

**Section 101: Development of MDRs**

**Section 102: Regulatory Journey**

2001

Approved Clinical Definition "non-surgically used stem cells (NSC)s."

2004

The International Society for Cellular Therapy (ISCT) proposed the standard definitions criteria for MDRs, which did not distinguish surgically used stem cells from stem cells.

2014

Approved Clinical Definition is being revised that MDRs are "surgically applied cells (SMR)s," clarifying that MDRs are not stem cells.

October 2019

FDA regulated the MDR criteria, emphasizing that MDRs allowed for consistent with stem cell testing, differentiation, and/or engraftment in vivo and in vitro.

August 2022

FDA published a proposal to (re)define "surgically used stem cells" and "non-surgically used stem cells" to clarify the concept of surgically used stem cells.

**Major Turning Point**

October 2024

The U.S. FDA approved the first global clinical trial for surgically used stem cells (SUC) (SUC-1) submitted by Tardy from C-Cell Biotech, clarifying regulatory distinctions between stem cells and stem cells.

February 2025

FDA published a proposal to (re)define "surgically used stem cells" and "non-surgically used stem cells" by single-cell transcriptomic analysis, establishing distinct definitions criteria for MDRs.

March 2025

FDA's CDRH approved Tardy's clinical trial for surgically used stem cells (SUC-1) (SUC-1).

2002

China (Government was involved in developing alternative MDR product pathway).

2003

The U.S. FDA disapproved Procyon and due to controversial efficacy data, insufficient manufacturing of manufacturing of services.

2005

Meridian acquired Procyon, receiving it as Myriad (Manufactured-L, conditioning effects for market approval).

2005, 2006

Myriad conducted Phase III clinical trials, but the patient failed appropriate efficacy measurements.

May 2019

Myriad's first FDA submission was rejected by the U.S. FDA for inadequate single-arm trial data and insufficient CMAC (Chemistry, Manufacturing, Controls Documentation).

August 2023

Myriad's revised FDA submission was rejected due to missing adult patient trial data and CMAC deficiencies.

December 2024

The U.S. FDA approved Myriad as the first surgically used stem cell based drug.



# A Chronographic Analysis Of The Nativity

**Michal Rosen-Zvi**



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