Realizing the Promise of Regenerative Medicine Therapies: Strengthening the Standards Development Process

Many promising regenerative medicine therapies that could help manage and even cure many conditions and diseases become stalled on the path to commercialization. Coordinated standards development can target common industry needs and reduce the timeline for moving therapies from the laboratory to commercial scale. Standards development benefits the regenerative medicine community by:

- **Reducing barriers to innovation** by replacing costly and time-consuming trial-and-error processes with researched best practices
- **Increasing the safety and reliability of therapies** by defining testing and processing parameters throughout the product life cycle, from raw materials sourcing to clinical administration
- **Allowing more efficient review processes** by eliminating the need for regulatory bodies to re-validate common operational steps for each new product
- **Decreasing costs of therapies** with the efficiency gains from standardizing equipment, methodologies, processes, and testing protocols

The Standards Coordinating Body for Gene, Cell, and Regenerative Medicines and Cell-Based Drug Discovery (SCB) complements the current SDO processes for standards development by engaging regenerative medicine stakeholders to ensure that new or revised standards provide the greatest benefits to the broad regenerative medicine community. To keep up with the fast-paced growth of regenerative medicine and advance standards specific to the field, SCB:

- **ENGAGES** the broader regenerative medicine community in the identification, prioritization, and advancement of potential standards to incorporate a range of perspectives and expertise
- **COORDINATES** and communicates about standards activities across the regenerative medicine community to accelerate standards advancement
- **EDUCATES** the community about available standards and their benefits, standards development processes, and standards implementation

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**What are standards?**

Standards ensure that something is fit for its purpose. They may be created by the government, or they may be developed by non-governmental standards developing organizations (SDOs).

**Documentary standards** for regenerative medicine therapies set consistent protocols, methodology, technical specifications, or terminology that ensure a high level of product quality and safety.

**Physical reference materials** with known properties are used to calibrate equipment and provide consistency and quality in measurement processes.
How SCB Supports the Standards Advancement Process

Pre-Development Process

1. Define the standards landscape and identify needs
   Allows stakeholders to more easily identify gaps and ways to move the field forward

   - Literature reviews and desktop research
   - Expert interviews
   - Stakeholder surveys
   - Facilitated sessions at meetings and conferences
   - Online feedback mechanisms

   GET INVOLVED by participating in these activities

2. Prioritize needed standards
   Allows resources to be focused on the standards that will have the greatest impact

   - Community survey of needed standards
   - Facilitated sector-specific working group sessions to prioritize standards in quadrant graphs with supporting rationale

   GET INVOLVED by participating in these activities

3. Conduct feasibility assessment
   Ensures that the standards selected are ready for development and likely to be adopted by the regenerative medicine community

   - Facilitated working group meetings to evaluate feasibility of developing and adopting high-priority standards based on four factors:
     - Technical Feasibility
       - Technical and scientific foundation
     - Implementation Feasibility
       - Costs and operational implications
     - Expert Availability
       - Champions committed to advancing standard
     - Other Factors
       - Development costs, time to develop, legal

   Summary of feasibility factor discussions and suggested next steps

   GET INVOLVED by participating in these activities
**Development Process**

= SCB supporting activity

4 **Coordinate and support standard development**

Drives efficiency and allows stakeholders from across the regenerative medicine community to make their voices heard

- Assemble experts
- Gather additional information and data

SDO technical committee develops standard:
1. Initiation
2. Initial Drafting
3. Review/Comment
4. Final Voting
5. Finalization

Build community-wide buy-in for standards in development

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**Post-Development Process**

= SCB supporting activity

5 **Educate and build awareness of standard**

Encourages adoption of the standard and helps stakeholders understand the benefits it can bring their organization

Educational materials that convey benefits of a specific standard, stakeholders impacted, relevant regenerative medicine sectors, and product development processes

- Case studies
- Fact sheets
- Blog posts
- Website content
- Social media
- Quarterly newsletter

Materials disseminated through:

- Educational webinars
- Annual regenerative medicine conference
- Facilitated workshops
- Regenerative medicine media channels
- Teleconferences and targeted meetings
- Networking at community events

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**GET INVOLVED** by participating in these activities
### How to get involved in the standards development process

<table>
<thead>
<tr>
<th>Identify and prioritize needed standards</th>
<th>Participate in surveys, phone interviews, and workshops to identify and prioritize needed standards</th>
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<tbody>
<tr>
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<td>Participate in regular sector calls to stay informed on standards in development</td>
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<td>Submit a project proposal idea to SCB</td>
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<td>Contribute to the Landscape of Regenerative Medicine Standards report</td>
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<td>Provide feedback on the Community Perspectives: Needed Standards in Regenerative Medicine report</td>
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<th>Draft and develop new or updated standards</th>
<th>Participate in SCB project working groups and SDO technical committees</th>
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<td>Provide subject matter expertise to help develop and review drafts of standards and best practices</td>
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<tr>
<th>Educate the broad community on new standards and the development process</th>
<th>Contribute to a case study on your participation in standards development efforts, or on the value of a standard to your organization</th>
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<td>Participate in community events and network with other attendees</td>
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<td>Share information on the development process or on new/updated standards through regenerative medicine media channels</td>
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<td>Attend or present during an SCB webinar*</td>
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<td>Attend the annual regenerative medicine conference*</td>
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<th>Follow SCB’s efforts</th>
<th>Join the SCB mailing list to get the latest news and updates about regenerative medicine standards (SCB: <a href="http://www.standardscoordinatingbody.org/contact">www.standardscoordinatingbody.org/contact</a>)</th>
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<td>Follow SCB on Twitter (@scbregenmed) and LinkedIn (company/standards-coordinating-body)</td>
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*Dependent on additional resources

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**About the development of the improved process**

In September 2017, the U.S. Food and Drug Administration awarded a contract to Nexight Group and SCB to engage with experts and recommend a process and plan to strengthen the development of standards for regenerative medicine and advanced therapies. In 2018, more than 300 experts from industry, academia, government, SDOs, and accreditation bodies provided their perspectives on how the process could be improved through interviews, during meetings and workshops, and through participation in an online survey. Nexight Group and SCB thank those who participated for their time and input.

For more information, visit [www.standardscoordinatingbody.org](http://www.standardscoordinatingbody.org)