

TECHNICAL ASSISTANCE WEBINAR

Prevention and Treatment through a Comprehensive Care Continuum for HIV-affected Adolescents in Resource Constrained Settings Implementation Science Network (PATC³H-IN)



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Structure of the Webinar

- **Questions during the webinar?**
 - We will get to as many as possible today
 - Frequently Asked Questions (FAQs) will be archived for those unable to attend today's videocast at <https://www.nichd.nih.gov/research/supported/PATC3H>
 - To ask a question, please use the Q&A Panel at the bottom of your screen
 - Questions we can't get to will be addressed via email or may be posted above as updated FAQs
 - Slides, updated FAQs, and recording will be made available within a week



Structure of the Webinar (continued)

- **Agenda**

- Introductory Slides
- UG1 funding opportunity announcement (FOA) presentation
- UM2 FOA presentation
- Selected FAQs
- Q/A Session

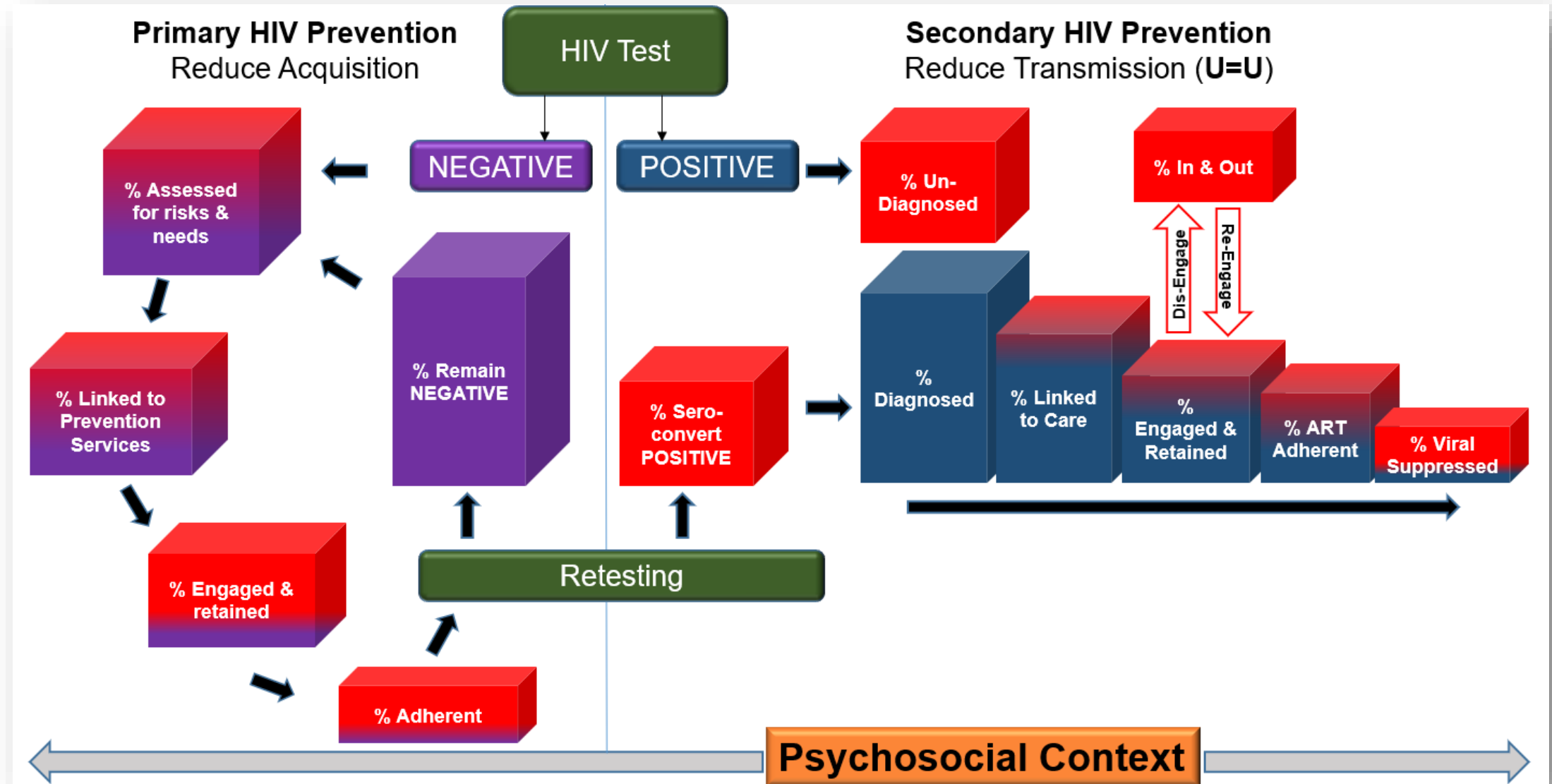


Evolution to new PATC³H-IN project cycle

- **These FOAs build on prior PATC³H work (2018-2021)**
 - **Establish a Network with highly integrated components**
 - **Expand and/or improve on successes achieved to**
 - New/additional geographic settings w/ limited implementation science (IS) capacity
 - New/additional risk populations poorly represented in LMIC adolescent HIV research
 - **Renew focus on an unmet, urgent public health need: The HIV epidemic among adolescents and young adults (AYA) in LMICs**
 - To improve AYA health outcomes across the HIV Prevention and Care Continuum (PHCC)



The HIV Prevention and Care Continuum



RFA HD-23-013 and RFA HD-23-014: PATC³H Implementation Science Network (PATC³H-IN) Clinical Research Centers (**UG1**) and Coordination, Translation and Advanced Methods and Analytics Center (**UM2**)

- **Part 1. Overview Information**
 - Key Dates
- **Part 2. Full Text of Announcement**
 - Section I. Funding Opportunity Description
 - Section II. Award Information
 - Section III. Eligibility Information
 - Section IV. Application and Submission Information
 - Section V. Application Review Information
 - Section VI. Award Administration Information
 - Section VII. Agency Contacts
 - Section VIII. Other Information

Anything not covered for **UM2** is the same as in **UG1**





**PATC³H-IN Clinical Research Centers (CRC)
(UG1)**

RFA HD-23-013 (UG1) Part 1

Overview Information

- Activity code: UG1 (cooperative agreement)
- **Released July 22, 2022**
- Key Dates
 - Open Date (Earliest Submission Date) November 06, 2022
 - LOI due November 06, 2022 (not required, more on this later)
 - Application due December 06, 2022
 - Peer Review March 2023
 - Council May 2023
 - Earliest funding July 2023
- Award
 - Up to \$940,000 (direct costs per UG1) to fund 4-5 awards in 2023
 - Up to 5 years
- Partner Organizations
 - NIDA, NIMH, NIMHD, FIC and OBSSR



RFA HD-23-013 (UG1) Part 2. Section I

Funding Opportunity Description

- **Purpose**

- Stimulate **implementation science (IS) research** in a neglected area of public health significance:
 - Prevention of new HIV infections among adolescents at risk in low-to-middle income countries (LMICs); *and*,
 - Identification of, linkage to and retention in care of, and long-term viral suppression among youth living with HIV in LMICs

- **Background**

- Adolescents & young adults (AYA, 10-24) are **> 1/4 of the world's population** and **90% live in LMICs**
 - UNAIDS estimates 3.9 million AYA aged 15-24 years old are living with HIV infection.
 - Each day, ~1,600 AYA acquire HIV infection and ~144 AYA die from an AIDS-related illness.
- Over prior decade, many revolutionary achievements in HIV prevention and treatment, **but high dependence on behaviors and structural determinants**
- Only ***rigorous implementation science*** can help **catalyze the field and overcome barriers** in management of adolescents and HIV



The PATC³H-IN Mission

- To evaluate promising **prevention innovations** contextually and developmentally tailored for HIV uninfected at-risk youth, *and* **treatment and care interventions** for youth living with HIV which have demonstrated efficacy and/or effectiveness in adolescent or adult populations and to translate them into public health practices.



Essential Features of PATC³H-IN – UG1

- **UG1 Clinical Research Centers (CRC)**
 - Multisite Research Project
 - 5 or more Clinical Research Performance Sites (CRPS)
- **UM2** Coordination, Translation and Advanced Methods and Analytics Center (CTAMAC)
- Scientific Leadership Committee (SLC)
- External Scientific Advisory Committee (ESAB)
- NIH PATC³H-IN Management & Oversight Committee (PMOC)



RFA HD-23-013 (UG1) Part 2. Section I (1 of 2)

Funding Opportunity Description

- Objectives

1. Improve understanding of the process of integration of research findings & evidence into public health, clinical practice and community settings and elucidate how to **sustain uptake, adoption, and implementation of evidence-based interventions for youth** who are at risk for or living with HIV in LMICs;
2. **Increase the scientific capacity and knowledgebase for IS research** on at-risk, uninfected adolescents and those living with HIV in new geographies with limited IS research capacity and risk populations who are poorly represented in international adolescent HIV research (e.g., sexual & gender minorities; commercial sex workers; drug users)
3. **Translate findings to inform national and global guidelines on the clinical management** of at-risk, uninfected adolescents and those living with HIV in these regions.



RFA HD-23-013 (UG1) Part 2. Section I (2 of 2)

Funding Opportunity Description

- **Scope (*highlights*)**
 - Research guided by **implementation science frameworks/theories** to improve the adoption, implementation and sustainment of evidence-based HIV prevention and care interventions to improve health outcome milestones on the PHCC of AYA in LMICs. **Hybrid Implementation-Effectiveness designs encouraged.**
 - Applications proposing studies in **new geographies with limited IS research capacity** (e.g., outside of South Africa) *and/or* **risk populations poorly represented in international adolescent HIV research** (e.g., sexual & gender minorities; commercial sex workers; drug users) will receive *additional program priority*.
 - Applications proposing interventions with **efficacious biomedical innovations** for prevention and treatment of HIV addressing the youth-specific PHCC (e.g., long-acting injectable, implantable or other sustained release platforms of antiretrovirals) will receive *additional program priority*.



RFA HD-23-013 (UG1) Part 2. Section III

Eligibility Information

- **Eligible Organizations**

- All US
- Foreign Institutions and/or Components

- **Eligible Individuals**

- Broadly inclusive (PI/PD with knowledge, skills, resources)
- Multi-PI applications accepted

- **Number of Applications**

- Applicant organizations may submit more than one application, provided that each application is scientifically distinct



RFA HD-23-013 (UG1) Part 2. Section IV (1 of 4)

Application and Submission Information

- **Letters of Intent (LOI)**
 - Due by COB November 06, 2022
 - Not required; not binding. Helps to plan review but does not impact it.
- **Include**
 - Descriptive title of proposed activity
 - Name(s), address(es), and telephone number(s) of the PD/PI(s)
 - Names of other key personnel
 - Participating institution(s)
 - Number and title of this FOA



RFA HD-23-013 (UG1) Part 2. Section IV (2 of 4)

Application and Submission Information

- Letters of Intent (LOI) should be submitted to:

Bill G. Kapogiannis, MD

Email: kapogiannisb@mail.nih.gov



RFA HD-23-013 (UG1) Part 2. Section IV (3 of 4)

Application and Submission Information

‘Standard instructions’ are *not* covered in this presentation

- **Research Plan (*highlights*):**
 - **Section A: Research Project Design**
 - A theoretically grounded, hypothesis-driven **Research Project** designed to address gaps along the HIV prevention and/or HIV care continuum (PHCC) among AYA in LMIC.
 - Primary outcomes **must include health outcomes on PHCC and ≥ 1 implementation science measure** (e.g., adoption, affordability, fidelity, penetrance, scale-up, sustainability, etc.).
 - **Section B: Justification of Proposed Clinical Research Performance Sites (CRPS)**
 - **Five (5) or more CRPS** that will implement the Research Project.
 - Each CRPS must submit **letters of support** from:
 - The targeted national and/or regional health ministry or other local health authority(ies), **and**;
 - The community-based HIV-related service provider entities.



RFA HD-23-013 (UG1) Part 2. Section IV (4 of 4)

Application and Submission Information

- **Research Plan (*highlights cont'd*):**
 - **Section C: Clinical Research Center (CRC) Collaboration Capacity**
 - Plans to implement required programs in partnership with the CTAMAC and its Cores
 - HIV implementation science capacity building
 - Emerging research pilots
 - Community engagement activities
 - Plans to engage with PATC³H-IN network
 - Data harmonization activities
 - Contribute unique expertise
 - Contribute CRPS capacity
 - Commitment to accurate data sharing with CTAMAC for NICHD progress updates



RFA HD-23-013 (UG1) Part 2. Section V (1 of 5)

Application Review Information

- **Standard plus RFA-specific review criteria**

- **Investigators**

- Is the time commitment of the PD/PI (s) and the investigators with decision making authorities appropriate for the stated study goals?
- Is there clear description of roles for each major key personnel involved in the research site?
- Are Key Personnel from relevant **(a)** national and/or regional health ministry or other local health authority(ies) AND **(b)** community-based HIV-related service provider entity(ies) included?
- If key personnel do not have a history of collaboration, is an appropriate plan in place to ensure successful coordination and communication?

‘Standard information’ is *not* covered in this presentation



RFA HD-23-013 (UG1) Part 2. Section V (2 of 5)

Application Review Information



- **Standard plus RFA-specific review criteria**
 - **Significance**
 - Does the Center address questions that will improve rates of prevention of new HIV infections among adolescents at risk and the identification of, and linkage and retention to care of and long-term viral suppression among youth living with HIV in low-to-middle income countries (LMICs)?
 - Does the Center address scalable, generalizable HIV treatment and prevention models in community settings?
 - Does the Center generate novel information about how to improve collaborations between **(a)** national and/or regional health ministry or other local health authority(ies) and **(b)** community-based HIV-related service providers to improve public health outcomes?
 - Does the research plan address potential sustainability?



RFA HD-23-013 (UG1) Part 2. Section V (3 of 5)

Application Review Information



- **Standard plus RFA-specific review criteria**
 - **Innovation**
 - Does this design test interventions or strategies that are potentially generalizable to other communities or settings?
 - Does this design test a practice or intervention that is widespread, but for which limited evidence is available?



RFA HD-23-013 (UG1) Part 2. Section V (4 of 5)

Application Review Information



- **Standard plus RFA-specific review criteria**

- **Approach**

- Sufficient access to the appropriate population(s)?
- Appropriate study plan to include discrete, non-duplicated subjects?
- Rigorous and appropriate design to the level of evidence for the targeted intervention?
- Appropriateness of methods assessing the HIV health outcomes along the PHCC of AYA?
- Likelihood to enroll & retain adequate numbers of high-risk groups?
- Likelihood will lead to statistically robust study of the individual and contextual factors associated with health outcomes along the PHCC for at-risk AYA and those with HIV?
- Likelihood to result in scalable and efficient study designs?
- Prospect for implementation and sustainability after the grant cycle has ended?
- Sufficiency of IS research capacity building plans to demonstrate how PATC³H-IN infrastructure and collaboration with CTAMAC and its Cores, will be leveraged to advance the mission of the network?



RFA HD-23-013 (UG1) Part 2. Section V (5 of 5)

Application Review Information



- **Standard plus RFA-specific review criteria**
 - **Environment**
 - What is the prospect of successful achievement of study outcomes given the description and justification provided for the proposed geographically distinct CRPS?
 - Is there sufficient evidence provided in the letters of support to demonstrate that the proposed HIV IS research is aligned with the designated LMIC's scale-up efforts for AYA HIV prevention and care?





**PATC³H-IN Coordination, Translation and Advanced
Methods and Analytics Center (CTAMAC)
(UM2)**

RFA HD-23-014 (UM2) Part 1

Overview Information

- Activity code: UM2 (cooperative agreement)
- **Released July 22, 2022**
- Key Dates
 - Open Date (Earliest Submission Date) November 06, 2022
 - LOI due November 06, 2022 (not required, more on this later)
 - Application due December 06, 2022
 - Peer Review March 2023
 - Council May 2023
 - Earliest funding July 2023
- Award
 - Up to \$2.5M (direct costs) to fund 1 award in 2023
 - Up to 5 years
- Partner Organizations
 - NIDA, NIMH, FIC and OBSSR



Essential Features of PATC³H-IN – UM2

- **UG1** Clinical Research Centers (CRC)
 - Multisite Research Project
 - 5 or more Clinical Research Performance Sites (CRPS)
- **UM2 Coordination, Translation and Advanced Methods and Analytics Center (CTAMAC)**
- Scientific Leadership Committee (SLC)
- External Scientific Advisory Committee (ESAB)
- NIH PATC³H-IN Management & Oversight Committee (PMOC)



RFA HD-23-014 (UM2) Part 2. Section I (1 of 2)

Funding Opportunity Description

- **Objectives**

- Provide coordination, infrastructure, statistical and data management leadership, and other supports for the PATC3H-IN network:
 - Scientific Leadership Committee (SLC)
 - Clinical Research Centers (CRCs)
 - External Collaborators
 - External Scientific Advisory Board (ESAB)
 - DSMB
 - Stakeholders Advisory Group (SAG)
 - Youth Advisory Board (YAB)
 - HIV Service Providers and Policy Makers



RFA HD-23-014 (UM2) Part 2. Section I (2 of 2)

Funding Opportunity Description

- **Scope (*highlights*)**
 - Provide the day-to-day operations, coordination, data management and analytic support for the network, and the infrastructure for rapid response and pilot trials, and research education and capacity building
 - Disseminate research from the cooperative to a wide variety of external stakeholders
 - Engage external stakeholders and facilitating bidirectional communication between external stakeholders and network investigators
 - Conduct hypothesis-driven implementation research to support effective translation of network outputs
 - Conduct novel empirical research to ensure timely understanding of changes in current practices across regions where PATC³H-IN CRCs are working to address the youth-specific PHCC to improve health outcomes for at-risk adolescents and youth living with HIV.



RFA HD-23-014 (UM2) Part 2. Section IV (1 of 8)

Application and Submission Information

‘Standard instructions’ are *not* covered in this presentation

The application should consist of the following *required* components:

Component	Component Type for Submission	Page Limit
Overall	Overall	12
Administrative Core	Admin Core	12
Data and Analytics Core	Data Core	12
Advanced Methodology and Emerging Science Core	Methods-Science Core	12
Dissemination and Community Engagement Core	Dissemination Core	12
Advanced Methodological Research Project	Modeling Project	12
Translation Research Project	Translation Project	12



RFA HD-23-014 (UM2) Part 2. Section IV (2 of 8)

Application and Submission Information

- **Application *required* components (Highlights):**

- **Overall**

- **Research Plan**

Section A: Overview, Purpose, and Objectives of the Program

Section B: Administration, Organization, and Operation

- Describe **Project Management Plan** with strategies & processes to manage the CTAMAC (milestones, timelines, etc)
- Support Research Projects and collaborative studies with CRCs, and **Emerging Research Pilots (ERPs)** and, with the CRCs, to **build adolescent HIV IS research capacity in LMICs**
- **Support the governance of the SLC**, including decision-making committees (composition; roles/resp).
- **Coordinate the functions of the CTAMAC** (Cores & Research Projects) & **across all PATC3H-IN CRCs**.
- Develop and adhere to a **network operations manual** (staff training, QA/QC, management of PATC3H-IN study development & databases, etc.)
- **Performance-based, efficient distribution of protocol-restricted funds** to site consortia based on accruals.



RFA HD-23-014 (UM2) Part 2. Section IV (3 of 8)

Application and Submission Information

- Application *required* components (Highlights):

- Overall

- Research Plan (*cont'd*)

Section C: Research Program Infrastructure

- Explain scientific **vision of evolving field** and an **emerging agenda** to improve the AYA PHCC
- Discuss **partnerships between academia & community** that will influence design & implementation of interventions
- Describe **synergy of the Cores** with each other and the Network



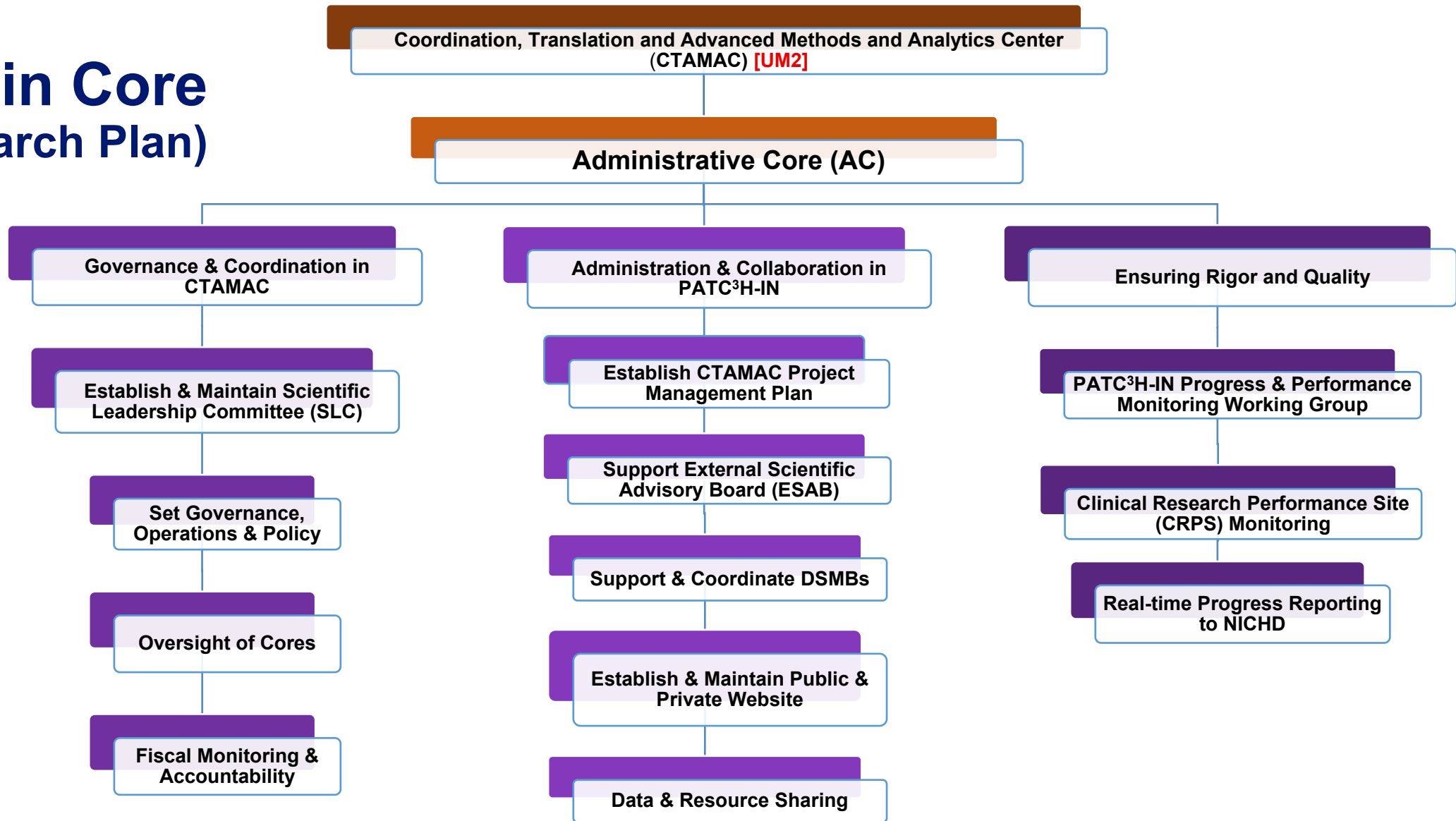
RFA HD-23-014 (UM2) Part 2. Section IV (4 of 8)

Application and Submission Information

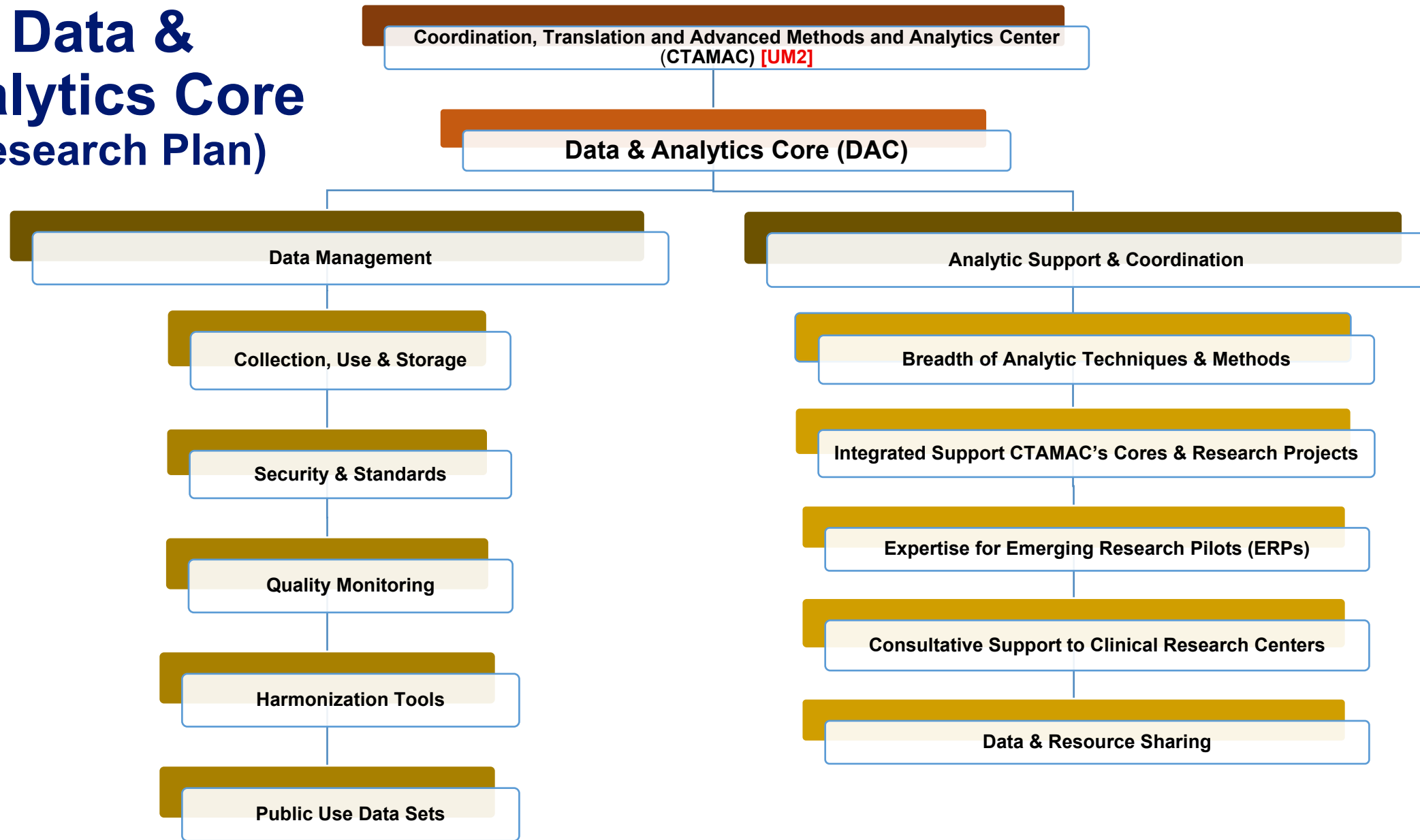
- Application *required* components (highlights cont'd):
 - Administrative Core (AC)
 - Budget
 - SLC meetings
 - Funds for travel of PD(s)/PI(s), each Core Lead, and support staff needed to coordinate all in-person SLC meetings.
 - SLC meetings & space: N=3 in year 1 & N=2 annually, afterwards; 2-3 days per mtg; Rockville, MD.
 - SLC Chair – **TBN after network established**
 - 2 months FTE at senior PI level;
 - Lead all SLC meetings
 - Travel and salary support
 - External Scientific Advisory Board (ESAB) – **TBN after network established**
 - **Independent** of network
 - Review progress in achieving goals of PATC³H-IN projects and activities
 - Biannual half-full day meeting; Rockville, MD



Admin Core (Research Plan)



Data & Analytics Core (Research Plan)



RFA HD-23-014 (UM2) Part 2. Section IV (5 of 8)

Application and Submission Information

- **Application *required* components (highlights cont'd):**
 - **Advanced Methodology and Emerging Science (AMES) Core**
 - **Research & Related Other Project Information → Other Attachments:** plan for appointment of Advisory Committee to monitor progress of the *Research Education, Training and Capacity Building* program.
 - **Budget →**
 - Emerging Research Pilots (ERPs)
 - ERP awards may be issued through the AMES Core as fixed price subawards, will not exceed \$110,000 in total costs and will not be longer than 24 months in duration
 - No more than \$375,000 in total costs will be made available annually for ERP awards
 - Research Education, Training and Capacity Building
 - Budgets are limited to \$500,000 in direct costs annually plus applicable F&A



RFA HD-23-014 (UM2) Part 2. Section IV (6 of 8)

Application and Submission Information

- **Application *required* components (highlights cont'd):**

- **Advanced Methodology and Emerging Science (AMES) Core**

- **Research Plan**

- ***Section A: Advanced Methodological Research Modeling***

- Describe advanced analytic expertise and methods, tools and techniques as infrastructure for the network

- ***Section B: Research Education, Training and Capacity Building***

- Proposed Research Education Program
- Program Leads, Faculty and Participants
- Plan for Instruction in the Responsible Conduct of Research
- Evaluation Plan
- Dissemination Plan

- ***Section C: Emerging Scientific Agenda and Research Pilots (Delayed Onset Studies)***

- Support the design & implementation of future research solicited by PATC³H-IN to address emerging scientific priorities during the project cycle through **recurring competitive open solicitations** for Emerging Research Pilots (ERPs).
- Developed & published by CTAMAC with direction, collaboration from PATC³H-IN SLC and NIH Scientists
- Supported by CTAMAC: **1)** receive apps, convene reviews, **2)** coordinate, support app prioritization by the SLC, and **3)** implement meritorious research through CRC-supported CRPS(s) after approval by NICHD



AMES Core (Research Plan)

Coordination, Translation and Advanced Methods and Analytics Center (CTAMAC) [UM2]

Advanced Methodology & Emerging Science (AMES) Core

Advanced Methodological Research Modeling

IS Research Education, Training and Capacity Building

Emerging Scientific Agenda and Research Pilots
[Delayed Onset Studies]

Modeling Research Project 1

Modeling Research Project 2

[Min 1, Max 2]

DESCRIBE IN MODELING PROJECT COMPONENT

Advisory Committee

Research Education Program

Program Leads

Faculty

Participants

Recurring Open Solicitations → Emerging Research Pilot (ERP)

ERP Peer Review

Prioritization by SLC

Meritorious ERPs Funded & Implemented



RFA HD-23-014 (UM2) Part 2. Section IV (7 of 8)

Application and Submission Information

- **Application *required* components (highlights cont'd):**

- **Dissemination and Community Engagement Core**

- **Senior/Key Person Profile**

- Core lead should have extensive experience in multi-site implementation science research studies.
- One or more collaborators with extensive experience working with practitioners in real-world implementation settings

- **Research Plan**

- ***Section A: Stakeholder Engagement in Network Leadership***

- Approach for active engagement of key stakeholders at **national, provincial & local levels** with network leadership
- Approach to recruitment & convening of Stakeholder Advisory Group (SAG) – **members TBN**
- Support the PATC³H-IN network-wide Youth Advisory Board (YAB) from each CRC (and adults, as appropriate)

- ***Section B: Outreach and Training for Stakeholders***

- User-friendly materials/tools **interpreting network findings** for practitioners, policy makers and community audiences

- ***Section C: Translation of Science-to-Service Program***

- Analytic expertise & infrastructure available to CRCs and all PATC³H-IN PIs on analytic techniques and methods for novel inquiry into translating scientific findings to wide-spread practice via **dissemination & implementation research**



DCE Core (Research Plan)

Coordination, Translation and Advanced Methods and Analytics Center (CTAMAC) [UM2]

Dissemination & Community Engagement Core (DCEC)

Translation of Science-to-Service

Translation Research Project 1

Translation Research Project 2

[Min 1, Max 2]

**DESCRIBE IN
TRANSLATION
PROJECT
COMPONENT**

Stakeholder Engagement

PATC³H-IN Youth Advisory Board (YAB) Lead

PATC³H-IN YAB Members

CRC YAB Members

Stakeholder Advisory Group (SAG)

Community HIV Service Providers

National, Provincial or Local Health Authorities

Outreach and Training

Key Stakeholder Communities

HIV Service Providers

HIV Policy Makers

AYA and Families



RFA HD-23-014 (UM2) Part 2. Section IV (8 of 8)

Application and Submission Information

- **Application *required* components (highlights cont'd):**
 - **Advanced Methodological Research Project (Modeling Project)**
 - **1-2 Research Projects** leveraging advanced methodologies from AMES (and DCEC, if appropriate) to interrogate existing data sources to address PHCC outcomes in AYA
 - Address how project will be unique, valuable contribution to network and how may inform future work when CRPS data become available
 - **Translation Research Project (Translation Project)**
 - **1-2 Research Projects** - hypothesis-driven studies to close the science-to-service gap on AYA PHCC outcomes by leveraging dissemination and implementation science expertise and methods from DCEC (and AMES, if appropriate)
 - Incorporate IS frameworks or theories to guide the design and/or evaluation of implementation strategies



RFA HD-23-014 (UM2) Part 2. Section V (1 of 5)

Application Review Information



- **Cooperative Program Project review will focus on**
 - UM2 CTAMAC Cooperative Program project as an **integrated and interdependent network** of Projects and Cores
 1. An integrated collection of Cores and Research Projects, and the overall scientific and technical merit of the program
 2. Each Individual Core
 3. Each Individual Research Project
- **Standard plus RFA-specific review criteria**

‘Standard Information’ is not covered in this presentation



RFA HD-23-014 (UM2) Part 2. Section V (2 of 5)

Application Review Information



- **Review Criteria for the Administrative Core**
 - Adequacy of strategies in Project Management Plan to manage CTAMAC
 - Appropriate plans for external & internal communications (CRC, Cores, Network), collaboration, logistical support and progress monitoring
 - Core leads with requisite experience, track record and qualifications for managing collaborative multidisciplinary clinical and public health research
 - Appropriate and nimble plans to establish, maintain and support SLC and any committees to address evolving/emerging science



RFA HD-23-014 (UM2) Part 2. Section V (3 of 5)

Application Review Information



- **Review Criteria for the Data and Analytics Core**

- Comprehensiveness of plan for provision of analytic support, DM, QA/QC and other supports across the entire network
- Adequacy of strategies for data security and standards
- Core leads with requisite experience, track record and qualifications for managing collaborative multidisciplinary clinical and public health research
- Breadth of investigators with quantitative, qualitative analytic and management expertise to support large-scale multi-site studies
- Strength of plans for integration of extant data resources



RFA HD-23-014 (UM2) Part 2. Section V (4 of 5)

Application Review Information



- **Review Criteria for the Advanced Methodology and Emerging Science Core**
 - Appropriate analytic and methodology expertise in modeling techniques for the network
 - Core leads with requisite experience, track record and qualifications for managing collaborative multidisciplinary clinical and public health research
 - Quality of the Research Education, Training and Capacity Building program, and for the recruitment for the program and the Advisory Committee to monitor its progress
 - Comprehensiveness, quality and rigor of plans to implement an Emerging Scientific Agenda and Research Pilots in collaboration with SLC and NIH



RFA HD-23-014 (UM2) Part 2. Section V (5 of 5)

Application Review Information



- **Review Criteria for the Dissemination and Community Engagement Core**
 - Appropriate analytic expertise and infrastructure for dissemination and implementation inquiry for the network
 - Core leads with requisite experience, track record and qualifications for managing collaborative multidisciplinary clinical and public health research
 - Quality of plans for identifying, convening & consistently engaging relevant and representative stakeholder groups, including a Youth Advisory Board
 - Quality of plans for educating practitioner audiences on research findings
 - Rigor of strategy for implementation and translation research



After PATC³H-IN awards are made

- PATC³H-IN kick-off meeting
- PATC³H-IN SLC, composed of CRC PIs, CTAMAC PI, CRPS PI and YAB representatives, and NIH will convene to expeditiously
 - Review the network's agenda and projects
 - Consider needs and devise a plan to address them
 - Review and approve or revise PATC³H SOPs
 - Develop and approve new PATC³H-IN SOPs
- Two PATC³H-IN meetings annually





Selected FAQs

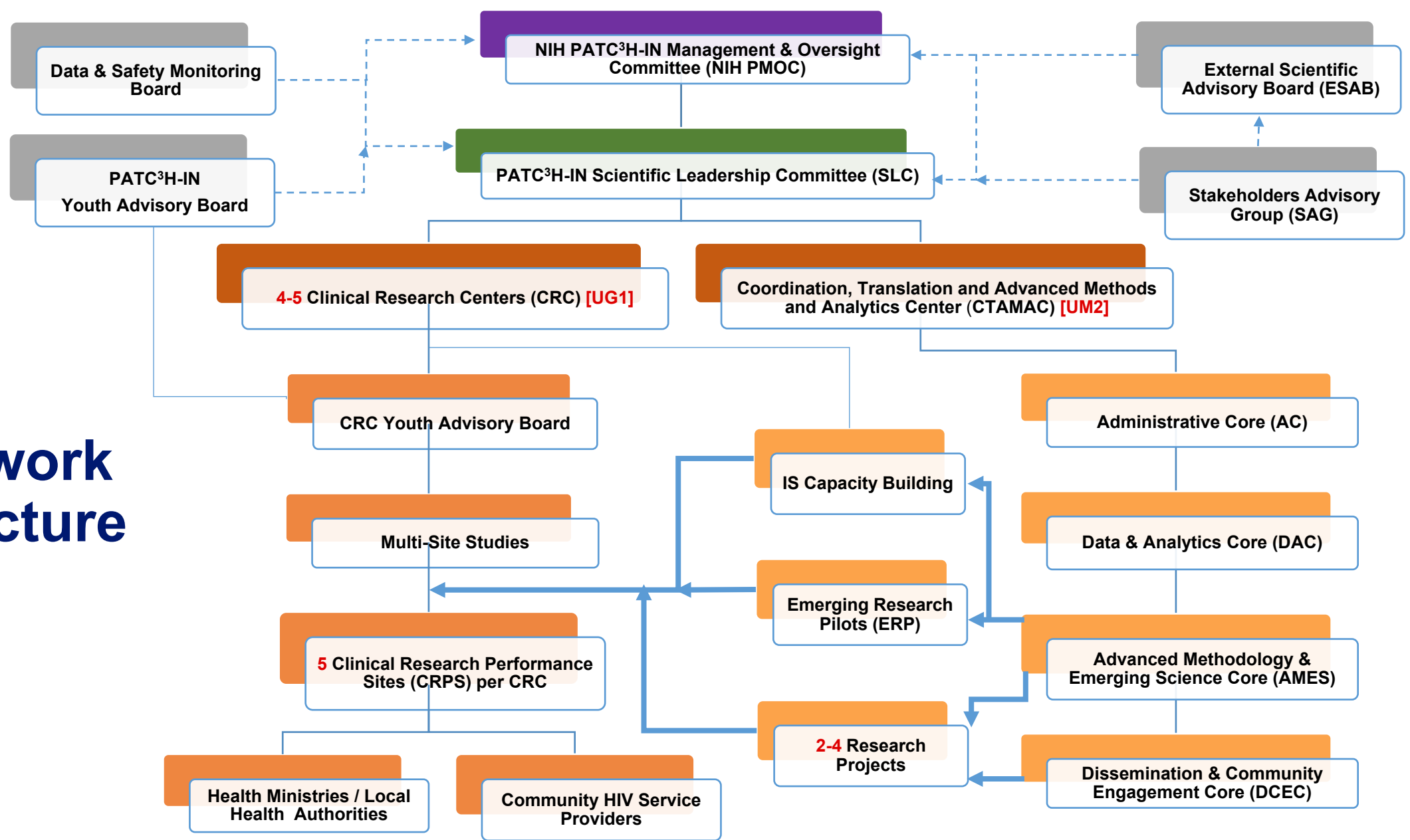
Selected FAQs (1 of 7)

1. What is the overall structure of PATC³H-IN?

- The overall structure of PATC³H-IN will consist of multiple interdependent functional parts:
 1. 4-5 Clinical Research Centers (CRC)
 2. A Coordination, Translation and Advanced Methods and Analytics Center (CTAMAC)
 3. A Scientific Leadership Committee (SLC)

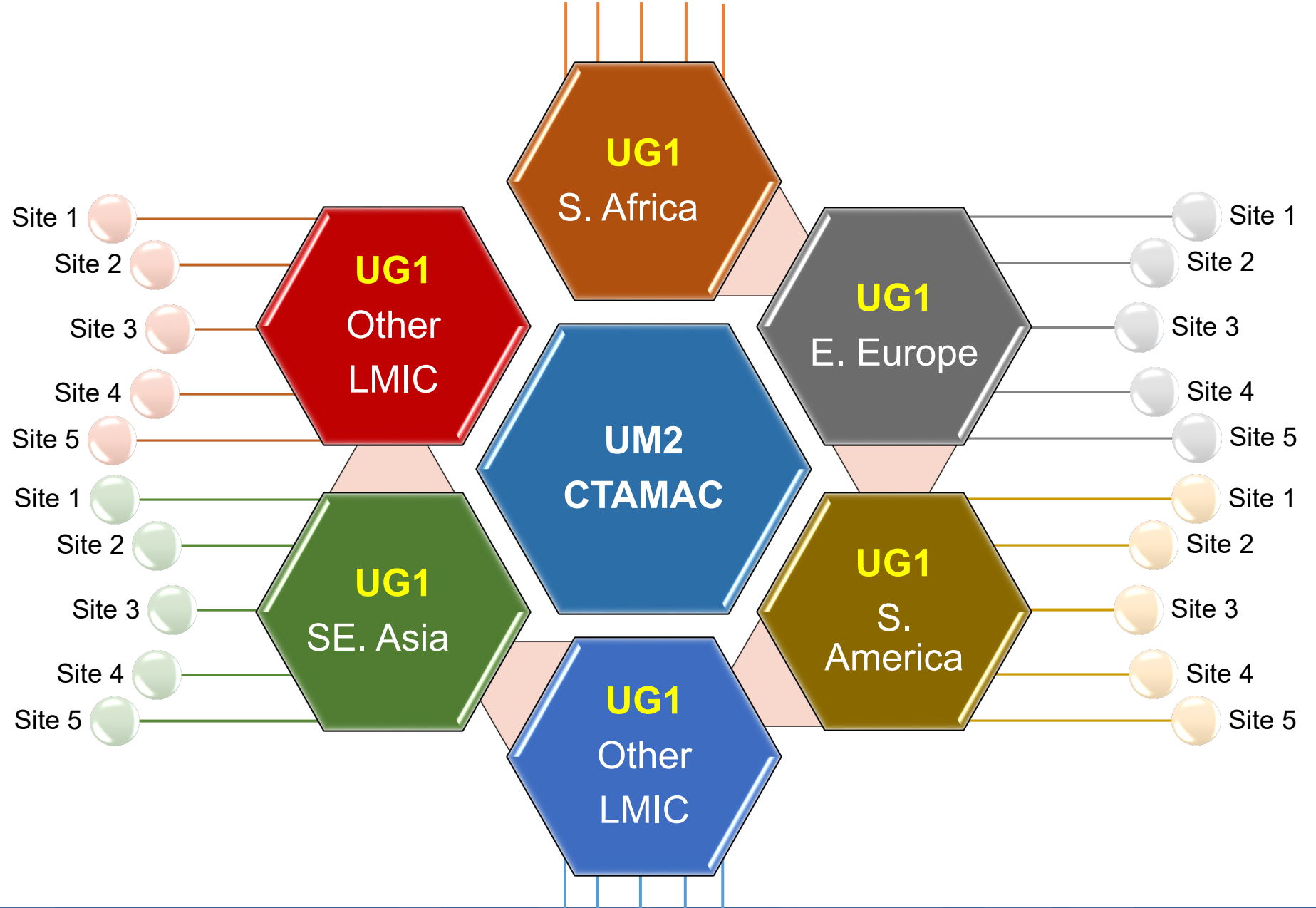


Network Structure



UG1-UM2 Cooperative Program

Example of Possible Composition



Selected FAQs (2 of 7)

2. What are the critical features of a Clinical Research Center (UG1)?

- A theoretically grounded, hypothesis-driven **Research Project** designed to address gaps along the HIV prevention and/or HIV care continuum (PHCC) among AYA in LMIC.
- Five (5) or more **Clinical Research Performance Sites (CRPS)** that will implement the Research Project. Each CRPS must submit letters of support from:
 - The targeted national and/or regional health ministry or other local health authority(ies), **and**;
 - The community-based HIV-related service provider entity(ies).
- **Collaboration capacity** to implement required programs such as HIV implementation science capacity building, emerging research pilots, and community engagement activities in partnership with the Coordination, Translation and Advanced Methods and Analytics Center (CTAMAC) and its Cores.



Selected FAQs (3 of 7)

3. What is a Clinical Research Performance Site (CRPS)?

- A CRPS is a partnership between a **national and/or regional health ministry or other local health authority** and one or more **community-based HIV-related service providers** (e.g., hospital, clinic, non-government organization (NGO) or other relevant service provider).
 - The health authority or authorities and the service provider must engage with a shared population of AYA who live or receive services in a defined geographic area (i.e., community).
- Clinical Research Center (CRC) applications must propose a multisite research project to be executed in five or more geographically distinct CRPS (i.e., five or more communities, non-overlapping patient populations).
- Each proposed CRPS must possess multidisciplinary, cross-sectoral collaborative relationships with various participant recruitment venues in their communities (e.g. academic, clinic, health department, community-based organizations, online, social media and other virtual health platforms, etc.).



Selected FAQs (4 of 7)

4. What are non-responsive Research Projects for a Clinical Research Center (UG1)?

- Studies focused primarily in geographic areas representing high-income or more developed countries (based on World Bank definition)
- Studies that do not propose ongoing engagement with youth and other key stakeholders throughout the study period
- IS research focused on interventions that do not have demonstrated efficacy on one or more milestones on the HIV prevention or care continua targeted by the application



Selected FAQs (5 of 7)

5. What are the critical features of the UM2 Coordination, Translation and Advanced Methods and Analytics Center (CTAMAC)?

- The CTAMAC, through its four Cores, is expected to provide **coordination, infrastructure, statistical and data management leadership**, and **other supports** for the PATC³H-IN network:
 - Provide the day-to-day operations, coordination, data management and analytic support for the network, and the infrastructure for rapid response and pilot trials, and research education and capacity building
 - Disseminate research from the cooperative to a wide variety of external stakeholders
 - Engage external stakeholders and facilitating bidirectional communication between external stakeholders and network investigators
 - Conduct hypothesis-driven implementation research to support effective translation of network outputs
 - Conduct novel empirical research to ensure timely understanding of changes in current practices across regions where PATC³H-IN CRCs are working to address the youth-specific PHCC and improve health outcomes



Selected FAQs (6 of 7)

6. Can a foreign institution receive an award without a collaborating US institution?

- Applications may be for collaborations between institutions in the U.S and an eligible LMIC or may involve just LMIC institutions if there is a previous track record of externally funded research and/or research training programs by the lead LMIC institution.

7. Can an institution apply to both RFAs for a UG1 CRC and the UM2 CTAMAC?

- YES. As long as these are distinct applications, and any senior or key personnel who overlap, do not play senior roles in more than one of the applications.



Selected FAQs (7 of 7)

8. In planning budget requests, are there any centralized resources or infrastructure that UM2 CTAMAC will provide for the UG1 Clinical Research Center?

- Applications for each RFA are expected to be reviewed independently and stand on their own scientific merits
- While the CTAMAC will provide resources for the Clinical Research Centers (CRC) (see [RFA HD-23-014](#)), the extent of overlap in some activities is intentionally not defined as there is expected variability in areas supported and over time as progress in the network matures.
 - For example, in provision of data management and analytic support, it would be expected that the CRC plan to provide its own support for these activities in their Research Project in accordance to [RFA HD-23-013](#). However, when considering how future research activities will be developed and implemented as in the Emerging Research Pilots (ERPs), it is expected that the CTAMAC plan to provide support for data management and analysis for these projects in accordance to [RFA HD-23-014](#).
- NIH reserves discretion with application selection to ensure optimal synergy and range of topics among the Network's CTAMAC and multiple CRCs to maximize the success of PATC³H-IN





Questions and Answers

Questions after today's webinar

Please submit your questions to:

- NICHD-PATC3H-IN-FOA@mail.nih.gov
 - Bill G. Kapogiannis, MD
 - Franklin Yates, MD



THANK
YOU!

