



QUALITY ASSESSMENT ROUND 2022

A Quality Assessment Scheme
for human induced Pluripotent Stem Cell lines



Quality Assessment Round

A Quality Assessment Round (QAR) is a process by which a community of scientists develops greater assurance that the testing carried out is consistent with that of others in the community (i.e. that testing is consistent and reliable across sites).

This QAR specifically focuses on one quality test, biomarker expression analysis by flow-cytometry, for iPSC lines where Pharmacopeial guidance is currently lacking, and seeks to provide greater confidence in the reliability of iPSC quality testing.

The QAR itself follows on from the publication of:

[‘Quality control guidelines for clinical-grade human induced pluripotent stem cell lines’](#)

in September 2018 and the first iPSC QAR in 2019. It is part of a larger ongoing QC process to enable use of clinical-grade iPSC lines as a starting material for the generation of cellular therapeutics. The ultimate goal of this larger QC process is demonstration of comparability of lines derived from different individuals and in different facilities associated with the GAiT global haplobank network.

Quality Assessment Round Organizers

The Quality Assessment Round is being organised by 2 organisations: The Centre for iPSC Research and Application Foundation, Kyoto University (CiRA F) and The Global Alliance for iPSC Therapies (GAiT).

More information about each Organisation can be found on the GAiT website.

Quality Assessment Round Cost

CiRA Foundation has secured a grant from the Japanese Ministry of Health Labour and Welfare (MHLW) to cover the costs of iPSC QAR 2022.

Pilot Study

A pilot study where 5 Participants were provided samples, materials and a protocol to analyse biomarker expression by flow cytometry, will be completed prior to the iPSC QAR 2022. This is to test the suitability and quality of the distributed materials and to assess logistics of shipping to ensure that provision of materials to all Participants in iPSC QAR 2022 progresses as smooth as possible.

Quality Testing

QAR Participants will be asked to carry out two Quality Tests. The first using the provided antibodies and protocol and the second as they normally do, according to their own protocols and procedures within the broad parameters outlined in the instructions.

	Samples	Antibodies	Protocol
Quality Test 1	CiRA F	CiRA F	Quality Assessment Round
Quality Test 2	CiRA F	Participants own	Participants own within the broad parameters outlined in the instructions

Data

Participants will be provided a codename and individual logins for the GAIT website portal where each Institute will be assigned a folder that only themselves and the QAR2 organisers can access.

All data will be anonymized and will remain the property of the Participant. Organisers will ensure Participants will only be able to access their own individual data sets and not those provided by other Participants.

The data will be collated and analysed, after which Participants will be able to see the full data set. It is intended that the data and findings from QAR 2022 will be discussed with all Participants and submitted for publication.

Enrolment

Participants are required to login to the GAIT Website (Link below) and formally register for the iPSC Quality Round 2022 by completing the Enrolment Checklist and uploading it to their assigned folder.

<http://www.gait.global/login/>

Accessing the assigned folder:

- When a Participant logs in, they should be redirected to their dashboard (or they can press member forums in the menu bar so they are taken to their dashboard)
- Within the dashboard there is a mini menu bar below the profile photo that has links, the last link is QAUpload.
- The Participant can click on QAUpload to access the file manager and upload files.

Additional Information

For more information on the iPSC QAR 2022 please follow the link below to the GAIT website. There you will find details of each stage of the process and have access to QAR2 documentation, including but not limited to: links to surveys, Quality Test instructions and templates.

[iPSC Quality Assessment Round 2022](#)

If you have any questions or queries please do not hesitate to contact Rachel Wood at rachel.wood4@nhs.scot.