

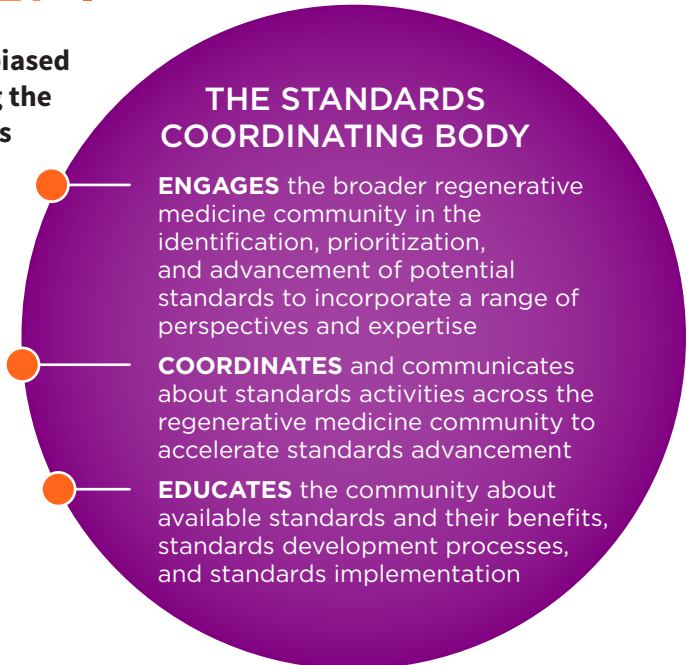
Want a say in the development of standards for regenerative medicine therapies?

# SCB CAN HELP.

The Standards Coordinating Body (SCB) is an unbiased non-profit organization dedicated to accelerating the advancement of standards that address the needs of the global regenerative medicine community.

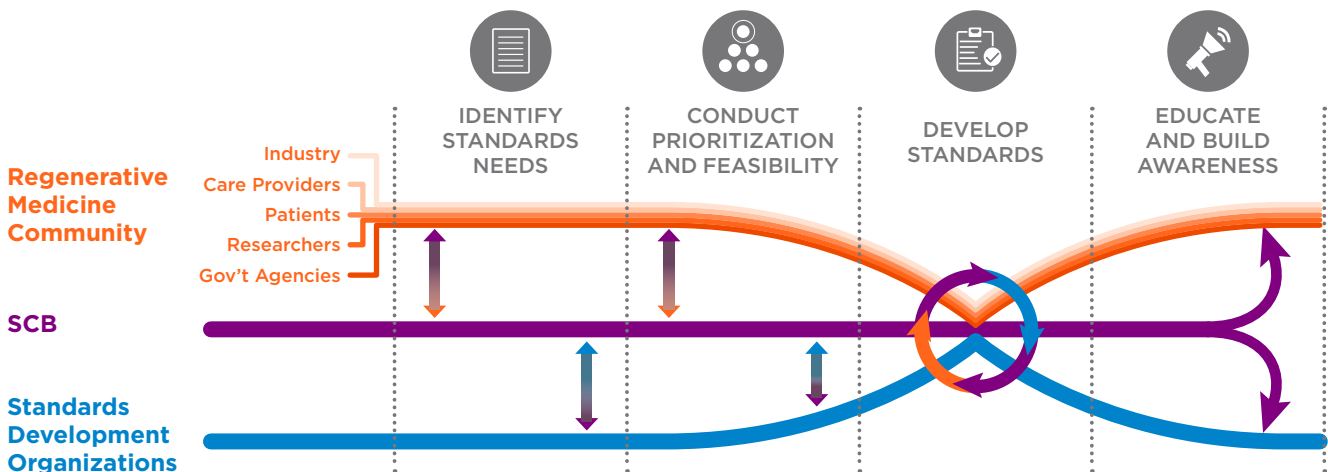
**SCB's coordination ensures:**

- Standards that impact the field have broad community input
- Time and resources are focused on the standards that could yield the greatest benefits to the field
- Those who are championing standards work together instead of duplicating efforts
- Hurdles are reduced for subject matter experts providing input into standards



**SCB connects the regenerative medicine community to the standards development process.**

Standards development for regenerative medicine therapies is being encouraged by the 21<sup>st</sup> Century Cures Act and will continue to ramp up as the field matures. With buy-in from a range of stakeholder organizations across the regenerative medicine community, our goal is to address your needs and support the advancement of standards that enhance the entire community and accelerate innovation.



# Highlights of SCB's current work



## The Regenerative Medicine Landscape

This report provides an overview of **more than 200 existing and in-development standards that are available for regenerative medicine stakeholders to use in their work.** Standards are organized by sector and functional area for easier navigation, and the report is updated annually based on community feedback.

---



## Community Perspectives: Needed Standards in Regenerative Medicine

This report outlines **standards needs that could have the greatest benefit to the field and improve the safety and quality** of regenerative medicine products. The report is intended to inspire and align community action around common standards goals. Initially informed by more than 250 stakeholder organizations, the report will continue to be updated as needs evolve.

---



## Standards Advancement and Community Engagement Projects

**SCB is coordinating working groups for various standards advancement projects** and is supporting several community outreach and education projects. Examples of SCB's projects include:

### STANDARDS ADVANCEMENT PROJECTS

- Ancillary Materials Used in Cellular Therapy Production (International Standard)
- ASME Thermal Medicine Tissue Properties
- Base Labeling Requirements for Apheresis Products for Regenerative Medicine Manufacturing
- Cell Collection Standards for Cell Therapies
- Chain of Custody (COC)/Chain of Identity (COI)
- Characterization of Fiber-Based Scaffolds
- Characterization of Human Cells for Therapeutic Use
- Cryopreservation of Cells (PDA-led project)
- Evaluating Pre-existing Immunity to Adeno-Associated Viruses
- Microphysiological System Standards Landscape Assessment
- Rapid Microbial Testing Methods
- Requirements for Cell Therapy Manufacturing Equipment
- Specifications for Biopinks and Bioprinters
- Tissue Engineering Lexicon
- Transportation Requirements of Cells for Therapeutic Use
- Viral Vectors (Lenti/AAV) for Gene Therapy

### OUTREACH AND EDUCATION PROJECT

- Applying Quality by Design (QbD) Principles to Gene Therapy Development



## WE NEED YOUR INPUT!

The success of SCB's efforts to coordinate standards advancement for the regenerative medicine community depends on your participation. **Contact SCB** to provide feedback on an SCB publication, join a standards advancement project working group, sign up for the SCB newsletter for updates, or learn other ways to **get involved**.

**CONTACT:** [www.standardscoordinatingbody.org/contact](http://www.standardscoordinatingbody.org/contact) [www.standardscoordinatingbody.org](http://www.standardscoordinatingbody.org)