INNOVATION IN IMPLEMENTING LONG-ACTING CABOTEGRAVIR+RILPIVIRINE REQUEST FOR PROPOSALS

Using Implementation Research to evaluate novel approaches to the delivery of CAB-RPV LA for HIV Treatment in the United States

Purpose
ViIV Healthcare is announcing the availability of up to five (5) one-time awards of up to $500,000 to HIV care centers in the United States (US) to better understand how to optimize healthcare services in the US to deliver Cabotegravir (CAB)- Rilpivirine (RPV) Long-Acting (LA) as treatment for People Living with HIV (PLHIV).

Objective
Though the Investigator Sponsored Studies (ISS) program, awardees will develop and execute implementation science (IS) research designed to better understand how to delivery CAB-RPV LA to diverse populations in the US. As CAB-RPV-LA is a new and novel treatment in the field of HIV, it is critical to understand “how” to effectively implement this treatment paradigm to ensure optimal impacts on service system- and patient-level outcomes.

Background
Long acting ART is being developed to enable therapy with monthly or every other monthly injection. These therapeutic options hold great promise for HIV treatment and represent an emerging paradigm shift for the treatment of HIV infection.

This new treatment paradigm will require changes to the current standard of prescribing oral antiretroviral therapies including the logistics of delivering a complete antiretroviral treatment regimen as LA injectable therapy. This new treatment paradigm will require more frequent visits by patients to see a provider to receive the injections, as well as potentially require greater resources in the clinical setting to administer the injection. As this is a promising new treatment modality for people living with HIV (PLHIV), it is important to understand how to optimize the delivery of CAB-RPV LA from a PLHIV, HCP and healthcare system perspective.

This RFP is aimed at supporting efforts to address current gaps in understanding of “how” to implement CAB-RPV LA in the real-world settings. Innovative implementation science research that will evaluate new modalities and innovations to deliver long-acting HIV treatment to high-risk or hard to reach populations is encouraged. Outreach and collaboration with county health departments, alternate injection facilities (i.e. STD clinics, pharmacy clinics, etc.), homeless programs, substance use treatment programs, and other integrated care initiatives are all approaches that would be strongly encouraged; however, funding is not limited to such projects.

This funding is intended to identify best practices that identify a sustainable modality to effectively deliver CAB-RPV to populations that would most benefit from this type of ART.

Applicants
Applicants are strongly encouraged to partner with a researcher(s) with experience or expertise in Implementation Science. The applicant setting(s) can include a variety of health care settings, but is not limited to,
/ Academic Centers

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Federally Qualified Health Centers
Private Practices
Sexual Transmitted Infection Clinics
Pharmacy Clinics
Correctional Facilities
Women’s Health Centers
Veteran Affairs Hospitals and Clinics
Integrated Health Systems (i.e. Kaiser Permanente)
Substance Abuse Clinics
Home Care with Medical Provider Concierge Service
Mobile Administration

Collaborations between multiple providers, departments of health, and other healthcare delivery settings is also strongly encouraged.

**Funding available**

These funds CAN be used for, but are not limited to:

- Advertising Costs for Recruitment Purposes
- Study Related Clinical Insurance
- Assay Reagents and Other Consumables for use with Site’s Equipment
- Study Close Out Fee
- Supplies
- Printing Fees
- Journal Fees
- Personnel Costs Specific to the Study
- Pharmacy Fees (set-up costs, storage etc.)
- IRB/EC Costs (initial and renewal)
- Site Start Up Costs
- Translations
- Shipping
- Archiving Fees
- Cost of Essential Study-related Activities (eg. Trial Steering Committee, site monitoring, IDMC)
- Patient Reimbursement for Visits

These funds CANNOT be used for:

- Information technology hardware, software, or services (telehealth equipment or services are considered clinical equipment, not IT)
- CAB-RPV-LA medication will not be provided for the study. Exceptions may be made where access is severely constrained.

**Timeline**

<table>
<thead>
<tr>
<th>Event</th>
<th>Date/Time</th>
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<tbody>
<tr>
<td>Letter of Intent Submission opens</td>
<td>July 22, 2019</td>
</tr>
<tr>
<td>Deadline for Letter of Intent</td>
<td>November 1, 2019 11:59PM EDT</td>
</tr>
<tr>
<td>Deadline for Submitting Final Proposals</td>
<td>November 15, 2019 5 PM EDT</td>
</tr>
<tr>
<td>Internal Review Process begins</td>
<td>October 1, 2019 (Rolling Basis)</td>
</tr>
<tr>
<td>Final selections</td>
<td>January 25, 2020</td>
</tr>
<tr>
<td>Notification of Funding</td>
<td>February 15, 2020</td>
</tr>
<tr>
<td>Project implementation</td>
<td>April 2020 – Oct 2021 (18 months)</td>
</tr>
</tbody>
</table>

**Application Requirements**

- Must be focused on one of the priority areas listed below (see section on Priority Areas)
- Must be designed as Implementation Science Research (see Appendix A for guidance)
- Must clearly articulate their implementation strategies and outline the implementation outcomes to assess both from provider’s perspectives and patient’s perspectives
- Clear quantifiable goals and objectives must be identified with a feasible timeline
- Must have a data dissemination and a publication plan
Applications must include written support from and signed by the relevant collaborators(s) assuring adequate organizational backing for the project.

**Implementation Research**

To be considered, all proposals must include implementation science principles including, but not limited to:

- Implementation science framework (i.e. Proctor, RE-AIM, EPIS, CFIR, etc)
- Implementation strategies
- Implementation outcomes (i.e. acceptability, feasibility, cost-effectiveness, sustainability, etc)

See appendix A for more details

**Priority Areas**

1. Implementation of CAB-RPV LA delivery models in non-HIV clinic settings (i.e. alternate injection facilities, pharmacy clinics, STD clinics, etc)
2. Feasibility and Acceptability of bringing CAB-RPV LA injections to the patient (i.e. home nursing care, mobile vans, etc)
3. Addressing challenges of CAB-RPV LA delivery amongst high risk populations (i.e. Black MSM in the Southeast US, women of color, transgender people, homeless/unstably-housed PLHIV, rural settings, correctional facilities, etc)
4. Use of creative technological modalities to improve the adherence to monthly injection visits including telehealth, mobile apps, or other innovative ideas.
5. Other innovative proposals that may propose a unique way to improve delivery, acceptability, and sustainability of CAB-RPV LA among high-risk populations.

**Letter of Intent**

Beginning July 22nd, 2019, the online submission form will be available for applicants to submit a letter of intent by going to [www.hivimplementationscience.com](http://www.hivimplementationscience.com). The deadline to submit a LOI will be November 1, 2019 11:59PM EST.

**Submission of Application**

Within a week of submitting a LOI, you will be notified of acceptance to submit a full application including proposal. Instructions on how to upload your full application will be emailed. Final applications must be uploaded to the VISIONS portal as a Microsoft Word document or Adobe Acrobat PDF. Applications must be written in 12-point Arial font for legibility and should be no more than 25 double-spaced single-sided pages. Proposals will be reviewed by a panel from ViiV healthcare as well as an external body convened specifically for this purpose.

Applications should contain the following:

1. Name and titles of applicant(s) and sponsoring facility or facilities
2. Title
3. Objectives (Clinical and Implementation)
4. Hypothesis
5. Background
6. Implementation framework(s)
7. Implementation strategy(s)
8. Methods - study design
9. Outcomes and Data Analysis Plan
10. Study personnel
11. Timeline
12. Budget (max $500,000)
13. Publication/Presentation Plan
14. Signed letters of support from relevant collaborators and facility leadership.
Application Evaluation Criteria

Proposal will be reviewed by both an internal ViiV Healthcare panel as well as an external panel and scored against the following criteria:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategic Priority for ViiV Healthcare</td>
<td>20</td>
</tr>
<tr>
<td>Quality of Implementation Research</td>
<td>20</td>
</tr>
<tr>
<td>Area of need identified</td>
<td>10</td>
</tr>
<tr>
<td>HIV care continuum statistic being addressed</td>
<td>10</td>
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<tr>
<td>Potential for exportability</td>
<td>10</td>
</tr>
<tr>
<td>Quantifiable results pre-post intervention</td>
<td>5</td>
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<tr>
<td>Organizational support for sustainability</td>
<td>5</td>
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<tr>
<td>Well defined scope and deliverables</td>
<td>5</td>
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<tr>
<td>Strength of applicant(s) qualifications</td>
<td>5</td>
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<tr>
<td>Innovation</td>
<td>15</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>100</strong></td>
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Reporting Requirements

Awardees will be required to submit written milestone reports at 6 months and 12 months, and 18 months after the award start date. Awardees are also required to submit their results from the study as a conference abstract or journal manuscript for publication.

ViiV Healthcare Accountable Person

The Head, Innovation and Implementation Science as well as The Global Medical Lead, Cabotegravir are responsible for this program. If you have any questions, please contact us at viiv.implementationscience@gsk.com
Appendix A

VISRC Proposal Guidance Document

I. Title of Research Project:

II. Background (limit 250 words):

   a. HIV epidemiology: please describe HIV care continuum in your setting.
   b. Setting: health department, healthcare setting (e.g., hospital, clinic, community health center, pharmacy, etc.), school, workplace, places of worship, other community settings
   c. Evidenced based Intervention = CAB + RPV Long Acting Injectable

III. Study Objectives:

   a. Implementation Questions
      i. Ex: Will in-person provider education (implementation strategy) improve acceptability and feasibility of the EBI?
   b. Clinical Questions
      i. Ex: Can a specific implementation strategy (e.g., audit and feedback) ensure 100% adherence to monthly injection visits?

IV. Methods

   a. Design of Implementation Research: (Choose One and explain why in 500 words or less)

      I. Hybrid designs (see Curran et al., 2012, and brief supplement for more information about Hybrid Designs)
         b. Hybrid design type 2: Co-primary aims: Clinical efficacy and implementation outcomes
         c. Hybrid design type 3: Primary aim: Implementation Outcomes and Secondary Aim: Clinical efficacy or effectiveness

      II. Pure implementation research: Focuses on implementation outcomes only without measurement of patient or clinical outcomes.
a. Examination of current routine care practices involving implementation of a novel innovation.
b. Pre-implementation research: Formative evaluation of context specific needs, barriers, facilitators, and key stakeholders.

b. Implementation Stage of Research Project: (choose one and explain why in 500 words or less, use the IS stage or stages to guide the proposal design)

i. Exploration: identifying the need for change, learning about possible evidence-based interventions that may provide solutions, learning about what it takes to implement the intervention effectively, developing stakeholders and champions, assessing and creating readiness for change, and deciding to proceed (or not).

ii. Installation/Preparation: establishing the resources needed to use an evidence-based intervention and the resources required to implement the intervention as intended.

iii. Initial Implementation: the first use of an evidence-based intervention by healthcare professionals or patients/service users and learning how to support the new ways of work.

iv. Full Implementation: the skillful use of an evidence-based intervention that is well-integrated and routinely and effectively supported.

v. Sustainment: processes are ongoing, with limited to no research support, where the evidence-based practice continues to be delivered in the form that results in the greatest public health impact of the implemented innovation. Further adaptations may be made in this phase to support the process.

c. Implementation Strategies: Implementation strategies are methods or techniques used to improve the adoption, integration, and sustainability of an CAB + RRV Long Acting Injectable. Implementation strategies can be discrete (e.g., clinical reminders, training only), multifaceted (e.g., training plus reminders, training + fidelity monitoring + coaching), or blended/comprehensive (e.g., Dynamic Adaption Process, Leadership and Organizational Change for Implementation). Please list and describe the primary implementation strategies to be used in this study (typically no more than 4).

1. Name and define the implementation strategy/strategies that were selected and any discrete components operationally using the following guidelines:

   https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-8-139

    *If relevant to a specific study design, use appropriate StaRI criteria checklist

2. How will the IS strategies be used?

3. What were the specific targets for each strategy?
Resources:

- Proctor, Powell, Baumann, Hamilton& Santens (2012): ERIC Discrete Implementation Strategy Compilation

**d. Framework: (see Appendix A1)** Implementation

Frameworks are proposed models or factors that are likely to impact the implementation and sustainment of an evidence-based practice, in this case, CAB + RPV long acting injectable (Aarons, Hurlburt, & Horwitz, 2011; Damschroder et al., 2009; Tabak et al., 2012). There are numerous frameworks to choose between. When deciding between frameworks, it is helpful to choose the one that seems to provide the best fit for your study. The online toolkit from Tabak and colleagues provides a helpful method to both identify and compare potential frameworks.

1. Identify and justify the IS model or framework which best supports your implementation question (Examples: Consolidated Framework for implementation Research, RE-AIM, EPIS, etc.)

2. How will the model/framework operationalized? (For example: Was the model/framework used to stage the project, to identify appropriate measures, or to assess progress, etc.)

3. Were these frameworks used proactively to guide the implementation process?

**e. Study Design:** Please identify the type of study you are proposing and fully describe the entire methodology. For example, how you plan on testing whether your EBI will impact health outcomes using your implementation strategies. Below are examples of the type of study you can use and is not intended to be an exhaustive list. Please note that in order to fully examine the research questions proposed in your project, mixed-methods approaches are highly encouraged to maximize the understanding of the context in which you are proposing your study. Mixed methods designs should be used to inform measurement considerations and analysis rather than be proposed as a larger study design. Instead, please identify the methodology proposed to achieve a greater understanding.
of external validity at the end of the study. Additional information can be found here. (500 word limit)

Implementation Study Design Examples
(adapted from: https://impsciuw.org/designing-is-research/)

I. Randomized Control Trials (RCTs): RCTs are experimental clinical studies where participants are randomly selected to intervention or control groups and followed over a predetermined amount of time. There are several types of RCTs, including:

a. **Cluster Randomized Control Trial:** An RCT with a parallel or cross-over design that randomly assigns pre-existing groups of participants into an intervention or control group.
   i. Related methodological resources: Hemming et al., 2017; Powell-Jackson et al., 2018

b. **Stepped-Wedge Design:** A randomized cross-over design where different groups or clusters cross-over to the intervention condition at different time points during the study so that all clusters eventually receive the intervention and the intervention continues in a given cluster once it has begun.
   i. Related methodological resources: Hemming et al., 2014; Ching Ting Fok et al., 2015; Hemming et al., 2015; Copas et al., 2015

c. **Effectiveness-Implementation Hybrid Design:** A design that allows for a focus on both clinical effectiveness and implementation. The hybrid design is broken into 3 types of designs:
   1. Testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation
   2. Dual testing of clinical and implementation interventions/strategies
   3. Testing of an implementation strategy while observing and gathering information on the clinical intervention’s impact on relevant outcomes
   i. Related methodological resources: Curran et al., 2012; Bernet et al., 2015

II. Intervention Optimization

a. **Multiphase Optimization Strategy (MOST):** A design for building, optimizing, and evaluating interventions via a three-phase method that identifies active intervention components and the levels of each component lead to optimal outcomes.
i. Related methodological resource: Collins et al., 2007

b. **Sequential Multiple Assignment Randomized Trial (SMART):** A randomized experimental design developed specifically for building time-varying adaptive interventions.
   i. Related methodological resources: Collins et al., 2007; Chow & Hampton 2018; Wallace et al., 2016

III. **Quasi-Experimental Designs:** estimate if an intervention has a causal impact on a target population without random assignment

   a. Resources for general methodology: Handley et al., 2018; Tugwell et al., 2017
   b. Interrupted Time Series: routine monitoring data is collected at evenly spaced time points before and after the intervention and the data collected prior to the intervention serves as the control group.
      i. Related methodological resources: Cruz et al., 2017; Linden 2017; Polus et al., 2017
   c. **Regression Discontinuity:** a design that utilized pretest-posttest examination of causal effects of interventions. The threshold determines who receives the intervention, which allows for the estimation of average treatment effect when randomization is not possible
      i. Related methodological resources: Moscoe et al., 2015; Walkey et al., 2018; Venkataramani et al., 2016
   d. **Regression Point Displacement:** pretest-posttest design where data is collected at the group level and often involves one treatment group and more than one control group
      i. Related methodological resources: Linden et al., 2006; Wyman et al., 2015

V. **Research and Analysis plan**

   a. **Primary Endpoints:** Either clinical or implementation endpoints
   b. **Secondary Endpoints:** Either clinical or implementation endpoints
   c. **Inclusion/Exclusion Criteria:** Please describe inclusion and exclusion criteria for applicable participants e.g. patients, staff, clinics, or other unit of analysis.
   d. **Sample Size:** (i.e. Number of Participants/Clinics): Please describe the anticipated number of participants. This may
include patients, clinic staff, clinic facilities, or other units of analysis.

**e. Statistical Analysis:** Provide an overview of the proposed statistical analysis plan, please include:

i. statistical hypotheses (or if none state why not),

ii. sizing considerations,

iii. randomization (where applicable),

iv. analysis of primary and major secondary endpoints,

v. control for bias in absence of randomization.

vi. Power calculation

**f. Outcome Metrics:** Please include the following: Outcomes, measurement methods, data source, and timepoints. (See Appendix A2). Describe how each outcome will be specifically measured (e.g., quantitative measure, qualitative interview guided by a specific framework) rather than only listing broad categories of outcomes.

i. Implementation Outcomes

ii. Service Outcomes

iii. Patient Outcomes

**VI. Timeline:** (Please be as detailed as possible, including recruitment and assessment timeline)

a. **Projected Enrollment Timeline:**

   Proposed Start Date:

   Data collection Timepoints:

   Proposed Finish Date:

**VII. Budget:** (see budget tool)

**VIII. Publication / Presentation Plan:**

a. Target journal

b. Conference

c. Timeline
Appendix A1: Five categories of theories, models and frameworks used in implementation science (Table adapted from: Nilsen, 2015)

Tool for choosing theories, models and frameworks for your study:

- [https://www.nccmt.ca/knowledge-repositories/search/254](https://www.nccmt.ca/knowledge-repositories/search/254)

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Selected Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process models (describe and/or guide the translation of research into practice)</td>
<td>Specify steps (stages, phases) in the process of translating research into practice, including the implementation and use of research. The aim of process models is to describe and/or guide the process of translating research into practice.</td>
<td>Model by Landry et al., model by Davies et al. model by Majdzadeh et al., the CIHR Model of Knowledge Translation, the K2A Framework, the Knowledge-to-Action Model, the Quality Implementation Framework, Exploration, Preparation, Implementation, Sustainment (EPIS) Framework</td>
</tr>
<tr>
<td>Determinant frameworks (understanding and/or explaining what influences implementation outcomes)</td>
<td>Specify types (also known as classes or domains) of determinants and individual determinants, which act as barriers and enablers (independent variables) that influence implementation outcomes (dependent variables).</td>
<td>PARIHS/IPARIHS, Understanding-User-Context Framework, Ecological Framework by Durlak and DuPre, CFIR, Theoretical Domains Framework</td>
</tr>
<tr>
<td>Classic theories (understanding and/or explaining what influences implementation outcomes)</td>
<td>Theories that originate from fields external to implementation science, e.g. psychology, sociology and organizational theory, which can be applied to provide understanding and/or explanation of aspects of implementation</td>
<td>Theory of Diffusion, social cognitive theories, theories concerning cognitive processes and decision making, social networks theories, social capital theories, communities of practice, professional theories, organizational theories</td>
</tr>
<tr>
<td>Implementation theories (understanding and/or explaining what influences implementation outcomes)</td>
<td>Theories that have been developed by implementation researchers (from scratch or by adapting existing theories and concepts) to provide understanding and/or explanation of aspects of implementation</td>
<td>Implementation Climate, Absorptive Capacity, Organizational Readiness, COM-B, Normalization Process Theory</td>
</tr>
<tr>
<td>Evaluation frameworks (guide evaluation of implementation)</td>
<td>Specify aspects of implementation that could be evaluated to</td>
<td>RE-AIM, PRECEDE-PROCEED, framework by Proctor et al.</td>
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</table>
## Request for Proposals / Innovation in Implementing Long-Acting Cabotegravir + Rilpivirine

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<tr>
<th>Category</th>
<th>Description</th>
<th>Selected Examples</th>
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</thead>
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<tr>
<td></td>
<td>determine implementation success</td>
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**Appendix A2: Service, Outcome, and Implementation Outcome Metric Tables**

**Proctor et al (2011) Outcome Classification:**

![Outcome Classification Diagram](image-url)
Example Outcome Tables-

These tables represent one potential way to outline the different outcomes in your proposal. Alternative formats are acceptable as long as enough detail is given about the method, level, and timepoint of measurement for each outcome.

### Service & Patient/Client Outcomes

<table>
<thead>
<tr>
<th>Outcome (Service/Patient)</th>
<th>Measurement method(s) (e.g. observations, surveys, routinely collected data)</th>
<th>Level of measurement, i.e. individual patient or service user, individual healthcare professional or service provider, health service facility (e.g. hospital)</th>
<th>Measurement time point(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td># HIV test performed (patient)</td>
<td>EMR extractions</td>
<td>Individual patients</td>
<td>Month 0, 3, 6, 12</td>
</tr>
<tr>
<td>Effectiveness (service)</td>
<td>Viral load</td>
<td>Individual patient</td>
<td>Month 0, 3, 6, 12</td>
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**Definitions of Service Outcomes (adapted from IOM and AHRQ):**

- **Efficiency:** The extent to which waste is minimized. This includes, but is not limited to, waste of time, equipment, supplies, ideas, and other resources.

- **Safety:** Decrease or limitation of harm to patients from the care that is intended to help them.

- **Effectiveness:** The extent to which services provided are based on scientific knowledge and available to all that might benefit from it while minimizing or eliminating providing services to those not likely to benefit (e.g., avoiding underuse and misuse).

- **Equity:** Providing the same quality care across characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

- **Patient-centeredness:** Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
- Timeliness: Delivering care in a manner that reduces waits and harmful delays for both those who receive and those who give care.

### Implementation Outcomes:

<table>
<thead>
<tr>
<th>Implementation Outcome</th>
<th>Measurement method(s) (e.g. observations, surveys, routinely collected data)</th>
<th>Level of measurement, i.e. individual patient or service user, individual healthcare professional or service provider, health service facility (e.g. hospital)</th>
<th>Measurement time point(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptability (Proctor et al): degree to which an intervention is perceived to be agreeable</td>
<td>Acceptability of Intervention Measure (AIM); Weiner et al, Implement Sci 2017;12:108</td>
<td>Patients</td>
<td>Month 0, 6, 12</td>
</tr>
<tr>
<td>Cost Effectiveness</td>
<td>Routinely collected data</td>
<td>Individual patient and system level</td>
<td>Month 6,12</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Feasibility of Intervention Measure (FIM; Weiner et al, 2017)</td>
<td>Service provider</td>
<td>Month 6, 12</td>
</tr>
</tbody>
</table>

Definitions of Implementation Outcomes (adapted from: Proctor et al, 2001 & Orientation To D&I-NCI):
- Acceptability: Perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory.
• Adoption: A decision to make full use of an innovation, intervention, or program as the best course of action available. Also defined as the decision of an organization or community to commit to and initiate an evidence-based intervention.
• Appropriateness:
• Cost (incremental or implementation cost): The cost impact of an implementation effort.
• Feasibility: extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting
• Fidelity: Degree to which an intervention or program is implemented as intended by the developers and as prescribed in the original protocol.
• Penetration: The integration of a practice within a service setting and its subsystems.
• Sustainability: The continued use of program components and activities for the continued achievement of desirable program and population outcome