Clinical iPSC Services for Cell Therapy Manufacturing

stemgent
A REPROCELL BRAND

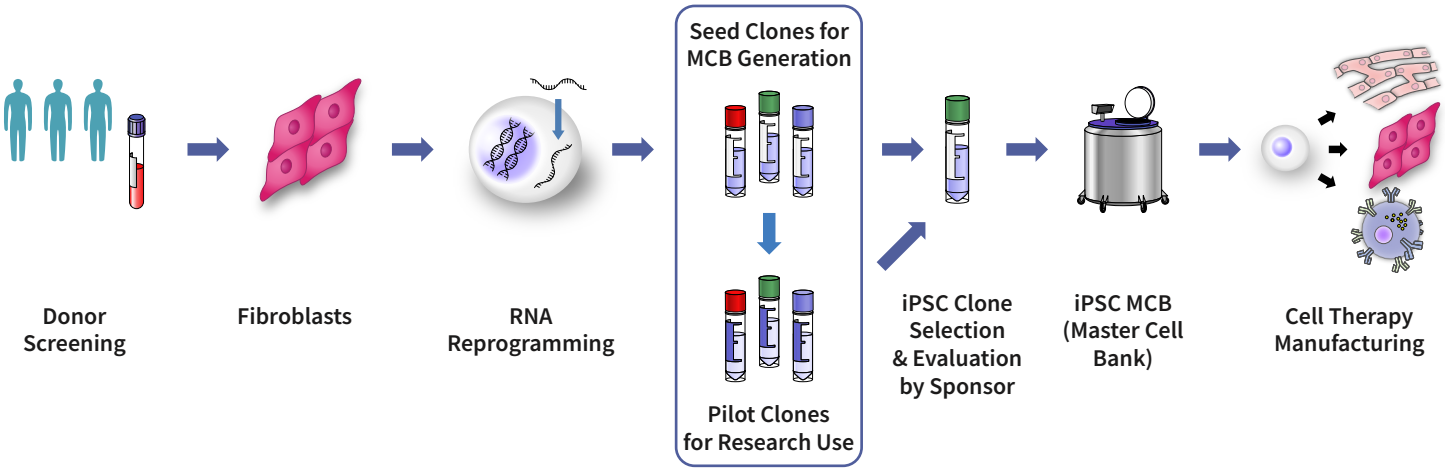
Regulatory compliant iPSCs

As a partner for your clinical cell therapy project, REPROCELL creates **StemRNA™ Clinical iPSC Seed Clones**. From a clone evaluated and selected by the Sponsor, we will first manufacture a GMP Master Cell Bank (MCB) that is compliant with the current standards outlined by the key regulatory agencies in the US, Europe, and Japan (FDA, EMA, PMDA) and eligible for downstream processing into a cell therapy product. We are committed to advancing your regenerative medicine project by providing all necessary quality and regulatory documents.

Your GMP partner

- **Footprint-free RNA reprogramming**
- **Ready-to-use and custom iPSC services**
- **Unique evaluation of Clinical iPSCs**
- **Comprehensive end-to-end clinical services**
- **Cell Therapy Manufacturing**
- **Clinical Gene Editing**
- **Simple commercial license**

Our Clinical Stem Cell Project Workflow



REPROCELL's process starts with skin biopsies from carefully screened and ethically consented donors. Fibroblasts isolated from these biopsies are reprogrammed into Seed iPSC Clones using our clinical StemRNA 4th Gen Reprogramming Technology. These iPSC Clones can be evaluated by the Sponsor to select a suitable clone for GMP MCB generation and down-stream Cell Therapy Manufacturing. From our bank of Seed Clones, we manufacture corresponding Pilot Clones which are suitable for research use to develop and evaluate your own protocols. The entire clinical process complies with regulations of the US FDA, European EMA, and Japanese PMDA.

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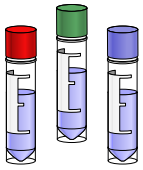
Three Ways to Access iPSC Clones

- We can create ***exclusive* StemRNA Clinical Seed Clones** for you starting with a donor that matches your criteria.
- We also have a bank of ***ready-to-use* StemRNA Clinical iPSC Seed Clones** for your evaluation.
- We have also created corresponding **StemRNA Clinical iPSC Pilot Clones** from these Seed Clones.

The difference between Seed and Pilot Clones

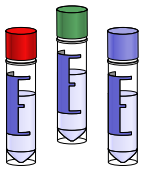


StemRNA Clinical iPSC Seed Clones

These cells are suitable for clinical use through subsequent regulated and approved processes, including processes resulting in a GMP Master Cell Bank and Working Cell Bank. StemRNA Clinical iPSC Seed Clones are generated under CGTP guidelines and covered by a rigorous quality control (QC) process that is compliant with US FDA, European EMA and Japanese PMDA regulations.

StemRNA Clinical iPSC Pilot Clones

Our non-exclusive *ready-to-use* iPSC Pilot Clones are directly expanded from our bank of StemRNA Clinical iPSC Seed Clones in a research setting. These clones are NOT suitable for development for clinical use and are for evaluation purposes only, but they provide a more cost-effective way to access StemRNA Clinical iPSCs to develop and evaluate your process.



The Advantages of the StemRNA Clinical Approach

- **Every step in the manufacturing process is covered by extensive QC to ensure compliance with FDA, EMA, and PMDA regulations**
  — Minimizes the Sponsor's risk of downstream obstacles
- **Reprogramming process uses the latest generation of clinical RNA reprogramming technology**
  — Eliminates risks associated with retention of reprogramming vectors
- **Evaluation period allows the Sponsor to pick the best clone for continuing with GMP manufacturing**
  — Ensures the suitability of the right iPSC clone
- **GMP compliant MCB and Cell Therapy manufacturing performed by experienced scientist in ISO certified clean rooms using high-quality procedures and systems**
  — Minimizes the risk of human error and environmental contamination
- **Pilot Clones provide a cost-effective tool for method development and research, while providing access to clinically-compatible clones for GMP manufacturing**
  — Minimizes the financial risk during the research and method development phase

Find out more: **www.reprocell.com/clinical-stem-cell-services**

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