Foundation for Interventional & Therapeutic Endoscopy

March 10, 2025

Background:

Through key leadership meetings at DDW 2023, FITE and several industry allies explored options around a collaborative approach to advancing the field of interventional endoscopy. This would leverage FITE's organizational infrastructure select needs identified by the ally.

FITE will be sponsoring 5 categories of offerings to our industry partners. These are designed to help industry partners as well as practicing interventional endoscopists to advance new devices and clinical procedures through education and development in an organized manner.
We see this advancing the field of interventional endoscopy through a more structured approach to education, device, and marketplace development. This will promote new minimally invasive and cost-effective therapies to a much greater number of patients.

1. **Standards and Education ("S&E") for Existing Products and Procedures**

   Background: FITE would develop educational material including: best practice for clinical application, suggestions regarding training, understanding and navigation of known complications, and limitations. FITE would also provide future opportunities for education future (for example, virtual lectures or even hands-on short 1 day training courses).

   Governance: Governing board and committees would be engaged with the industry partner in development. A designated FITE Physician Executive leader would be assigned to each Standards & Education (S&E) endeavor. They would be compensated for their time along with other physicians working on the project. They would engage other FITE experts who would also be compensated through FITE.

   Funding/Promoter of Material: The industry partner would provide funding to FITE for the activity and FITE would generate the educational material and develop standards (This would make it a

FITE-sponsored endeavor rather than directly sponsored by an industry partner). Industry input is of course welcomed.

Example Biliary stents:

-Education regarding safety, training and appropriate use for:
-Off label EUS use
-Bile duct drainage via ERCP
-When to use covered/partial uncovered

2. **Device Introduction ("DI")**

Background: Market Development for new products which are pending or just received 5-10k approval. This would replace the "limited launch" approach. It would provide a structured approach to introduction for the device and its initial exposure, and understanding of clinical utilization, risks and benefits.

Governance: Governing board and Committees chairs would be engaged with the industry partner in development.
A designated Physician Executive leader would be over each Device introduction (DI) endeavor. They would be compensated for their time along with other physicians working on the project.

Funding/Promoter of Material: The industry partner would provide funding to FITE for the activity and FITE would generate the "device introduction" algorithm, develop the sites (in conjunction with input from industry partner), test the device, track use data, and create all educational material (This would make it a FITE-sponsored endeavor rather than directly sponsored by an industry partner). We would also want to track financial impact which could help show physician effort in complex cases and the value of cost reduction to the patient/payor for future codes.

Example: Novel device

- FITE Physician executive leader: Dr XXX
- Identify key opinion leaders in FITE
- Develop multiple centers with teams to initiate utilization and collect data
- Financial impact tracking
- Limited launch trial with data collection for multiple sites
- Publish the initial experience
- Develop safety and quality data from early adoption
- Create a training curriculum for other interventional endoscopists
- Develop Use guidelines

3. **Pathways for Existing Product Expansion and Improved Adoption ("E&A")**

Background: Market Development for existing products or those that exist but go through a product update. This would encompass expanded indications, novel updates, or a goal to increase adoption by select regions or improve utilization in specific disease states.

Governance: Governing board and Committees chairs would be engaged with the industry partner in development. A designated Physician Executive leader would be over each educational endeavor. They would be compensated for their time along with other physicians working on the project.

Funding/Promoter of Material: The industry partner would provide funding to FITE for the activity and FITE would generate an "education & adoption plan (E & A)" The Physician Executive Leader

selects various educational experts to participate in the global effort around the "refresh of the device." The E & A plan, reviewed by the selected group of experts from FITE in conjunction to input from industry partner), has the following components:

1-Membership of the team: FITE experts, industry leaders from the company, administration
2-Time lines
3-Defined Key Concepts
4-Educational plan for Interventional endoscopists
5-Educational plan for other specialties
6-Research needs and plans for execution
7-Regular cadence of meetings

We would also want to track a "clinical impact" which could help show potential effort in complex cases on behalf of the physician and the value of cost reduction to the patient/payor for future codes.

Example:

FITE Physician Executive Leader: Dr XX- Novel imaging or processing with EUS

- Develop a series of targeted talks for markets where use has trailed off: identification of tumors, staging of cancers, etc.
- Future opportunities which will allow the tech to be additionally utilized
- NCCN guidelines and engaging multi-d teams
- Ability to link to PACS
- Education for medical, radiation and surgical oncologists

4. **R&D testing**

Background: Market Development for New Products which are in the development pipeline – could be concept or early prototypes.

Governance: Industry partner would lead the process. FITE would be in support. Governing board would help get the thought leaders with appropriate expertise.

Funding/Promoter of Material: The industry partner would come to FITE with NDA around concepts or an early form of a device. FITE would help get a list of thought leaders to work on the device. This also serves as early market development.

Example:

- Providing en vivo & ex vivo expertise at labs or collaborative discussions with engineer and MDM teams - along with other feedback for premarket development
- Performing bench trials (with design from industry research engineers)

5. **Education for TM Education for physicians**

Background: With changes post-Covid in Sales forces and the approval & implementation of novel devices there is a clear need for educations of Territory managers/Sales forces and others who are our industry partners. We can gather a group of experts from FITE to help virtual and onsite TM education.

Governance: FITE would take guidance from our industry partners and help with creating opportunities for education. These endeavors would be virtual lectures and onsite observations. A FITE Physician Executive Director would be assigned to each device education to arrange the creation of the curriculum and work directly with respective industry executives to review the educational curriculum. A group of FITE expert physicians would also be involved to help facilitate education (FITE is willing to take input from industry).

Funding/Promoter of Material: The industry partner would provide funding to FITE for the activity and FITE would compensate the FITE physician Executive Director and the appropriate physician experts who are providing education.

Example: EUS Needle

(use the EUS committee to help develop multiple sites for TM training)