QUALITY ASSESSMENT
ROUND 2022
**A Quality Assessment Scheme
for human induced Pluripotent Stem Cell lines**

Glossary of Terms

Development of novel cellular therapies requires different areas of expertise across many functions, and inconsistent use of key terminology can remain undetected and yield misunderstandings [3]. These can, in turn, influence the final product quality to a significant degree. Thus, an important part of the Quality Assessment Round process will be to precisely and simply define what is meant by key terms to remove variation of Participants' understanding.

CiRA Foundation Japanese iPSC R&D Institute in Kyoto University. CiRA's mission is the promotion of the seamless translation of iPSC fundamental research to preclinical and clinical applications and to allow Japan to benefit from Prof. Yamanaka's Nobel Prize winning work.

GAiT A Non-profit Organisation funded by non-commercial partners (see website) with a mission to build a global haplobank network to assist with allogeneic iPSC therapeutic development worldwide. GAiT's mission is to enable the global human community the opportunity to benefit from the new generation of cell therapies by facilitating the development of, and access to, clinical-grade and haplotyped induced pluripotent stem cells for the manufacture of cell therapy products.

Haplobank A stem cell repository where cells have been HLA-haplotyped prior to deposition.

Haplobank Network A virtual network of practices of standards, definitions, and processes allowing the efficient sharing of clinical-grade iPSC lines between haplobanks.

Instructions In the context of this Quality Assessment Round, instructions refer to:

- Those routinely issued by suppliers with the Quality Assessment Round components
- Instructions relating to Quality Assessment Round deadlines, MOUs, purchasing, uploading raw and analyzed data to the Data Portal (including the Participant Quality Survey and data templates), and manuscript preparation.

As the purpose of the Quality Assessment Round is to assess variability and comparability of Quality Testing, it is important that Participants follow the instructions closely.

Organiser Any organisation that is directly involved in supplying resources and developing process documentation for the Quality Assessment Round process.

Participant Any institution or individual who has registered to participate in the Quality Testing outlined in the Quality Assessment Round process.

Quality Assessment Round A process by which a community of scientists gets greater assurance that their quality testing is consistent with others in the community (i.e. that testing is consistent across sites). In this document the term refers explicitly to testing for specific release criteria listed in Sullivan et al. (2018) [4].

Quality Assessment Round Data Portal Accessed through the GAiT.global website using a username and password, this interface is where Participants can input their shipping information, upload their raw and templated datasets, and see the anonymized and amalgamated dataset generated from all Participants data.

Quality Assessment Round materials These comprise a set of numbered control samples for testing biomarker expression analysis by flow cytometry (CiRA F) and instructions.

Quality Assessment Round Participant Survey This is a survey filled out by all Quality Assessment Round Participants on how they understand and test quality of their iPSC lines. It also asks specific technical questions as to how the Quality Tests were carried out (e.g. which antibodies or model of flow cytometer is to be used to assay biomarker expression).

Quality Testing Any activity which tests for characteristics thought or known to affect the utility of iPSC lines in therapeutic development

Tester Any institution or individual that is directly involved in the Quality Testing activity described in this Quality Assessment Round process. A tester can be a Quality Assessment Round Participant or a third party acting under direction from the Participant (e.g. CRO, quality testing service provider). Accreditation details of testers should be included in the Quality Assessment Round Participant survey where appropriate.