## Tuberculosis Scientific Committee Mentored Investigator Meeting

Anneke C. Hesseling, Amita Gupta IMPAACT Annual Network Meeting 29 June 2021





International Maternal Pediatric Adolescent
AIDS Clinical Trials Network

#### Chair and Co-chair

Chair: Anneke Hesseling Desmond Tutu TB Centre Vice Chair: Amita Gupta, Johns Hopkins University

#### **Elected Committee Members**

Kelly Dooley, Johns Hopkins University Vanessa Rouzier, Les Centres GHESKIO Anne-Marie Demers, Stellenbosch Universit Lindsay McKenna, Treatment Action Group

#### **SDMC Representatives**

Grace Montepiedra, SDAC, Harvard School of Public Health

Soyeon Kim, SDAC, Harvard School of Public Health

Mattie Bartlett, Data Management Center, FSTRF

#### **Community Advisory Board**

Dichaba Siane, Botswana-Harvard AIDS Institute Partnership Gloria Moche, Soweto, Johannesburg, South Africa

#### Social Behavioral Science Core

Jessica Haberer Massachusetts General Hospital

Nicole Montañez, IMPAACT Operations Center, FHI 360

#### Leadership and Operations Center

Nicole Montañez, IMPAACT Operations Center, FHI Rachel Scheckter IMPAACT Operations Center, FHI Veronica Toone IMPAACT Operations Center, FHI Rhonda White, FHI 360, IMPAACT Community Program Representative Sharon Nachman, MPAACT Network Chair, SUNY at Stony Brook

#### **NIH Representatives**

Patrick Jean-Philippe, DAIDS Tafadzwa Kasambira, DAIDS Sai Majji, NICHD

#### **Laboratory Center**

Nicole Tobin, University of California, Los Angeles Samantha Solomon (University of California, Los Angeles



## 2022 Global New TB Drug Pipeline<sup>1</sup>

Discovery	Preclinical Development		Clinical Development			
Lead Optimization	Early Stage Development	GMP / GLP Tox.	Phase 1	Phase 2	Phase 3	Regulatory Market Approvals
PanD inhibitors	JSF-3285*	FNDR-20081*	BVL-GSK098*	Delpazolid	Results Reported / Expected in 2022	
Diarylthiazoles	MPL-446, 447*	TB-47*	GSK-286*	Sutezolid	TB Practecal	
DprE1 Inhibitors Direct InhA Inhibitors	CPZEN-45*	GSK-839*	TBAJ-587	Sudapyridine (WX-081)	ZeNix	Bedaquiline*
Mtb energy metabolism	NTB-3119*	OTB-658	TBAJ-876	BTZ-043*	Simplici TB	Delamanid*
Macrolides Mycobacterial Gyrase	TZY-5-84	Sanfetrinem	TBI-223	TBA-7371*	(4-month regimen)	Pretomanid*
Inhibitors Arylsulfonamides	MBX-4888A (1810)*		Macozinone* (PBTZ-169)	OPC-167832*	Truncate TB (2-month regimens)	
Inhibitors of MmpL3, Translocase-1, Clp, PKS13, F-ATP synthase	FNDR-10045*		Pyrifazimine	GSK-656* (070)	STREAM 2	
Oxazolidinones	FNDR-20364*		(TBI-166)	SQ-109* Telacebec*		<u>rline</u> = updates October 2021
				SPR720*		

Clinical Davidonment

<sup>&</sup>lt;sup>1</sup> New Molecular Entities not yet approved, being developed for TB or only conditionally approved for TB. Showing most advanced stage reported for each. Details for projects listed can be found at <a href="http://www.newtbdrugs.org/pipeline/clinical">http://www.newtbdrugs.org/pipeline/clinical</a>



www.newtbdrugs.org

Proclinical Davolonment

Discovery

<sup>\*</sup>New chemical class. Known chemical classes for any indication are color coded: fluoroquinolone, rifamycin, oxazolidinone, nitroimidazole, diarylquinoline, benzothiazinone, imidazopyridine amide, beta-lactam.



Remembering

## Carol Onyango

1973 - 2021



# Update on Mentored Investigator Program

Nicole Montañez and Rachel Scheckter 29 June 2022



ANNUAL MEETING

2022

### Goal of the MI TB SC Program

For mentors with experience and expertise in successfully developing and conducting IMPAACT TB protocols to provide guidance for new, emerging, or interested investigators to become aware of Network policies and procedures, to successfully lead a study, DACS, NWCS, and integrate into the IMPAACT Network working towards mentoring others.





## TB SC MI Overview

An informal program developed within TB SC - with a big impact

#### **Mentors**

- Anneke Hesseling
- Amita Gupta
- Tony Garcia-Prats
- Ethel Weld
- Grace Montepiedra
- Soyeon Kim

#### **Graduated Mentors**

- Anthony Garcia-Prats
- Christy Beneri
- Pauline Howell
- Nicole Salazar-Austin
- Ethel Weld
- Lisa Cranmer
- Jyoti Mathad
- Sylvia Lacourse
- Jennifer Hughes
- Yael Hirsh-Moverman

#### Mentored

#### **Investigators**

- Megan Palmer
- Louvina van der Laan
- Jeff Tornheim
- Mandar Paradkar
- Graeme Hoddinott
- Faeeza Patel



### Graduated Investigator Accomplishments

Mentored Investigators who have transitioned to becoming protocol chairs or vice-chairs on IMPAACT TB protocols, or ancillary studies, or who have taken up other leadership positions within the IMPAACT Network. May provide experience and expertise for Mentored Investigators and/or move into the mentor role within the network as interested.

#### **Lisa Cranmer**: *IMPAACT affiliations*:

- IMPAACT/HVTN TB Vaccine Working Group
- Study Chair IMPAACT 2035/HVTN 604

#### **Jyoti Mathad**: *IMPAACT affiliations:*

- Investigator IMPAACT P1078
- Study Chair IMPAACT 2001
- NWCS 626

#### Pauline Howell: IMPAACT affiliations:

- Investigator IMPAACT 2020
- Study Vice-Chair IMPAACT 2034

#### **Christy Beneri**: *IMPAACT affiliations:*

- Study Co-Chair 2024
- DACS 658 & 717

#### **Nicole Salazar-Austin**: *IMPAACT affiliations:*

Study Co-Chair 2024

#### Yael Hirsh-Moverman:

IMPAACT affiliations:

Investigator IMPAACT 2024

#### **Jennifer Hughes**:

IMPAACT affiliations:

Investigator IMPAACT 2026





**Protocol chairs** 



# IMPAACT Early Career Investigators Programs

Lisa Levy 29 June 2022



ANNUAL MEETING

2022

## **Program Goal**

To prepare the next generation of health care professionals with skills to maintain and strengthen HIV programs for IMPAACT's populations of interest, experience the collaborative nature of network research, hone presentation skills, and develop a scholarly work that is suitable for publication.



## Program Eligibility

- Affiliated with the IMPAACT Network who holds a current masters or doctoral degree or MD (or local equivalent) and is within 10 years of graduation
- Experience either developing or participating in clinical research
- Support of employer or work institution
- Proposals may be submitted for studies concluded within the last 5 years



## Mentors

- Applicants must identify a mentor who has been an investigator on an IMPAACT study and is ideally a current member of an IMPAACT Scientific Committee
- Applicants are also encouraged to identify another mentor from their region and/or institution.



## Parameters of Research

- This program will only support investigations using existing data and/or stored samples from completed IMPAACT clinical trials
- This program is not intended to
  - 1) develop a new clinical trial,
  - 2) use data and specimens from ongoing studies, or
  - 3) collect prospective data.
- The proposed work must be completed and submitted for publication within two years
- IMPAACT Statistical and Data Management Center statistical support may be requested

## **Expected Outcomes**

 Approved applicants will be expected to present findings at an IMPAACT Annual Meeting and at one or more other scientific meetings. They will also be expected to submit a manuscript to a peer-reviewed journal by the end of the 2-year program period.

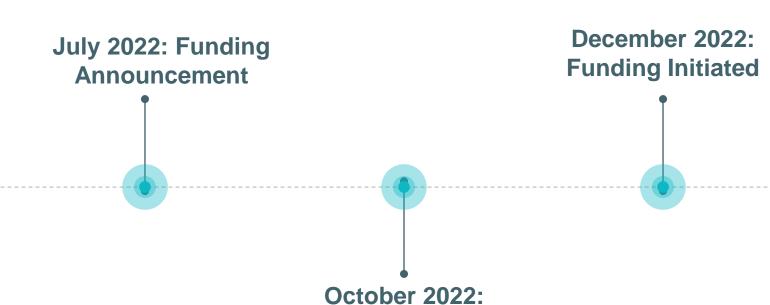


## Funding and Anticipated Awards

- A maximum total dollar amount of \$100,000 is available for each award
  - Additional \$25,000 if the application includes sample shipment/ laboratory testing
- Funding may include level of effort support for the investigator, and the following as applicable, laboratory assays, materials, shipping of samples to the laboratory of interest, analysis
- Equipment costs cannot be supported
- Approximately 3 investigators will be funded this cycle
- Project duration of two years for each investigator, additional selections in each year will stagger entry and exit



## Timing and Next Steps



**Submission Deadline** 



#### Discussion

- General feedback and questions on ECI program
- What lessons learned from the TB MI program could/should be applied to the ECI program?
- With the launch of the ECI program, will the mentored investigator program change? If so, how?

