

# 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

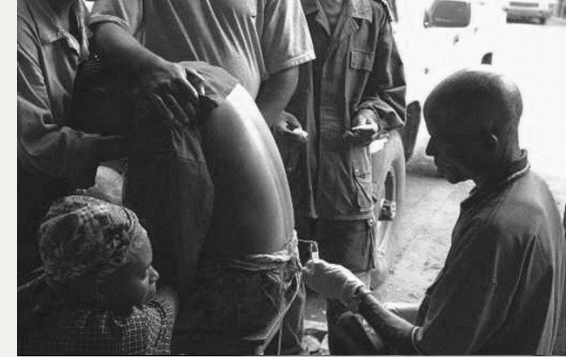
# Origins of DNDi

## 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

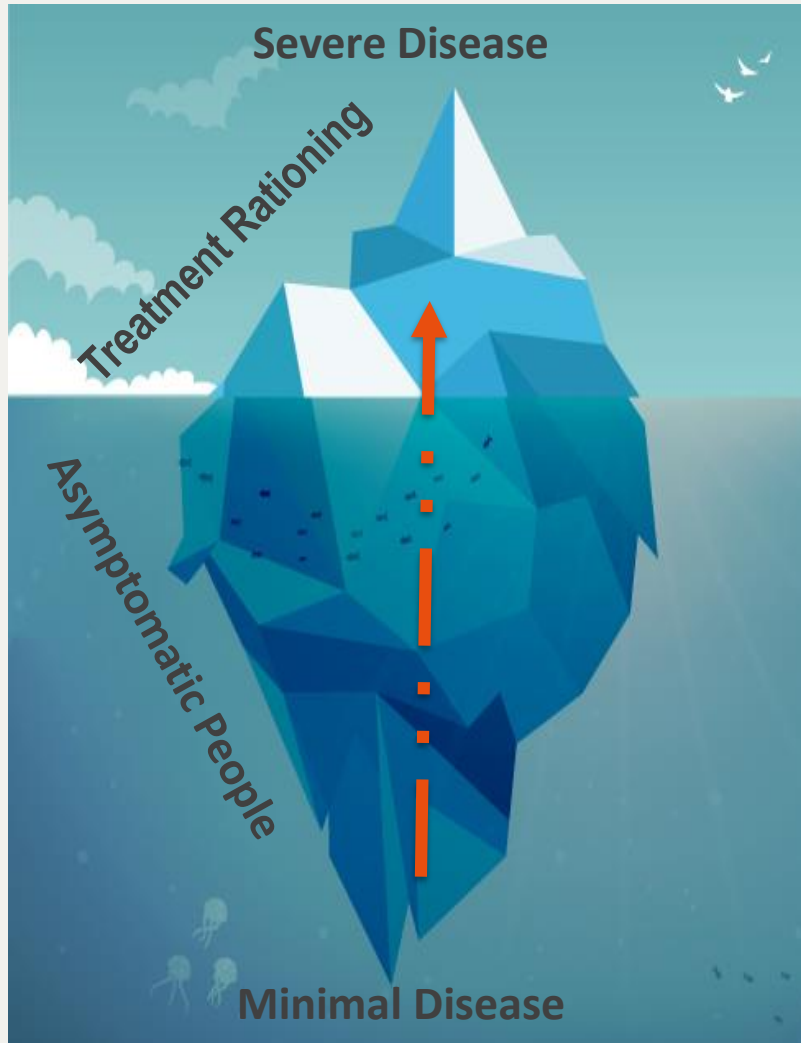


DNDi's PRIORITY:  
Neglected  
Patients



...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

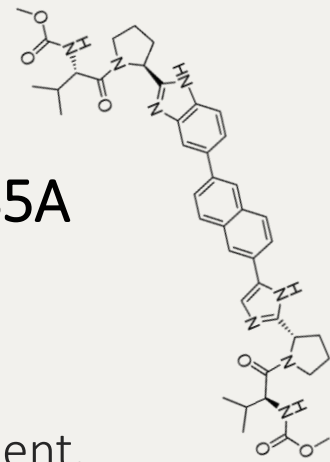
Working with health providers to scale – up treatment



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

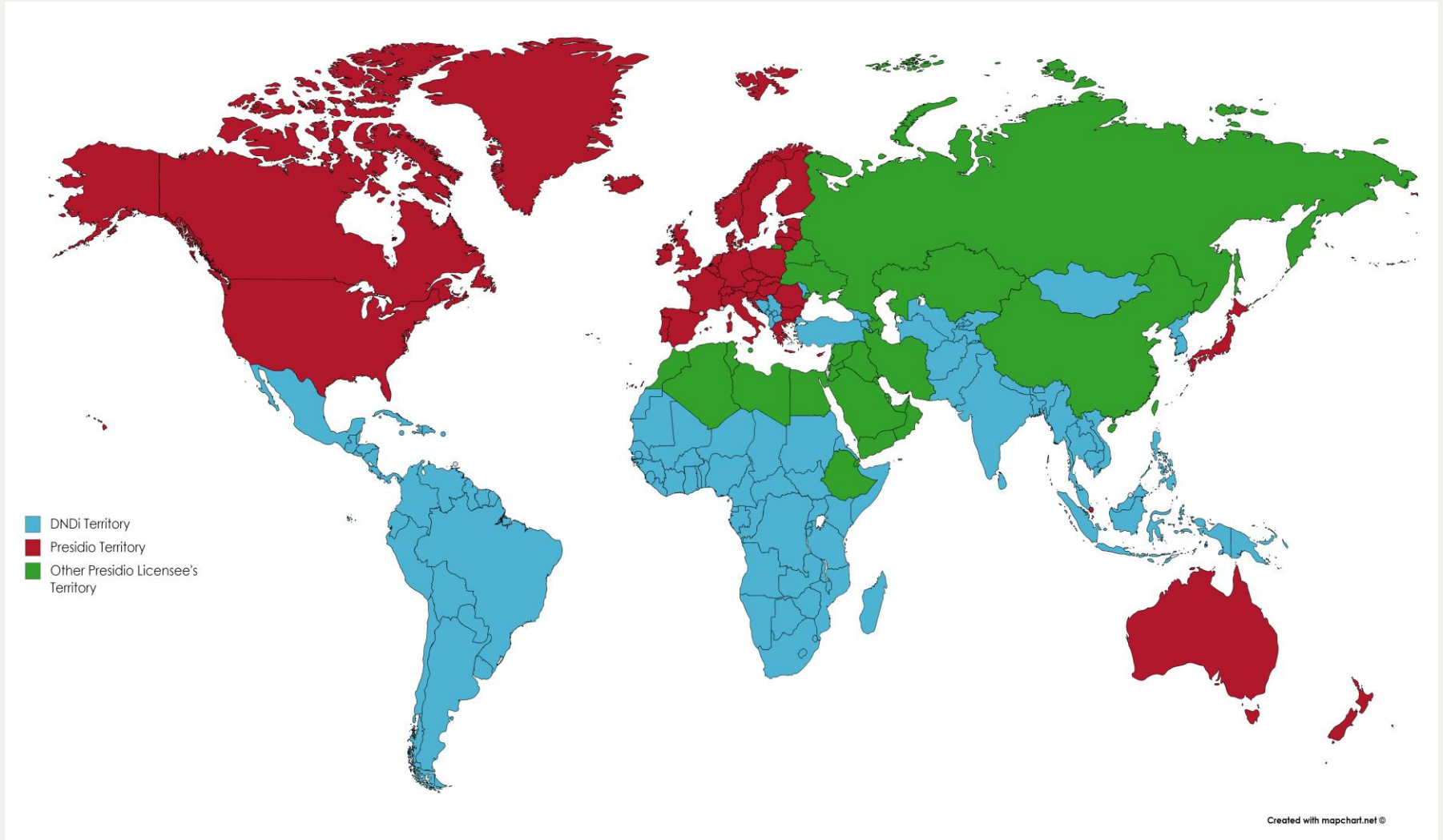
Gamal Esmat<sup>1</sup>, Tamer Elbaz<sup>1,\*</sup>, Maissa El Raziky<sup>1,2</sup>, Asmaa Gomaa<sup>3</sup>, Mahmoud Abouelkhair<sup>1,2</sup>, Hadeel Gamal El Deen<sup>1</sup>, Aliaa Sabry<sup>3</sup>, Mohamed Ashour<sup>1,2</sup>, Naglaa Allam<sup>3</sup>, Mohamed Abdel-Hamid<sup>4</sup>, Ola Nada<sup>5</sup>, Sherine Helmy<sup>6</sup>, Hanaa Abdel-Maguid<sup>6</sup>, Richard Colonna<sup>7</sup>, Nathaniel Brown<sup>7</sup>, Eric Ruby<sup>7</sup>, Pamela Vig<sup>7</sup>, Imam Waked<sup>3,\*</sup>

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

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# Develop new, affordable, pan-genotypic TT for HCV

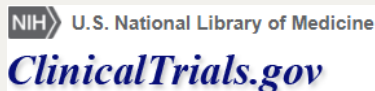
## *Ravidasvir License Territory*





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



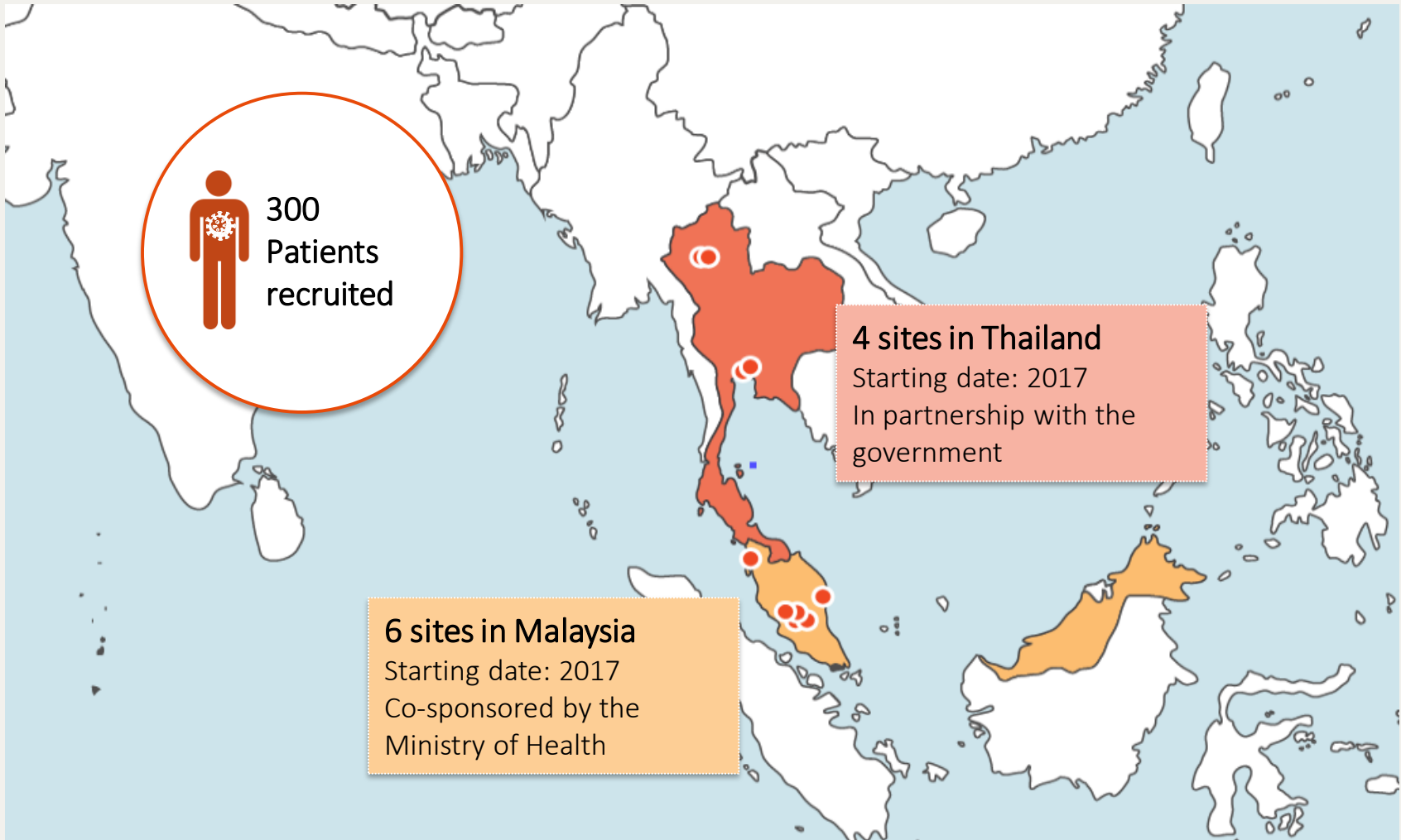
## **Sofosbuvir Plus Ravidasvir for the Treatment of HCV Chronic Infection**

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

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



# 1

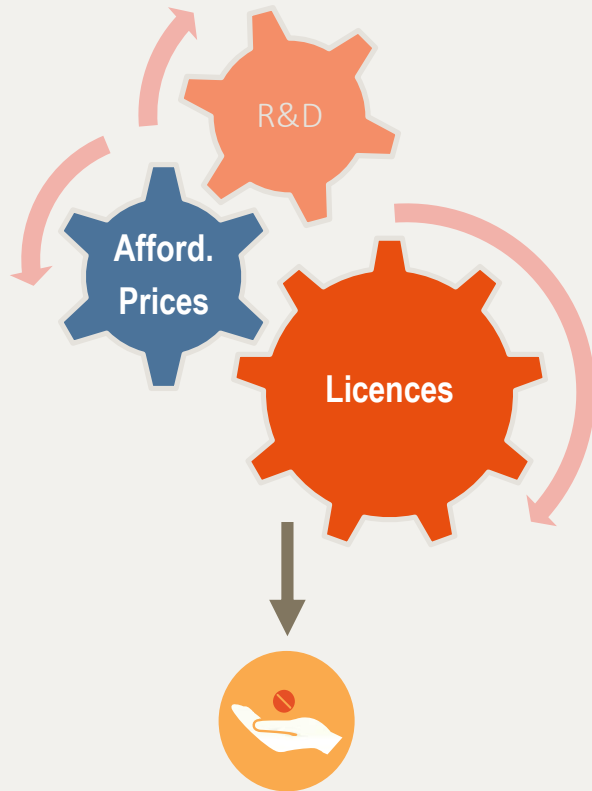
## Accelerating the development of promising drug candidates



- 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



**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 Ford<sup>1</sup>, Tracy Swan<sup>2</sup>, Peter Beyer<sup>3</sup>, Gottfried Hirschall<sup>1</sup>, Philippa Easterbrook<sup>1</sup>, Stefan Wiktor<sup>1,\*</sup>

<sup>1</sup>Department of HIV/AIDS, World Health Organization, Geneva, Switzerland; <sup>2</sup>Treatment Action Group, New York, USA; <sup>3</sup>Department 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<sup>a,b</sup>, Teri Roberts<sup>b</sup>, Valerianna Amorosa<sup>c</sup>, Maud Lemoine<sup>d</sup>, and Andrew Hill<sup>e</sup>

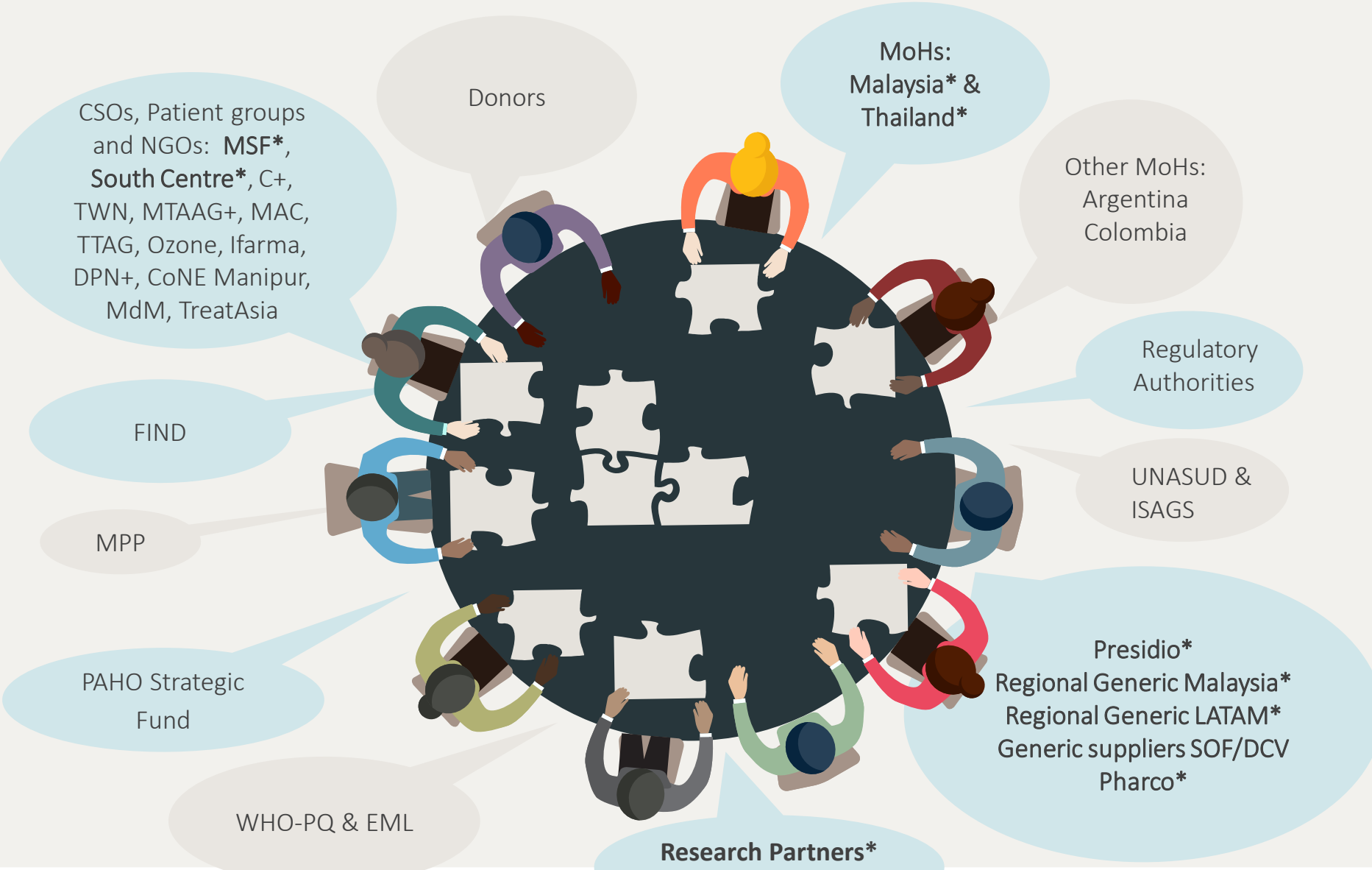
## Expansion of Treatment for Hepatitis C Virus Infection by Task Shifting to Community-Based Nonspecialist Providers:

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



CSOs, Patient groups and NGOs: **MSF\***, **South Centre\***, C+, TWN, MTAAG+, MAC, TTAG, Ozone, Ifarma, DPN+, CoNE Manipur, MdM, TreatAsia

Donors

MoHs: **Malaysia\* & Thailand\***

Other MoHs: Argentina, Colombia

Regulatory Authorities

UNASUD & ISAGS

Presidio\*  
Regional Generic Malaysia\*  
Regional Generic LATAM\*  
Generic suppliers SOF/DCV  
Pharco\*

**Research Partners\***  
CRM, PHPT, CRC

WHO-PQ & EML

PAHO Strategic Fund

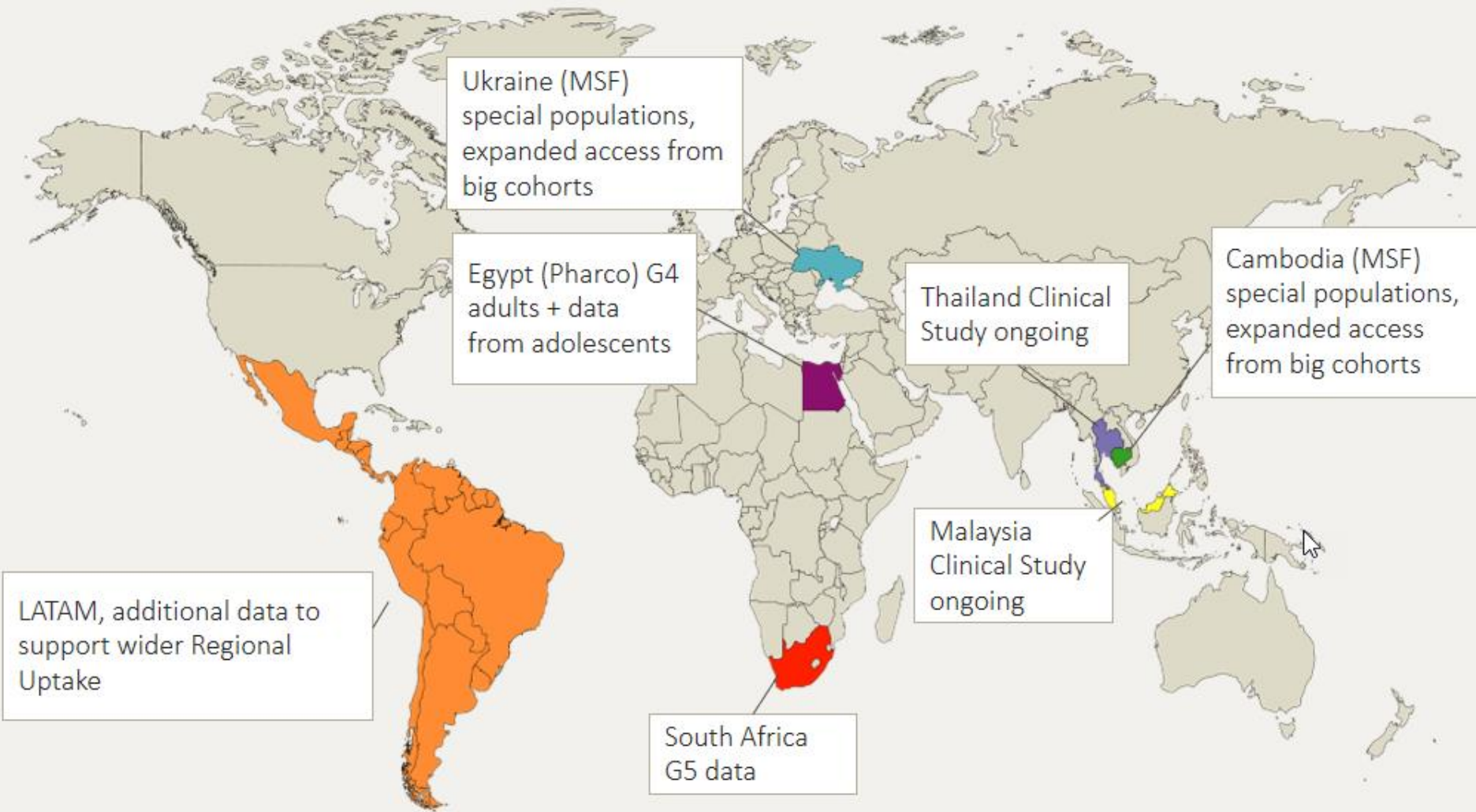
MPP

FIND

CSOs, Patient groups and NGOs: **MSF\***, **South Centre\***, C+, TWN, MTAAG+, MAC, TTAG, Ozone, Ifarma, DPN+, CoNE Manipur, MdM, TreatAsia



# Future developments with Ravidasvir



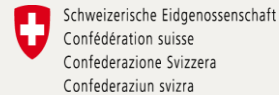


# THANK YOU

TO ALL OUR  
PARTNERS &  
DONORS

**DNDi**  
Drugs for Neglected Diseases initiative

**DNDi**  
Drugs for Neglected Diseases initiative



THE STARR FOUNDATION

