

Measuring Osteoinductivity of Demineralized Bone Matrices

CHALLENGE



Regenerative medicine products containing demineralized bone matrices (DBM) can induce new bone growth in patients, but researchers and manufacturers lacked a standard methodology to assess and compare product efficacy. **Documented bone regrowth varied widely between products due to differences in measurement methodology**, making it difficult to compare products and complicating regulatory review processes.

SOLUTION



As part of a group of stakeholders including the U.S. Food and Drug Administration and Virginia Commonwealth University, the team at **LifeNet Health**—a provider of allograft bio-implants and organs for transplantation—**helped develop an ASTM standard that provides a common methodology to implant DBM and measure new bone formation**. The working group hoped to increase result uniformity across reporting bodies—including in academic literature and marketing materials—and to facilitate more streamlined regulatory submissions.

During the standard development process, the working group recognized that many companies were already committed to their own measurement methodologies. **They met one-on-one with stakeholders** to understand their concerns and find opportunities for compromise, building consensus around a standardized approach. The working group then crafted the standard—**recommending techniques without mandating them—and conducted round robin testing** to ensure the standard was useful to all practitioners.

IMPACT



DBM product **sponsors can now use the standard to help document the efficacy of their product in regulatory submissions**. This supports more efficient and robust product reviews, ultimately bringing impactful new therapies to patients as quickly as possible. The standard also allows the regenerative medicine community to more effectively compare outcomes of DBM technologies, supporting **more targeted research and development**.

LESSONS LEARNED



Based on their experience, **LifeNet Health** recommends **bringing new partners on board** throughout the standards development process to maintain an energized team. They stress the importance of **defining a narrow scope** for a new standard, recognizing that a standardization goal may be best advanced through multiple, discrete documents. They also encourage **prioritizing efficiency over perfection** to ensure new standards aren't outpaced by technological innovations.

Get Involved in Standards Development through SCB

As a coordinating body, **SCB** helps streamline the standards advancement process by driving momentum, aligning stakeholder efforts, and helping projects overcome obstacles.

Individuals can provide feedback to **SCB** on needed standards or join **SCB**-coordinated projects to advance standards that benefit the broad regenerative medicine community.

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