

IDEAL and Innovation: Rethinking IDEAL, IDEAL - D and TPLC concepts



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Uniqueness and Strengths of IDEAL

- Applicability to multiple clinical areas
- Critical framework for explicitly capturing the development of surgical procedures
- Proving indispensable in helping to create an environment to stimulate innovative surgical procedure developments that are safe and effective

Adding the devices to the concept.....

- As medical devices have been either specifically developed to be integrated with certain surgical procedures or surgical procedures developed specifically to enable the use of certain medical devices, these fields have inevitably begun to overlap
- This led to the concept of IDEAL -D.

IDEAL -D and TPLC regulatory aspect

- IDEAL - D framework modifies the surgical IDEAL framework to take into consideration various differences between device and procedure development
- During the development of the concepts integrated in IDEAL -D, it had been expressed that the IDEAL framework might provide an additional valuable support and/or framework to aid in some TPLC regulatory aspects of medical devices that are used with emerging surgical procedures.

Innovative approaches to regulation

- The U.S. FDA/CDRH has been developing the world's highest standard for regulatory approval of medical devices for over 50 years and has recently instituted policy changes that fundamentally are aimed at improving patient access to innovative medical devices (least burdensome, risk-based, etc.)
- Additionally a fundamental tenant of the IDEAL framework (Stage 4), i.e. early and continuous learning based on long-term registry data collection is currently being developed within the National Evaluation System for health Technology (NEST) system.

Opportunities for IDEAL-D: Thinking differently about the concept

- For surgical procedures that utilize existing or evolving medical devices that the IDEAL framework be integrated into TPLC regulatory framework rather than vice-versa
- This approach would take advantage of the highest standards for evidence generation while simultaneously addressing some of the challenges inevitable in placing devices within the IDEAL framework



Thank you!

5/10/2017