐X Determination of Infectious Titer
- ☐X Short-term Stability Study
- ☐X Other Characterization
- ☐ Donation of Supplies/Other Services for Characterization Phase