**Follow-up to**

**ISSCR 2021 Virtual Poster Session**

**REGULATORY PRIMING: WHAT MAKES A STEM CELL LINE SUITABLE FOR THERAPEUTIC USE?**

**Poster Session 10, 6/26/2021**

The Human Pluripotent Stem Cell Registry (hPSCreg; hpscreg.eu) is actively developing two resources that deal with clinical aspects of hPSC lines:

***1. Clinical study database.*** As published in Stem Cell Reports (https://doi.org/10.1016/j.stemcr.2020.06.014), hPSCreg has established a database solely for clinical studies that involve hPSC-derived cells for interventional therapy.

***2. Registry for "regulatory primed" hPSC lines (i.e. cell lines specifically prepared to be suitable as starting materials for clinical trials).*** This new resource is an extension of the current registry of hPSC lines used in basic research. The registry for regulatory primed hPSC lines will enable all stakeholders to follow the path of hPSC lines from research to clinical translation.

hPSCreg® would greatly appreciate feedback on the development of these two resources to better serve the stem cell community's needs.

Questionnaire for your feedback

1. **What is your primary area of work? Please check all that apply.**

[ ]  academic research

[ ]  clinical development or banking hPSC for clinical use

[ ]  other, please specify: Click or tap here to enter text.

1. **Clinical study database (https://hpscreg.eu/browse/trials)**
	1. What improvements would you like to see in the display of the clinical studies? In the search function? Please mark all that apply:

[ ] Multiple factor filter functions:

|  |  |  |
| --- | --- | --- |
| [ ] Clinical trial phase | [ ] Source hPSC type (hESC, hiPSC, hpPSC, SCNT-hESC) | [ ] Regulatory authority |
| [ ] Study sites (country) | [ ] Source hPSC cell line name | [ ] Regulatory authority country |
| [ ] Indication for treatment | [ ] hPSC-derived cell type used for therapy |  |

[ ] Graphical display of search results

[ ] Other, please specify: Click or tap here to enter text.

* 1. Should the clinical study database include studies with regulatory approval but not performed as part of a formal clinical trial process (e.g., expanded access / compassionate use cases, hospital exemptions).



1. **Registry for "regulatory primed" hPSC lines**
	1. Should regulatory primed hPSC lines have more stringent evidence to demonstrate pluripotency than research lines?



Click all assays below that should be "must-haves" for regulatory primed hPSC lines?

 hPSC lines

[ ] Marker expression

[ ] Pluripotency assays

[ ] Adventitious agent testing

[ ] Cell line genetic stability

hPSC-derived cell types:

[ ] Functional assays for differentiated cells

[ ] Differentiated product tumorigenicity

Others? Please give details: Click or tap here to enter text.

* 1. Regarding genomic aberrations in regulatory primed hPSC lines, would you consider the availability of whole genome sequencing (WGS) to be a minimum requirement for these lines?



What would be the value of whole genome sequencing in assessing genomic aberrations in regulatory primed hPSC lines? Click or tap here to enter text.

What other methods would you recommend to assess the tumorigenicity of regulatory primed hPSC lines? Click or tap here to enter text.

* 1. Which cell line data fields might be different for cells line for research use and regulatory primed hPSC lines? Please tick all that apply:

[ ] Donor consent

[ ] Indication of whether the data is for release for clinical trial or informational

[ ] Indication as to whether assays used are validated for manufacturing

[ ] References for relevant clinical trials

[ ] Adventitious agent testing

[ ] Genetic stability testing

[ ] Regulatory compliance for the derivation facility

[ ] Quality standards adopted

[ ] Other, please specify? Click or tap here to enter text.

* 1. How should data for development of cell stocks in different locations from the same original source material be differentiated?

Click or tap here to enter text.

* 1. Is there any information that would not help to identify a cell line suitable for use in clinical trials? Click or tap here to enter text.
	2. What information about regulatory primed hPSC lines would you value the most? Click or tap here to enter text.

If you have any other comments or suggestions about the clinical study database or the regulatory primed hPSC line registry, please let us know.

Please return the questionnaire to Dr. Nancy Mah (nancy.mah@ibmt.fraunhofer.de)

Thank you from the hPSCreg® Team!