Leids Universitair Medisch Centrum

Information Note

Automation of Cell line development for genetically modified hiPSCs

First information note

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Introduction

General
This Information Note contains our answers and reactions to question and notes made by interested parties. This Information Note forms part of the Procurement Documents and shall prevail over the Descriptive Document and its accompanying Appendices.

Questions/comments from Interested Parties and answers/responses from LUMC

Ref. Nr.	Subject	Question	Answer
1	Appendix 3 - 2	The platform must be able to do at least 20 workflows simultaniously (see Appendix workflow). Though not necessarily started at the same time. Could you please confirm whether the 20 workflows refer only to those listed in the “Workflow and SOP” tab? Additionally, does this requirement mean that you would like to initiate multiple batches of plates on different days, starting each batch from the beginning of the workflow while earlier batches are already further along in the process?	We confirm that we aim to automate the workflow and related SOPs as indicated in the "Workflow and SOP" tab. In future, we might adapt our workflow or add additional workflows, we therefore wish flexibility in workflow design. However, other workflows will not be taken into account when assessing this tender and the proposed throughput. We also confirm that we would like to initiate multiple batches of plates on different days, each beginning at the starting point of the workflow, while other batches are already in process.
2	Appendix 3 - 4	4. It is desirable for the platform to reliably run autonomously for at least 60 hours, over the weekend, when operators are not usually present. Only imaging and refreshing steps will be done during the weekend. Does this mean that the automated imaging and refreshing steps need to take place over the weekend? If not, could you please clarify what is meant by the comment that these steps will only be carried out during the weekend?	What we meant by point 4 is that we would like the platform to preform some tasks, but not all, over the weekend when operators are not present. We envision that imaging and refreshing can be done on the weekend in the absence of operators. While we think that other processes would require operator presence and thus can only be performed during regular working hours.
3	Appendix 3 - 13	The platform must have anti-microbial worksurfaces to reduce potential sources of contamination. Could you please clarify what is meant by “antimicrobial worksurfaces”? Additionally, how do you define the “platform” in this context? As most of the devices will be integrated and labware will need to be transferred between them, I would also like to understand how this requirement applies across the system. Given that the setup will include a Biosafety Level I enclosure, would this already address the requirement in question?	In the context of worksurfaces, we mean any (support) tables or other surface area that is not part of an instrument, like the liquid handler or incubator. These surfaces should be resistant to chemicals and be non-porous. Currently, we use “Trespa® TopLab®PLUS” for our laboratory workbenches which fulfill the requirements set by our health and safety department.
4	Appendix 3 - 43	The liquid handler deck can be optimally reached by the robot arm.	See below
5	Appendix 3 - 48	The robot arm should be fully capable of accessing all critical positions on the liquid handler's deck, ensuring efficient handling of time-consuming tasks like the passaging of hiPSCs. As this requirement is currently marked as a “must,” we would like to ask whether it could be reconsidered as a “wish,” given that our solution does not require the robotic arm to access the liquid handler deck.	We are not willing to make the presence of the robot arm a “wish”. Although we acknowledge that an initial design without a robotic arm is possible, we think it will very much limit our future expansion capabilities.

6	Appendix 3 - 66	The software must allow protocols to be run with diverse labware and adjust protocols automatically. Could you please clarify what is meant by “adjust protocol automatically”? Under what circumstances would this need to occur? Is this referring to situations where changing the labware in the software would automatically update the corresponding protocols or methods?	What we mean by 'adjusting the protocol' is that when we need to use alternative labware, for instance 12-well plates instead of 6-well plates in step P+4, that the culture medium volume is adjusted according to the labware dimensions.
7	Appendix 3 - 66	The software must allow protocols to be run with diverse labware and adjust protocols automatically. Do you mean multiple brands-types of the same plate format (e.g. variations on 6-well plates) or also across plate formats (e.g. run a 6 well protocol on a 12 well plate) ?	Both should be possible. Because we are relying on what our institute supplies as “standard” culture plates, the brand might change every now and then, however Corning and Greiner are the most used brands. In addition, we would also like the system to automatically adjust culture medium volume according to the labware dimension that is being used. E.g. a 12-well plates instead of 6-well plates in step P+4 results in adjustment of the culture medium volume from 2mL to 1mL per well.
8	Appendix 3 - 56	The Platform should comes with software that controls and integrates all components. A single program is used to set-up protocols and execute experiments/workflow. Does this allow the ability of the system control software to delegate instrument specific tasks by calling predefined protocols in the integrated equipment software such as the Cytena UP-sight or the liquid handler? Or should those sub-task protocols be built in detail from the main control software?	We are fine with the system control software delegating instrument-specific tasks to equipment software. However, planning and initiation of processes should be run from one software system.
9	Appendix 3 - 51	The incubator(s) should have a total storage of minimum 60 multiwell plates. As 12-well and 6-well plates are not defined by the ANSI-SLAS plate standards, dimensions may vary between brands. What are your referred or common Brand(s) and type numbers of 12-well and 6-well plates?	Corning: 6well (Cat#3506), 12-well (Cat#3512). Greiner: 6-well (Cat#657165), 12-well (Cat#665165), 96-well (Cat#655180), 384-well (Cat#781182)
10	Appendix 3: LIMS integration	Is it foreseen to connect the automation platform to a LIMS? And if yes, can you please provide information on the type of LIMS?	An institute wide ELN has not been implemented yet, however it is being looked into. Most likely candidate is ELabNext/SciSure, however nothing is finialized as of yet. We would like integration into such a ELN platform when it is rolled out in our institute.
11	Appendix 3: Labware	Please provide a list of labware types to be used. If this is not possible at the current stage, please provide information on the PCR plate used for the Quick Extract DNA purification workflow. In particular, if this is a non-skirted or half-skirted plate type that requires a specific adapter.	We are currently using the follwoing products for our manual pipe-line: Corning: 6well (Cat#3506), 12-well (Cat#3512), Greiner: 6-well (Cat#657165), 12-well (Cat#665165), 96-well (Cat#655180), 384-well (Cat#781182) Bio-Rad PCR plates: Cat#MLL9601 Quick Extract: Lucigen Cat#QE09050 The Bio-Rad plates are non-skirted.

12	Appendix 3: Preferred tip types	Is it possible to use non-filtered tips? Since tip loading capacity is a major bottleneck this would allow us to stack tip racks and thus greatly increase the number of tips that can be loaded on deck. In contrast, by using only filtered tips, walkaway time would be dramatically reduced due to the requirement for more frequent tip reloading. Most of our customers use non-filtered tips for cell culture applications and never experience contamination.	Appendix 3, pos 10 states that we would like a platform that can handle many different hiPSC lines without risk of mix-up or cross-contamination. The use of filtertips is one of the measures to reduce risk for cross-contamination. We are less concerned about bacterial/fungal contamination via pipetting tips and more concerned about cross-contamination of hiPSC lines. Although the chances of cross-contamination are low with the non-filtertips, the consequences would be devastating and would mean many projects need to be re-started. We there for will require filter-tips to be used in the system.
13	Appendix 3 - Workflow: Number of culture media	How many different types of cell culture media are foreseen to be used simultaneously on the automation platform?	We will primarily use one type of culture medium (eTeSR from StemCell Technologies). However, additional components will need to be added to the culture medium throughout the cell culture protocol (e.g. CloneR2). Normally, we premix these components with the culture medium before dispensing the mixture to the cells. Alternatively, it is also possible to add the additional components to each well individually, however this would not be our preferred method. Normal Culture: eTeSR P+1, Day 0 and Day 2: eTeSR + CloneR2 (1:10) After passaging: eTeSR + Rock Inhibitor (1:1000)
14	Appendix 3: Imaging time	Please provide a time estimate for imaging the different cell culture plate types (384w; 96w; 12w; 6w) in the Cytena UP.SIGHT instrument. This is important for correct throughput calculations.	Imaging of a full plate (irregardless of format) will take approximately 6 minutes.
15	Appendix 3	Could you please confirm whether the workflow must be followed exactly as described, or whether alternative approaches are acceptable? We may handle certain steps differently but can still deliver the same required output. Additionally, for must have requirements, if we cannot meet the exact specification but have an alternative that achieves the same outcome, would that be considered compliant? For example, POS 33 in Appendix 3 Program of Requirements) requires cell dissociation and transfer cells into separate tubes, however our platform supports plate format with the same result. Would that be acceptable?	Our current protocol is based on manual handling. We encourage suppliers to make our protocol better and more suitable for automated systems. However, the main goals (output) should still be reached. The goals are indicated in RED in the workflow tab. In the case of pos 33, if you reach the same outcome: dissociated cells from different wells into separate containers/wells/tubes to be processed further, other labware than tubes are a possibility. Be aware that the volume of dissociated cells from a 6well plate is currently 1mL, so this should fit in the chosen labware.