REGENERATIVE MEDICINE

ORGANIZATIONAL SPECIFICS

Standards Organizations:	Standards Coordinating Body (SCB)
Technical Committees:	
Other Partnering Organizations:	Various
Government Organizations:	DHS, NIST, FDA
Industry Sector(s) / Technology:	Regenerative Medicine
Program / Activity Website URL(s):	https://www.standardscoordinatingbody.org/organization

STANDARDS DRIVEN PUBLIC-PRIVATE PARTNERSHIP (PPP) OBJECTIVES

PPP Drivers:

The Standards Coordinating Body (SCB) began as an initiative of the Alliance for Regenerative Medicine (ARM) and other regenerative medicine stakeholders and industry to facilitate the development of standards for the nascent regenerative medicine industry. The first of advanced therapies, including cellular and gene therapies, are on the cusp of approval and standards are urgently needed to manufacture and test these new therapies.

PPP Goals:

The primary goal of this PPP is to coordinate the accelerated advancement and improved awareness of the standards and best practices that address the rapidly evolving needs of the global regenerative medicine advanced therapy community.

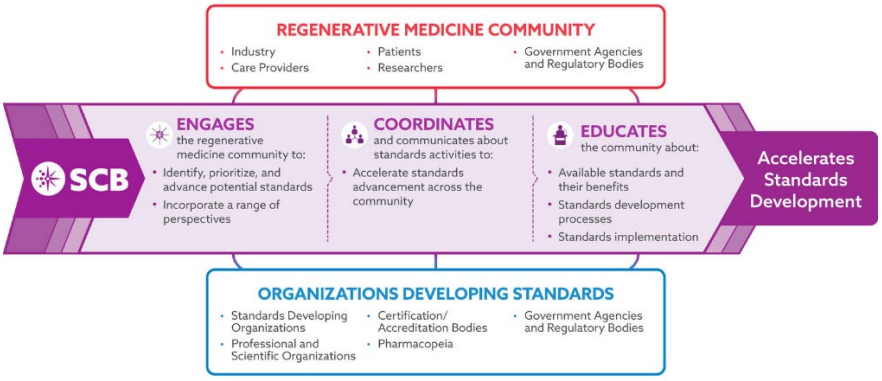
Public Sector Role & Participation:

In September 2016, the National Institute of Standards and Technology (NIST) and SCB established a Memorandum of Understanding (MOU), forming a partnership to jointly advance standards for the regenerative medicine community's needs. This MOU provides a mechanism for more cooperation with other U.S. agencies to work with industry, standards development organizations, and other stakeholders.

- The NIST laboratory programs provide supporting measurement science and data to support the development of innovative science-based standards and technology in support of the bio-economy. NIST scientists collaborate with industry, academia, and other entities through both formal and informal arrangements. NIST works with other government agencies including the U.S. Food and Drug Administration (U.S. FDA) on research collaborations, workshops, and standards development activities. NIST administers the US Mirror Committee to ISO/TC 276: Biotechnologies, which is developing standards relevant to cell and gene therapies. Lastly, NIST sits on the SCB Board of Directors as liaisons.

Formally launched in January 2017, SCB is now a fully independent, functioning non-profit organization. During the same year, FDA awarded a one-year contract to Nexight Group and SCB to engage with experts to recommend processes and outline a strategic plan for developing standards in regenerative medicine and advanced therapies. This work has helped to lay the foundation for standards development in regenerative medicine research and product development.

Following the initial contract, FDA has continued to provide Nexight Group and the SCB with funding to increase and accelerate the number of regenerative medicine standards being advanced in the field. These activities are intended to continue supporting the vision of the 21st Century Cures Act of 2016.



Implementation Methods:

SCB operates through project working groups, which are collaborative forums in which volunteers from the regenerative medicine community discuss and address standards needs.

Measurement of Success:

Since its inception, SCB has been successful at significantly reducing the time required to advance standards and standards drafts. In particular, SCB, in partnership with Nexight Group, has increased the efficiency of working with the broad regenerative medicine community to identify needed standards, prioritize those needs that will have the greatest impact on the field, and assess the feasibility of developing and implementing standards in these areas.

With SCB the average rate of a standard's development timeframe has decreased three-fold, significantly shortening the time from the establishment of need to the completed consensus standard from over 12 years to less than four. The most significant time savings occurs at the first steps of standards development, which involve coalescing generalized needs to a small set of finite problems that can be addressed by consensus standards. According to the SCB website, without a coordinating body like SCB, these pre-development steps can take up to six years; however, with SCB's support, these steps take only six months to one year.

Key Takeaways:

- SCB has significantly shortened the time from the establishment of need to the completed consensus standard.
- By engaging and coordinating with stakeholders, SCB leverages expert experience and knowledge to identify and establish consensus standards that provide benefits to the regenerative medicine and advanced therapies community.

Advice for Others:

Establish a solid partnership through mutual support, shared goals, regular check-ins, and clearly defined roles and responsibilities.

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