



**Partner Organization Report**

<b>Partner Organization:</b>	ARM
<b>Committee Name (if applicable):</b>	Standards Coordinating Body
<b>ISCT Representative(s):</b>	Kurt Gunter
<b>Role of ISCT Representative:</b>	Board of Directors
<b>Last Committee Report Submitted on:</b>	First report
<b>Date of Upcoming Board of Directors Meeting for Submission:</b>	June 20, 2018

**1. How often has this committee met during the last 12 months?**

The SCB Board of Directors met on the following dates in the past 12 months:

- Oct 24, 2017
- April 6, 2018
- May 21, 2018

**2. What was accomplished during the meeting(s)? (To answer this question, you may attach conference call reports or meeting minutes.)**

- Acquired new office space at NIST
- Partnership with Nexight in August for management
- FDA contract awarded in September
- First standards webinar under the FDA contract delivered in December
- Submission of the standards landscape report to the FDA in December
- Hiring of two program managers

Quote from press release from Sep 2017:

“On September 27, 2017, the U.S. Food and Drug Administration (FDA) awarded a one-year contract to Nexight Group and the Standards Coordinating Body for Gene, Cell, and Regenerative Medicines and Cell-Based Drug Discovery (SCB) (see [press release](#)) to engage with experts to recommend a path forward for developing standards in regenerative medicine and advanced therapies. This work will create a foundation that allows industry, regulatory authorities, and other stakeholders to reduce barriers to regenerative medicine research and product development and accelerate the market readiness of these life-changing medical treatments.”

Meeting minutes are attached.

**3. What are the key goals and initiatives for the next 6 months to 1 year?**

See attachments

**4. Are there any activities within this time period that ISCT should be aware of or take part in?  
Specifically, are there activities that any ISCT Committees can comment on?**

I recommend that the lab practices, NALRA and all scientific committee chairs review the SCB project list and determine if ISCT should engage on some of these projects.

**5. Additional comments or feedback:**

The SCB is a new organization and is still trying to figure out its mission and to differentiate itself from other similar organizations like FACT and AABB. Importantly the SCB has still not determined how it will sustain itself (business model). It is possible SCB will ask partner organizations like ISCT to contribute towards SCB operations, or SCB may seek to attract individual and corporate dues paying members. They have also discussed holding annual meetings.

Submitted respectfully,

Kurt Gunter, MD