

Hepatitis C

Dr. Graciela Diap-MD, Access HCV

**18th International Congress on Infectious
Diseases (ICID) - XIII Congreso SADI**

Buenos Aires, Argentina

March 1-4, 2018

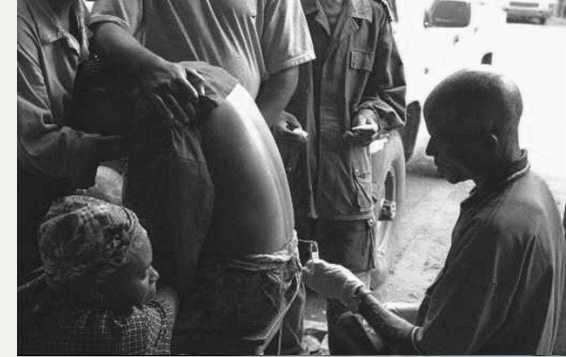
Origins of DNDi

1999

- First meeting to describe the lack of R&D for neglected diseases
- MSF commits the Nobel Peace Prize money to the DND Working Group
- JAMA article: 'Access to essential drugs in poor countries - A Lost Battle?'

July 2003

- Creation of DNDi
- Founding partners:
 - *Institut Pasteur, France*
 - *Indian Council of Medical Research, India*
 - *Kenya Medical Research Institute, Kenya*
 - *Médecins Sans Frontières*
 - *Ministry of Health, Malaysia*
 - *Oswaldo Cruz Foundation/Fiocruz, Brazil*
 - *WHO –TDR (Special Programme for Research and Training in Tropical Diseases) as a permanent observer*



Responding to the Needs of Neglected Patients

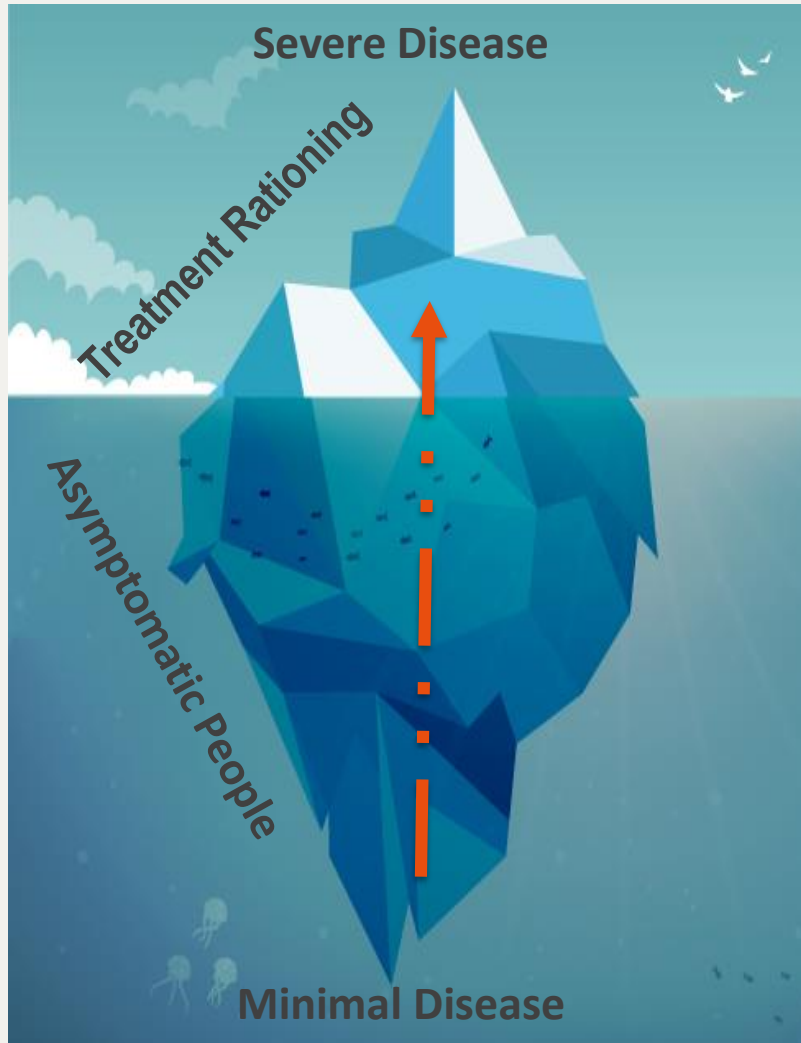


DNDi's PRIORITY:
Neglected
Patients



...from Bench to Bedside

DNDi-HCV strategic objectives:



- Develop new, affordable, pan-genotypic TT for HCV
- Simplify HCV test & treat strategies and develop innovative models of care to support scale up
- Improve access (IP, regulatory, pricing, etc.) and affordability of HCV TT in countries

DNDi Hepatitis C Strategy: 3 pillars

1

Accelerate
R&D

Accelerating the development of **promising drug candidates**



with



Pharma
companies



Governments

2

Catalyse
ACCESS

Supporting **affordable access to all DAAs**



with



Pharma
companies



Civil Society
organisations



Governments

3

Simplify
TREATMENT
STRATEGIES

Working with health providers to scale – up treatment



with

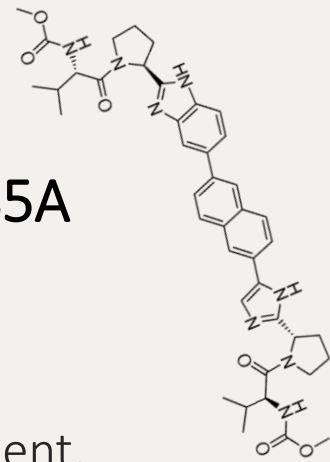


Primary
healthcare
doctors



Non
Governmental
Organizations

Ravidasvir: Towards a pan-genotypic treatment



- DNDi's pipeline analysis identified ravidasvir (RDV), an NS5A inhibitor drug candidate with pan-genotypic potential
- DNDi **obtains licence** to RDV from Presidio (US): development, manufacture and distribution in LATAM, SEA and Africa
- DNDi **is developing RDV** with Pharco (Egypt): Pharco is also producer of generic SOF (no patent in Egypt)
- **DNDi partnership in Malaysia:** with Pharco and Pharmaniaga (Malaysia): manufacture and supply of RDV and supply of SOF
- **New - DNDi collaboration with InSud Pharma, Laboratorio Elea (Argentina) and Pharco:** Register, manufacture, distribute RDV + SOF in Argentina + LATAM

Research Article

Viral Hepatitis

JOURNAL
OF HEPATOLOGY

Effectiveness of ravidasvir plus sofosbuvir in interferon-naïve and treated patients with chronic hepatitis C genotype-4

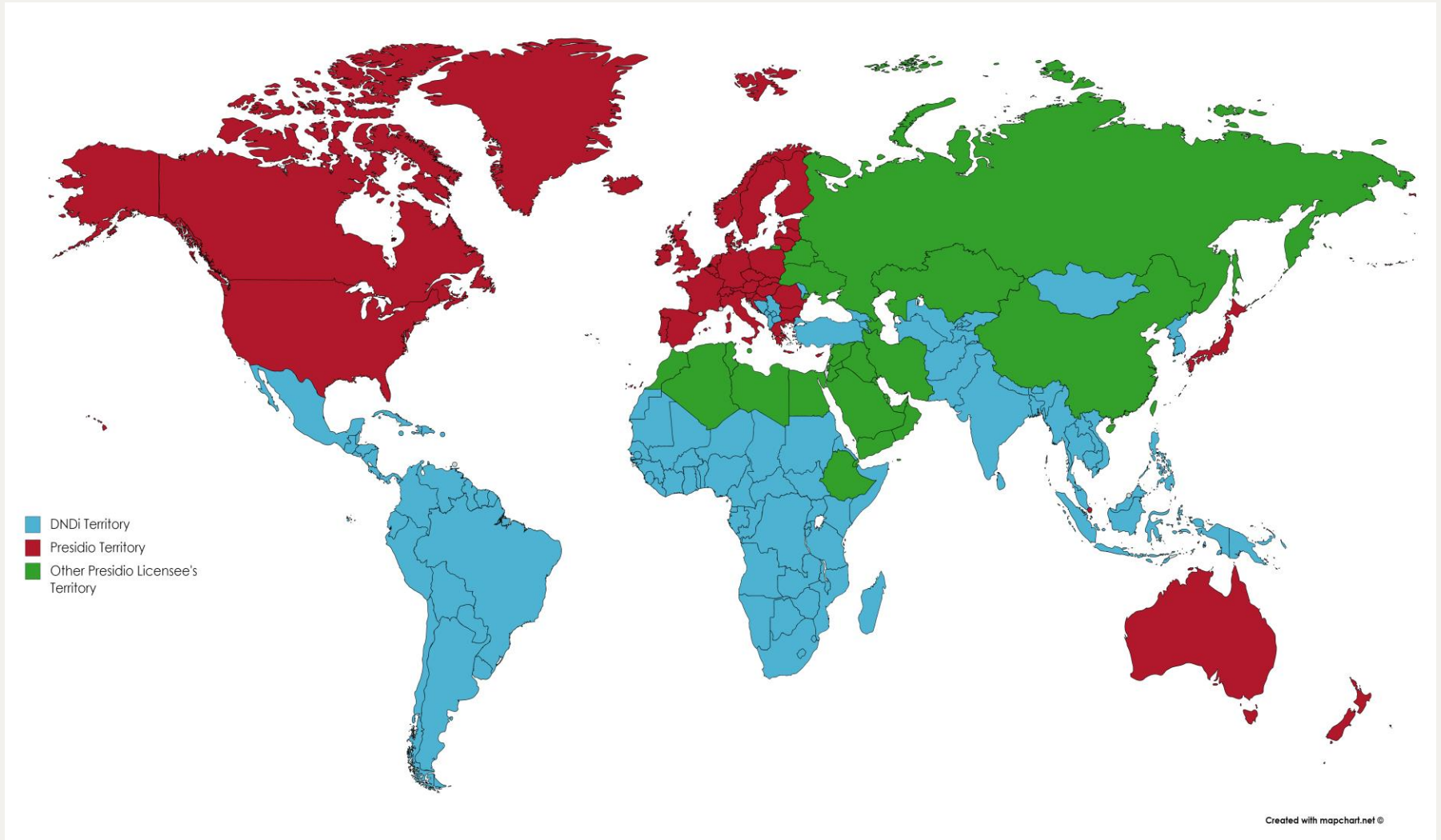
Gamal Esmat¹, Tamer Elbaz^{1,*}, Maissa El Raziky^{1,2}, Asmaa Gomaa³, Mahmoud Abouelkhair^{1,2}, Hadeel Gamal El Deen¹, Aliaa Sabry³, Mohamed Ashour^{1,2}, Naglaa Allam³, Mohamed Abdel-Hamid⁴, Ola Nada⁵, Sherine Helmy⁶, Hanaa Abdel-Maguid⁶, Richard Colonno⁷, Nathaniel Brown⁷, Eric Ruby⁷, Pamela Vig⁷, Imam Waked^{3,*}

¹Endemic Medicine Department, Faculty of Medicine, Cairo University, Egypt; ²Cairo Fatemic Hospital, Ministry of Health, Egypt; ³National Liver Institute, Menoufiya University, Shebeen EL Kom, Egypt; ⁴Department of Microbiology, Faculty of Medicine, Minia University, El Minia, Egypt; ⁵Pathology Department, Faculty of Medicine, Ain Shams University, Cairo, Egypt; ⁶Pharco Pharmaceuticals, Amriya, Alexandria, Egypt; ⁷Presidio Pharmaceuticals, Inc., San Francisco, California, USA

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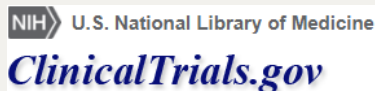
Develop new, affordable, pan-genotypic TT for HCV

Ravidasvir License Territory



1

Develop new, affordable, pan-genotypic TT for HCV *Study design in Malaysia & Thailand*



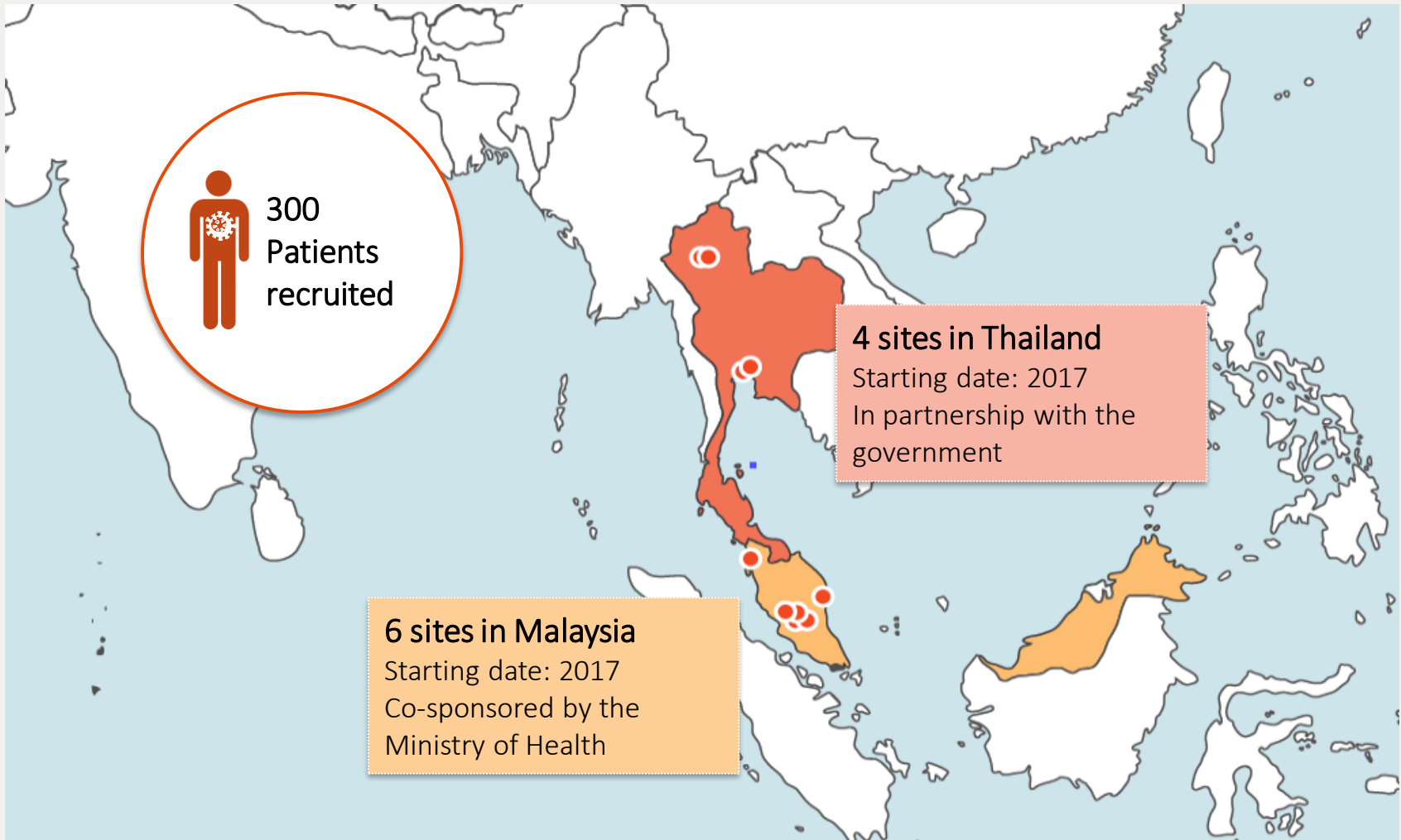
Sofosbuvir Plus Ravidasvir for the Treatment of HCV Chronic Infection

ClinicalTrials.gov Identifier: NCT02961426

Open Label Phase II/III, Multicenter, Trial to Assess the Efficacy, Safety, Tolerance, and Pharmacokinetics of Sofosbuvir Plus Ravidasvir in HCV (+/- HIV) Chronically Infected Adults With no or Compensated Cirrhosis in Thailand and Malaysia

1

2017: Starting clinical trial of Ravidasvir & Sofosbuvir for the treatment of HCV chronic infection in 2 countries



1

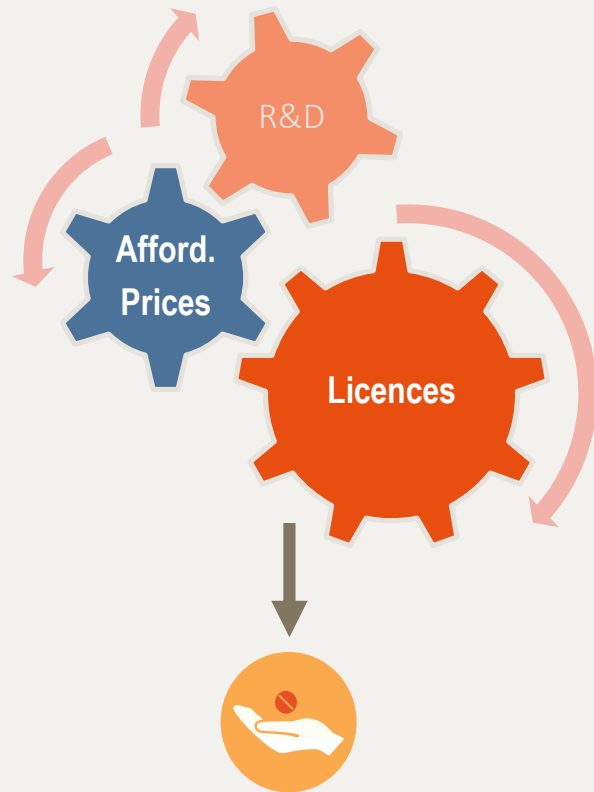
Accelerating the development of promising drug candidates



- Complete **development of ravidasvir for use with sofosbuvir as pan-genotypic treatment for HCV**
- **Registration of ravidasvir in priority countries** willing to adopt a Public Health strategy
- Contribution to develop **local and regional strategies to promote a Public Health approach** and reduction of Access barriers

2

Catalysing affordable access to all DAAs



- Raise **political commitment & accountability**
- Encourage **policy change** for the sustainable adoption of test & treat with DAAs
- Promote **access to affordable**, safe, quality and efficacious DAAs
- Address **regulatory and intellectual property** barriers for access to HCV diagnostics & medicines

2

Partners catalysing affordable access to DAAs

RDV as a Public Health Tool



Country/ MoH
engagement

- Political commitment
- Resource mobilization
- Public Health Approach



Civil society
pledge

- Define patient needs
- Linkage to care/services
- Community mobilization
- HCV disease advocacy
- HCV treatment literacy



Payer/Donor
commitment

- National/Regional Priorities
- Public Health imperative
- Sustainable Development Goals



Policymaker/
Regulators
undertaking

- Policy change
- Simplification Models of Care
- Drug Registration
- Public Health Approach

3

Developing innovative models of care to support scale-up



- Efforts to **decentralize** from central hospitals to the primary healthcare level and to peripheral health Centres
- To develop **task-shifting** which would reduce reliance on doctors and other highly qualified medical personnel,
- To **boost community involvement** to support uptake and acceptance

Simplify HCV test & treat strategies and develop innovative models of care to support scale up

Journal of Hepatology Update: Hepatitis C



CrossMark

EASL EUROPEAN ASSOCIATION FOR THE STUDY OF THE LIVER | **JOURNAL OF HEPATOLOGY**

Simplification of antiviral hepatitis C virus therapy to support expanded access in resource-limited settings

Nathan Ford¹, Tracy Swan², Peter Beyer³, Gottfried Hirnschall¹, Philippa Easterbrook¹, Stefan Wiktor^{1,*}

¹Department of HIV/AIDS, World Health Organization, Geneva, Switzerland; ²Treatment Action Group, New York, USA; ³Department of Essential Medicines and Health Products, World Health Organization, Geneva, Switzerland



HHS Pub

Author manuscript
Ann Intern Med. Aut



Simplified diagnostic monitoring for hepatitis C, in the new era of direct-acting antiviral treatment

Published in final edited form as:
Ann Intern Med. 2017 September

Jennifer Cohn^{a,b}, Teri Roberts^b, Valerianna Amorosa^c, Maud Lemoine^d, and Andrew Hill^e

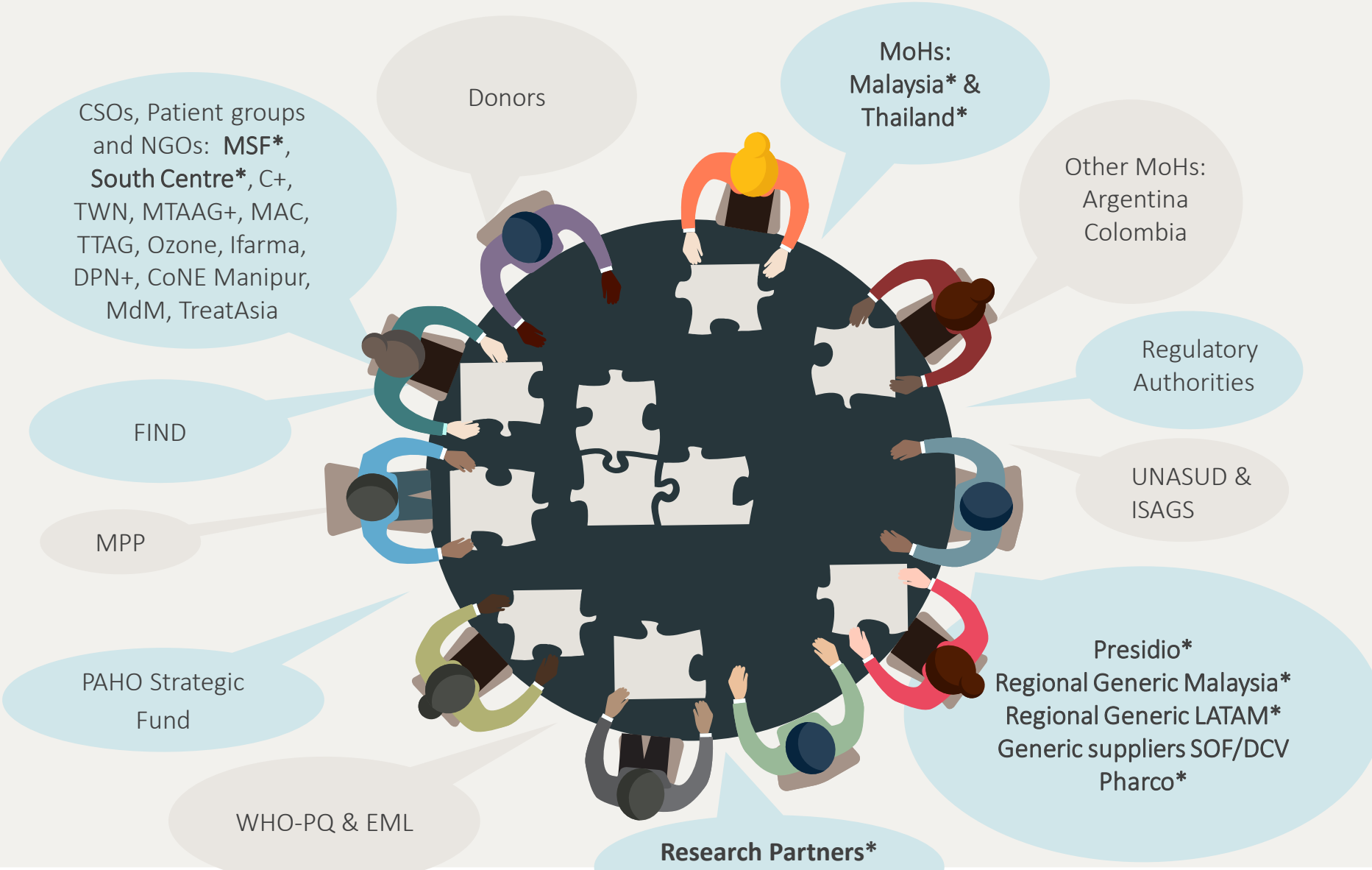
Expansion of Treatment for Hepatitis C Virus Infection by Task Shifting to Community-Based Nonspecialist Providers:

A Nonrandomized Clinical Trial

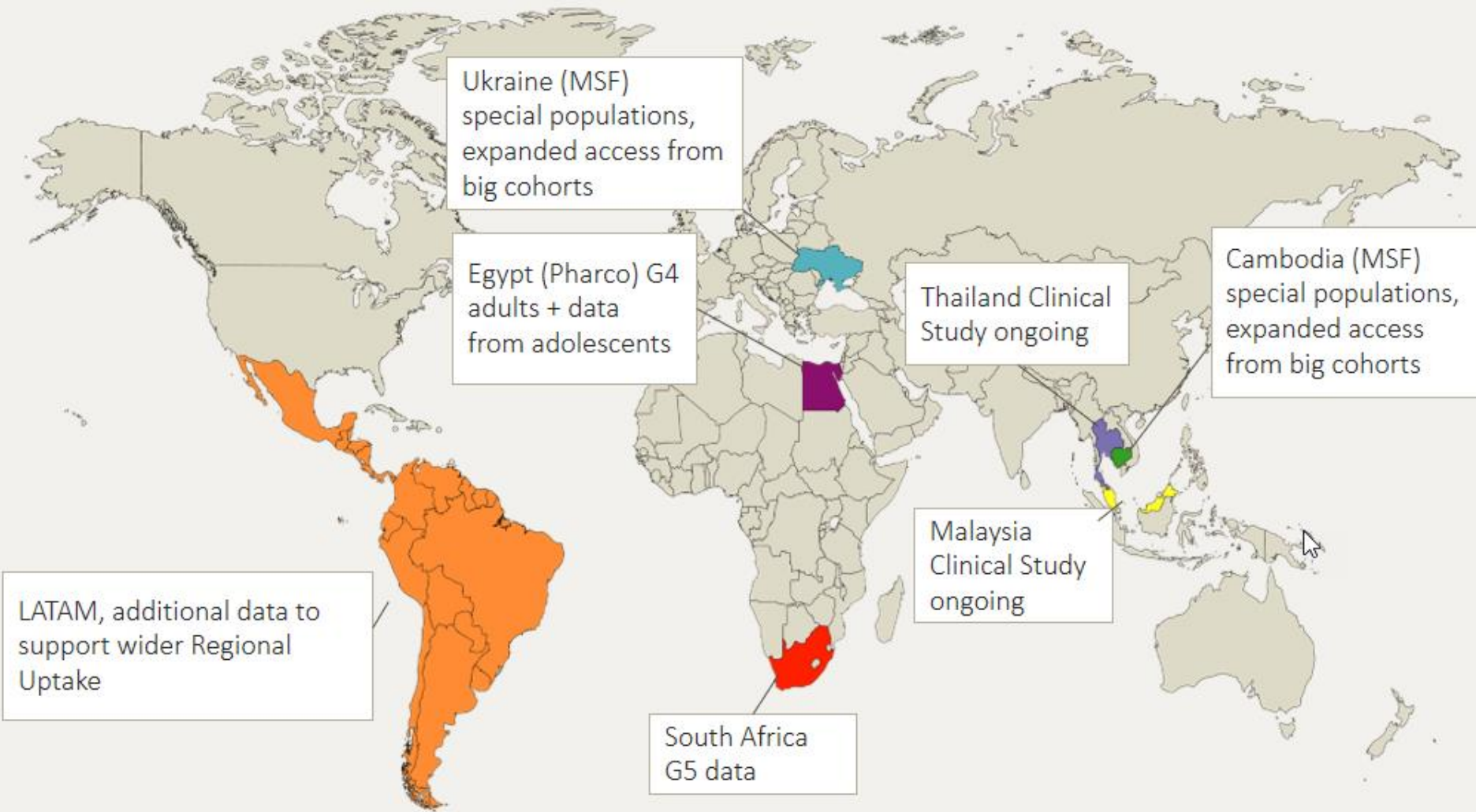
Drs Sarah Kattakuzhy, MD,

Division of Clinical Care and Research, Institute of Human Virology, University of Maryland School of Medicine, Room S222, 725 West Lombard Street, Baltimore, MD 21201

Partners engaged with DNDi to implement the HCV strategy



Future developments with Ravidasvir



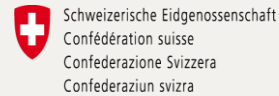


THANK YOU

TO ALL OUR
PARTNERS &
DONORS

DNDi
Drugs for Neglected Diseases initiative

DNDi
Drugs for Neglected Diseases initiative



THE STARR FOUNDATION

