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PLEASE NOTE: BY FILLING OUT THIS APPLICATION IN FULL, YOU AGREE TO ATTEND THE MANDATORY EVENTS OF THE PROGRAM.

PLEASE ALSO NOTE: A recording of the PROGRAM INFORMATION WEBINAR pertaining to this year's CAP (including Q&As and FAQs) is available in the program Portal. You may find this helpful in preparing your application.

PLEASE MARK YOUR CALENDAR FOR THE MANDATORY LAUNCH EVENT AT WHICH WE EXPECT PARTICIPATION BY THE CEO OR KEY MANAGEMENT CONTACT (DECISION MAKER) FROM THE APPLICANT'S COMPANY.

All participants for the NIH CAP will be required to attend the **Commercialization Training Workshop (CTW)** in Los Angeles, California on October 24-25, 2017:

Participants selected for the Commercialization Training Track (CTT), will also be required to attend a FeedForward™ Session EITHER in Irvine, CA on February 26-27, 2018 OR in Washington, DC on March 8-9, 2018. Participants selected for the Advanced Commercialization Track (ACT) or the Regulatory/Reimbursement Training Track (RTT) are not required to attend a FeedForward™ Session.

By checking this box, I acknowledge and agree that our company will attend the mandatory events if our company is selected to participate in the program.



APPLICATION FOR 2016-2017 NIH-CAP

SUBMISSION DUE DATE: August 21, 2017 11:59PM (Pacific Daylight Time)
(Changes may be made online until 8:00 pm EDT)

SELECTION ANNOUNCEMENT: Week of September 11, 2017

It is recommended that the person completing the form be the company CEO or a person specifically designated on his/her behalf and who (if selected) will be your company's representative.

All information provided will be held in the strictest of confidence. [Please click here for confidentiality details.](#)

Non-Disclosure: All application information will be held in the strictest of confidence and Larta, Inc. will not use, disclose, or otherwise permit any person or entity access to any of the information other than as required in the performance of Larta’s services for the Company or the National Institutes of Health (NIH).

The NIH-CAP Application consists of four (4) sections:

- SECTION I- Company Demographics and Information
- SECTION II- Technology Vision
- SECTION III- Business and Market Vision
- SECTION IV- Company Vision

SBIR/STTR AWARD INFORMATION

1. Are you a Past CAP Participant*? Yes No

1a) If Yes, please indicate the year and the HHS SBIR/STTR award (grant/contract) number under which you applied and were accepted.

**Note: Previous CAP participants may only re-apply with a different technology and different SBIR/STTR award.*

Previous Participation Year (past CAP):

Previous Award Number:
(Example: 5R44 AA012345-03 grant, or HHS-N-276-2009-0004C contract)

Please Identify Funding Institute/Center (IC) (e.g., NCI, NIAID, etc.)

1b) What progress have you made since your participation in that previous CAP? What did you learn or “take away” from that experience? Finally, what do you feel you need or can achieve from going through another cycle of CAP?

2. Please provide the single HHS SBIR/STTR Phase II award (grant/contract) covering the technology to be addressed during this CAP. Note: the award must have been an active SBIR or STTR Phase II award (includes Phase II B and Fast-Track) within the last five years. (Please refer to the [Program Description](#) for eligibility details.)

Award Number

Award Amount

Year Award Granted

Funding Institute/Center (IC)

2a) If the award is an STTR grant, please indicate the name of the affiliated non-profit research institution

3. PLEASE: Upload the 1st page of your Phase II Grant notification with your grant information and institute information

4. Please provide any and all SBIR/STTR award number(s) that support the technology you intend to commercialize via the CAP. Multiple awards may contribute to one product, so you may include several HHS awards and/or those awarded from other agencies.

*NOTE: A recording of the Information Session webinar pertaining to this year's CAP (including Q&As and FAQs) is available on the program Portal. You may find this helpful in preparing your application.

SECTION I- COMPANY DEMOGRAPHICS AND INFORMATION

This section seeks information on your company, including a description, key executives to be involved in CAP, length of operation, employee count, and field of business.

I. **1. Company name:** (State clearly the full name of your company, or as you would like your company to be represented during CAP)

I. **2. Mailing address:**

Address

City

State Zip

I. **3. When was your company founded?**

I. **4. Company form (how is your company registered?):**

LLC INC B-Corp C-Corp S-Corp Sole Proprietorship Partnership Other

I. **5. Company CEO:**

First Name:

Last Name:

Phone:

E-mail:

I. **6. CAP leader:** (if different from CEO, he/she should have the authority to make company business decisions deriving from strategies uncovered during the CAP. **The CAP leader will serve as the primary point of contact in**

the program and attend all mandatory program events.

First Name:

Last Name:

Title:

Phone:

E-mail:

- I. **7. Company description:** (Please briefly describe what your **company does** (Limit 100 words). Please note this summary may be repeated in the Executive Summary (see below).

- I. **8. Executive Summary:** Please use the outline provided [here](#) as a guide to complete and upload your non-proprietary Executive Summary (**Limit 1 page of no more than 600 words**)

- I. **9. Company website:**

Twitter:

LinkedIn:

YouTube:

Facebook:

- I. **10. Company Logo** (Only ".jpg", ".png", and ".gif" image file types are allowed. Please do not upload a logo larger than 5MB.) [Select & Upload Image]

- I. **11. Does your company's executive team include one or more (in combination) of the following military or minority classifications?**

- African American Asian Pacific American Hispanic American Native American
 Subcontinent Asian American Veteran A Woman in the C-Suite or on the Executive Team
 Women-Owned or Operated

- I. **12. How many full- and part-time employees does the company have on its payroll?**

Total number full-time employees

Total number part-time employees

- I. **13. Is this a University Spin Out? Y/N**

Please select the name of the university

- I. **14. Have you participated in an accelerator or incubator program? Y/N**

14a) If Yes, please provide the name?

I. 15. Rate the average level of commercialization experience in your management team

1=novice Has attempted commercialization of technology in the past.

5= expert Has successfully commercialized technology multiple times to a high degree.

I. 16. Total number of successful "exits" (i.e. acquired by another firm, IPO, management buy-out/buy-in, etc.) by this team or senior executive members of the team

I. 17. Total number of successful start-ups by the management team

I. 18. From the following list, which sector best describes your company and technology? (select the most appropriate option)

18a. Technology Sector

Aerospace and Defence

Agriculture/Food

Cleantech/Energy

Education

Information Technology

Life Science/Healthcare

Logistics (Transportation, Packaging, etc.)

Material Science

Other (Please specify) _____

Technology Sub-Sector (regardless of the above, please indicate the specific area your technology is best classified under):

Biotechnology: Involves the use of microorganisms, such as bacteria or yeasts, to perform specific industrial or manufacturing processes; includes so-called "bioengineered" compounds, therapies, and components.

Pharmaceuticals: Involves the development of drugs as chemical substances used in the treatment, cure, prevention, or diagnosis of disease and/or used to otherwise enhance physical or mental well-being; includes so-called "naturopathic" or naturally-derived substances in alternative care regimens.

Research Tools: Involves the development of (new or improved) tools to enhance laboratory studies on humans and animals (e.g., animal models and cell culture). This also includes tools to broaden the research knowledge base in a specific area of the life sciences or affiliated domains.

Medical Devices: Involves the development and/or use of instruments or machines, for the diagnosis of diseases or in the cure, mitigation, treatment, or prevention of diseases or conditions associated with the deterioration of physiological function (e.g., prostheses); this would also include the use of innovative materials to construct new "devices".

Diagnostics: Involves the use of tools (software, hardware, or combinations) to identify the nature of medical conditions, determining whether specified diseases or disease processes are present in living organisms; it includes the use of these tools to provide insights in the work of clinicians, providers, manufacturers of equipment, and companies involved in therapies associated with disease.

Healthcare IT: Involves approaches and tools derived from information technology that allow for the management of medical information and exchange between health care consumers and providers; also includes software, media, and educational tools and solutions that provide for communication, organization, and promotion of effective exchange among these groups.

Industrial Biotechnology : Industrial biotechnology uses enzymes and micro-organisms to generate industrially useful products in sectors such as chemicals, food and feed, detergents, paper and pulp,

textiles and bioenergy (such as biofuels or biogas). In doing so, industrial biotechnology uses renewable raw materials (feedstock), may contribute to lowering greenhouse gas emissions, and may promote an environmentally-sustainable process.

Other, please specify

18b. Market Sector - Who are your customers i.e. those buyers who either currently buy your product or service directly or indirectly from you, or who you know to be interested in doing so? If you don't currently have customers, please indicate your understanding of potential customers for your product. Please be as specific as you can:

Please identify your customers, either by name or by type of organization/company they represent. Note: these could be end-users i.e. those who directly use your product as intended or intermediate customers, i.e. those who buy your product and in turn sell to an end-user.

- Consumers
- Fortune 500 or large company, examples _____
- Healthcare Institutions (hospitals, medical offices and clinics)
- Research Institutes (university, laboratory, clinical research company, etc.)
- Other (Please specify) _____

SECTION II - TECHNOLOGY VISION (TO BE FEATURED IN THIS CAP)

This section focuses on the SBIR or STTR-funded technology that will be addressed during CAP; its regulatory status (if applicable), current Intellectual Property (IP) status, your perspectives, and opinions with respect to your vision. In describing your vision, please be as specific as possible.

- II. **1. Technology description:** Describe in non-proprietary terms the innovation inherent in the technology and the commercial applications of this technology (limit 100 words). *If your company is organized around more than this technology area or product/service line, please note its strategic importance to the company as a whole.*

- II. **2. What barriers and/or gaps do you see as critical in the adoption of your technology?** From the following list, please check which external barriers (i.e., those over which you may have no control) hinder the adoption of your technology by customers, partners, etc. (Check all that apply.)

- Implementing a regulatory/reimbursement strategy is the principal barrier to getting this product into use and adoption (the product needs regulatory approval or pathway)
- Product differentiation is not explicit (your product/service does not stand out among similar offerings)
- Reimbursement codes are not in place (e.g., if the technology is new or untested)
- The current product(s) is/are well-entrenched (they have a strong position in the market)
- The field is crowded with competitors pushing other products that are similar to ours (the number of competitors is large)
- We have no competitors

- We're a start-up and it is difficult to get the attention of large players in the market (larger players overlook or discount the existence of a start-up). Please specify
- Other. If other, please specify:

II. 3. List top competitors by Company or Trade Name. Be sure to include those whose product/service your technology/solution will disrupt.

II. 4. Please state if technology requires regulatory approval or reimbursement from CMS or private payers. (e.g., PMA, 510K, Pre-IND etc.)

- YES NO

4a) If your technology needs regulatory approval, please check one or more of the following:

- Pre-IND submission stage
- IND already submitted
- Had Preliminary meeting(s) with FDA to discuss next steps
- We have already identified our reimbursement strategy
- We have obtained reimbursement codes
- We need to develop a regulatory and/or reimbursement strategy
- Other _____

If you are subject to regulatory approval, how far are you from a key regulatory milestone e.g. IND, 510K etc.? (as an example, 18 months away from IND, 510K etc.)

II. 5. Please state the current intellectual property status of the technology to be commercialized in this CAP (e.g., patent, trademark, copyright, etc.) and the number of these IP filings associated with the technology.

Number of Disclosures (NDA, CDA, etc.)	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2-3	<input type="checkbox"/> 4-5	<input type="checkbox"/> More than 5
Number of Provisional Patents:	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2-3	<input type="checkbox"/> 4-5	<input type="checkbox"/> More than 5
Number of Pending Patents:	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2-3	<input type="checkbox"/> 4-5	<input type="checkbox"/> More than 5
Number of U.S. Granted Patents:	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2-3	<input type="checkbox"/> 4-5	<input type="checkbox"/> More than 5
Number of International Pending Patents:	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2-3	<input type="checkbox"/> 4-5	<input type="checkbox"/> More than 5
Number of International Granted Patents:	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2-3	<input type="checkbox"/> 4-5	<input type="checkbox"/> More than 5
Number of Copyrights:	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2-3	<input type="checkbox"/> 4-5	<input type="checkbox"/> More than 5
Number of Trademarks:	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2-3	<input type="checkbox"/> 4-5	<input type="checkbox"/> More than 5

5a) Do you consider these to have "blocking" potential (i.e., you have a legal and competitive edge and you could legally challenge a third party developing a technology solution in this area)?

- YES NO

II. 6. How developed is the technology? Please note you could be involved with manufacturing and still be at the proof of concept stage. In this case please check both boxes.

- Clinical Trials (if applicable)
- Pre- Proof of Concept
- Proof of concept
- Manufacturing Stage

- Market Development
- Product Development
- Research & Development
- Revenue Generating

II. **7. Do you believe your technology solution meets an “unmet need”** (i.e., existing solutions do not address or resolve a problem or need being felt by specific users, but yours does)? **What is the “unmet need” that you address? How will your solution advance knowledge, usage, or the technology state of the art?** (Limit to 100 words)

SECTION III - BUSINESS AND MARKET VISION

This section seeks to understand (from your point of view) the issues, obstacles, barriers, and drivers behind your business and market, your commercialization priorities, and your near-term business goals. These relate mostly to the SBIR/STTR-funded technology being commercialized, except where noted. As with Section II, we are seeking for informed opinions, not blanket assertions.

III. **1. Business Goals and Vision**

What are your specific NEAR TERM business goal(s) over the next 18-24 months? (Limit to 100 words)

III. **2. Please tell us what you consider to be the most challenging gaps or deficiencies** (internal to your enterprise), **as obstacles to successful commercialization, either of your technology or your overall company?** (Examples, for guidance purposes only, may include: lack of, or incomplete, management team, lack of regulatory expertise, inadequate internal communication, internal disagreements on commercialization direction, technical or technology issues and/or problems, lack of funding, etc.) Please list and elaborate, as necessary.

III. **3. How well do you know your market, your customers, and your product?**

- | | | |
|---|------------------------------|-----------------------------|
| Have you identified (a) customer(s) for your product or service? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you need more assistance in identifying or refining your customer profile? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Have you done a market study for this product/service? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you need further assistance in understanding your market? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you know the size of your potential market? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you consider your product/service to be a “niche” product? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Do you need further assistance in defining this “niche”? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

III. 4. What do you feel are your most important commercialization priorities for the CAP?

Use the following list to rank in order of importance your top commercialization priorities for the SBIR/STTR developed technology (1 being the highest and 8 being the lowest) and check all of the boxes that apply to your current situation/requirements for each category.

___ **Financial Issues and Business Model**

- Understand general subject of capital-raising
- Determine valuation options
- Begin search for private investors
- Develop/refine business and revenue model
- Develop/refine financial model

___ **IP Strategy**

- Understand IP position
- Understand and study licensing opportunities
- Develop an IP position for negotiation and licensing transactions

___ **Management team**

- Develop a management team
- Expand the existing management team

___ **Market Strategy**

- Understand the competition
- Develop or improve marketing materials
- Increase sales/revenues

___ **Regulatory Process**

- Understand the Regulatory Process
- Seek regulatory approvals and perform clinical trials
- IRB approval of pivotal study design
- Classification of product
- Submission/approval of 510k or PMA Package

___ **Reimbursement**

- Identify the steps in Reimbursement
- Develop the framework to establish reimbursement strategy/codes
- Identification of assigned CPT codes and any related MS-DRG/APC codes
- Technology Add-ons
- Insurance Coverage and payment, including public and private payers

___ **Strategic Business Planning**

- Understand framework of general business planning, including SWOT analysis
- Identify core business value and societal expectations
- Develop strategic business/commercialization planning
- Refine current strategic business/commercialization planning

___ **Strategic Partnership Planning**

- Understand and study strategic partnership opportunities
- Identify the right partner

- Establish strategic partnerships
- N/A

III. 5. What would you like to gain from your participation in CAP (in your own words):

SECTION IV - COMPANY VISION

This section focuses on your vision for where your company is headed and the types of internal resources your company may have that can facilitate commercialization. These can include: team, company management, company experience with respect to partnerships, investors, and investors; and company IP and licensing profile.

IV. 1. What is your vision for the company's future? (Check only one)

- As a stand-alone company mostly based on *commercial sales of products or services*
- As a stand-alone company mostly based on *licensing revenue and/or commercial (R&D) contracts*
- As a stand-alone company mostly based on *government R&D grants and contracts*
- Spin-off
- To merge with, or be *acquired by, another company*
- Initial Public Offering - *IPO*
- Unsure

IV. 2. Are there people on your management team with relevant experience in commercialization?

- Yes No

2a) If "Yes", please identify their experience in the following areas (Check all that apply)

- Partnerships Product Sales Licensing Investment Regulatory/Reimbursement

Other (Specify)

2b) Is one of the executives with this experience the CEO or the CAP leader?

- Yes No

IV. 3. Partnerships - Please check the following, as appropriate:

3a) Are you currently seeking partnerships? Yes No

If "Yes", what kind of partnerships are you seeking?

(Check one or more, as appropriate):

- Strategic partner Licensing partner Manufacturing Distribution
 Technical collaboration Other (Please specify)

3b) If "Yes" what is your timing for seeking a partner?

- We are ready to engage this year
- We are investigating partnership now and expect a meeting soon.
- We are ready to engage within the next 2-3 years
- We are ready to engage within the next 5 years

Not sure

3c) Are you currently or have you ever been involved with the following activities with potential partners or investors? (Please specify, enter zero "0" if not applicable)

Activity	Number of partnership/investor-related activities in which your company has engaged in 2015-2016	Details of the activity (briefly describe the nature of this interest)
Contacts with Partners Count only contacts with whom you had a meaningful conversation with about your mutual interests		
Meetings with Partners Meetings can be face-to-face or by phone/web, but should involve exploration of potential deals in some detail		
Confidential Disclosure Agreements Signed CDA (NDA) agreements are generally a pre-requisite for any serious discussion with potential partners		
Negotiations with Partners At this stage, all parties are interested in the deal and you are exploring various give and take scenarios		
Initial Proposals and Term Sheets These are proposals of key terms of the deal and serve as the basis for a final agreement		
Deals Signed legal documents, committing partners to a process, timeframe and outcome. If appropriate to the "deal(s)", please indicate the dollar amount(s) involved		

IV. **4. What is the current status of your search for investment and your current status with respect to funding?** Please check the following, as appropriate:

4a) Are you currently seeking equity investment? Yes No

4b) If "Yes," will this be your first institutional round? Yes No

4c) If "Yes," what is your timing for securing additional investments?

We are ready to engage with outside investors now

- We are investigating sources now and expect a meeting soon
- We will be ready for outside investment and funding within the next 2-3 years
- We will be ready for outside investment and funding within the next 5 years
- Not sure

4d) What is the amount of anticipated capital that you seek in the equity investment?

4e) How can the CAP program help you be more attractive to investors?

4f) What is the approximate amount of funding (not including revenue) currently generated from each source indicated:

Dilutive Funding

- \$ _____ Angel Investors
- \$ _____ Crowd Funding
- \$ _____ Employees, Friends, and Family
- \$ _____ Strategic Investment
- \$ _____ Venture Capital
- \$ _____ Other (Please specify)

Non-Dilutive Funding

- \$ _____ Bank Loans and other Alternative Funding
- \$ _____ Commercial R&D Grants, Milestones-Based Arrangement with Industry, or Other Partner(s)
- \$ _____ Federal, State, and Local Government R&D Grants
- \$ _____ Foundations
- \$ _____ Other (Please specify)

IV. 5. How many years has your company been receiving government grants?

IV. 6. Revenue status:

6a) Are you currently generating revenue? Yes No

6b) If "Yes," please indicate dollar range of your company's revenue for the past year (*include sales and licensing revenues*)

R&D Contracts (not your SBIR/STTR/ Phase II,) \$ (Under \$10,000,000)

Sales from Products and Services \$ (Under \$1,000,000) (Under \$5,000,000) (over \$5,000,000)

Licensing Fees and Royalties \$ (Under \$1,000,000) (Under \$5,000,000) (over \$5,000,000)

IV. 7. Please state the current intellectual capital assets that your company has overall? Indicate the kind of IP (patents, trademarks, copyright, and trade secrets), whether they are pending or approved, and the number.

IV. **8. Does your company have any licensing deals?** (Specify the number, or enter 0 if not applicable)

Number of In-Licensing Partners:

Number of Out-Licensing Partners:

Have you identified licensing opportunities? Yes No Not Applicable

IV. **9. What level of business/commercialization expertise resides in your company?**

In terms of your knowledge of, and exposure to commercialization, please check ONE box below to indicate your company's current level of expertise. This also corresponds to the level of assistance sought from the NIH CAP program. (Check only one)

Low: Our team is comprised of mostly scientific staff with and has **little business experience** in seeking assistance with basic business, strategic planning and tools; needs significant guidance in IP, market position, competitive placement, strategic partnering, market approaches, and funding/financing.

Medium: Our team is comprised of staff with some business experience, but is seeking to further business acumen and **refine existing business model and strategic approach**; needs guidance in product development, market development, manufacturing, IP, market position, competitive placement, approaches, strategic partnering, and funding/financing.

High: Our team is comprised of staff with considerable business experience in seeking targeted and high-level strategic and tactical help, and **has commercialization experience** (e.g., securing investments, forming strategic alliances, negotiating licensing deals, manufacturing or scaling up product, have revenue from sales, and seeking or having achieved regulatory objectives).

Non-Disclosure: All application information will be held in the strictest of confidence and Larta, Inc. will not use, disclose, or otherwise permit any person or entity access to any of the information other than as required in the performance of Larta's services for your company or the National Institutes of Health.

Now that you have completed the Program application form, please indicate your **preferred track** (refer to the [Program Description](#) for more details on the three tracks as needed):

Commercialization Transition Track (CTT):

This track is suitable and relevant for the majority of HHS SBIR/STTR Phase II companies.

In this track, you will receive the tools to understand and put into practice the commercialization plans and activities critical to your company's stage, level, and background. It also provides you with the opportunity to receive direct industry feedback at a live (in-person) session.

You will also address: What qualities do you have to give you a competitive advantage in the commercial marketplace? What "channels" could you develop to enable you to grow and establish a solid revenue base (customers, investors, partners, license prospects, etc.)? What is the strategy "roadmap" that you need to develop to guide your specific commercialization actions over an 18-month period, both during and long after the Program?

Participants work one-on-one with a "Principal Advisor" throughout the program and with industry experts, as needed.

Advanced Commercialization Track (ACT):

This track is suitable and relevant to a group of companies that have some history of accomplishment in commercializing products and/or services, generated and maintained revenue streams, or are currently servicing a well-defined and steady customer base and have established partnerships.

In this track, you will focus on a specific “gap” or applicable issue whose resolution is crucial to your company’s continued progress and development. These issues may include (as examples only): developing a term sheet for identified investors, negotiating terms on a license, finalizing a product design with specifications for an identified target, etc.

This track specifically deploys “Expert Resources” (domain experts) to help participants achieve their set outcomes.

Regulatory/Reimbursement Training Track (RTT):

This track will apply to a select group of HHS-funded companies seeking regulatory approval by the Food and Drug Administration (FDA) or reimbursement issues related to the regulations by CMS and private insurance.

In this track, you will focus on addressing a specific regulatory or reimbursement related issue (such as a regulatory plan or application using appropriate codes, etc.) whose resolution is key to their success with the FDA approval or ensuring payment from Medicare and U.S. Private Payers, etc. This track is not intended to create a comprehensive regulatory or reimbursement outcome, but rather to focus on the key issues guiding you on your regulatory path or reimbursement pathways and achieve one (1) tangible outcome within the scope of this program.

This track specifically deploys regulatory or reimbursement experts to help participants achieve these outcomes.
