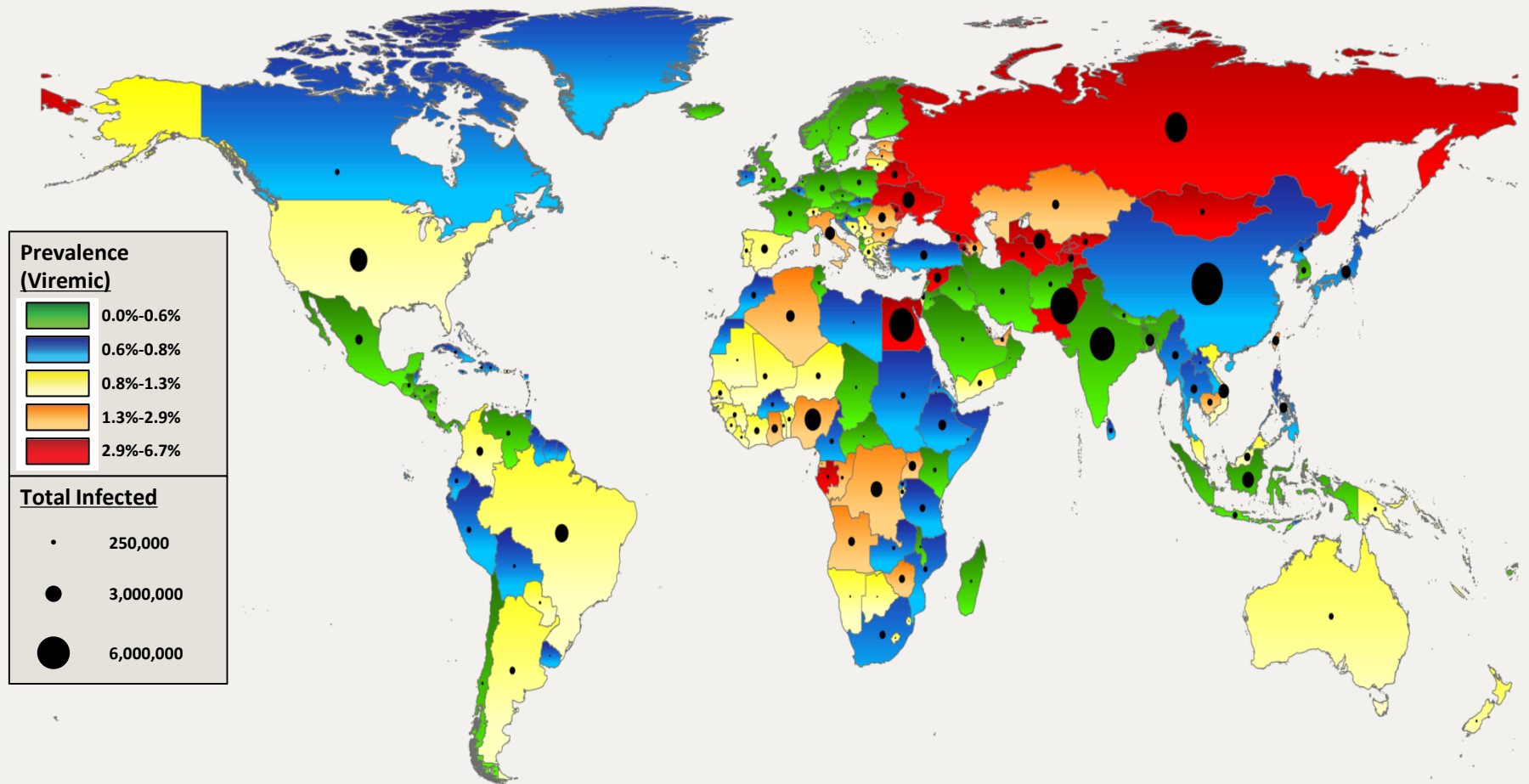




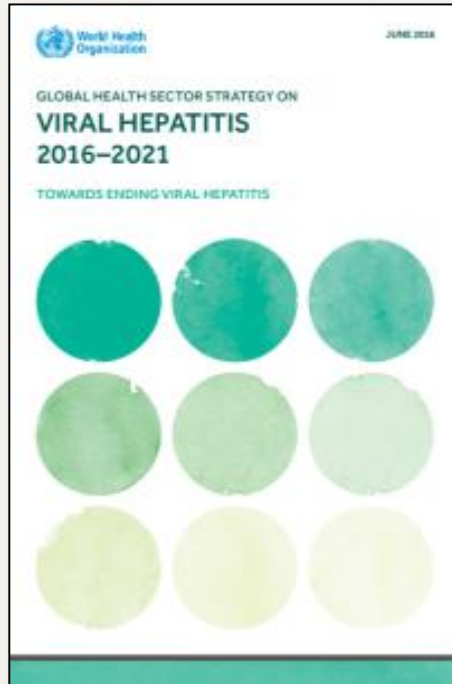
Hepatitis C

Graciela Diap
X Congress of the SEMTSI
Bilbao, 23 October 2017

An estimated 70 million individuals are infected with HCV (viremic), a prevalence of ~1% in 2016



The first-ever Global Strategy on Viral Hepatitis, 2016-2021



AIM: to test 90% and treat 80% of people with HCV by 2030, however in 2015...

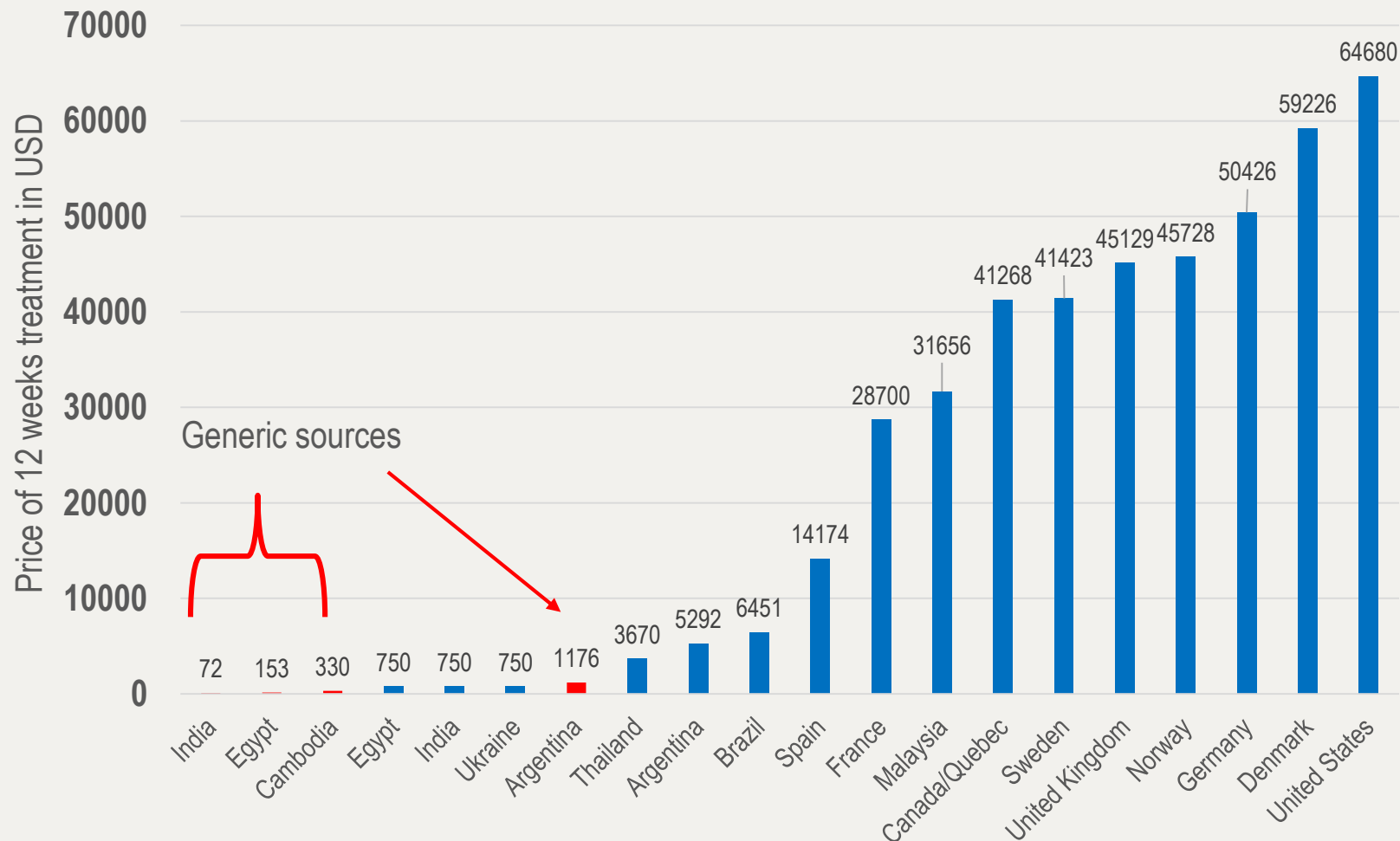
Only 20% of all HCV infections were diagnosed

~ 1.75 million people were newly infected with HCV in 2015 and only 1.1 million people had started treatment in 2015

DAA's approved

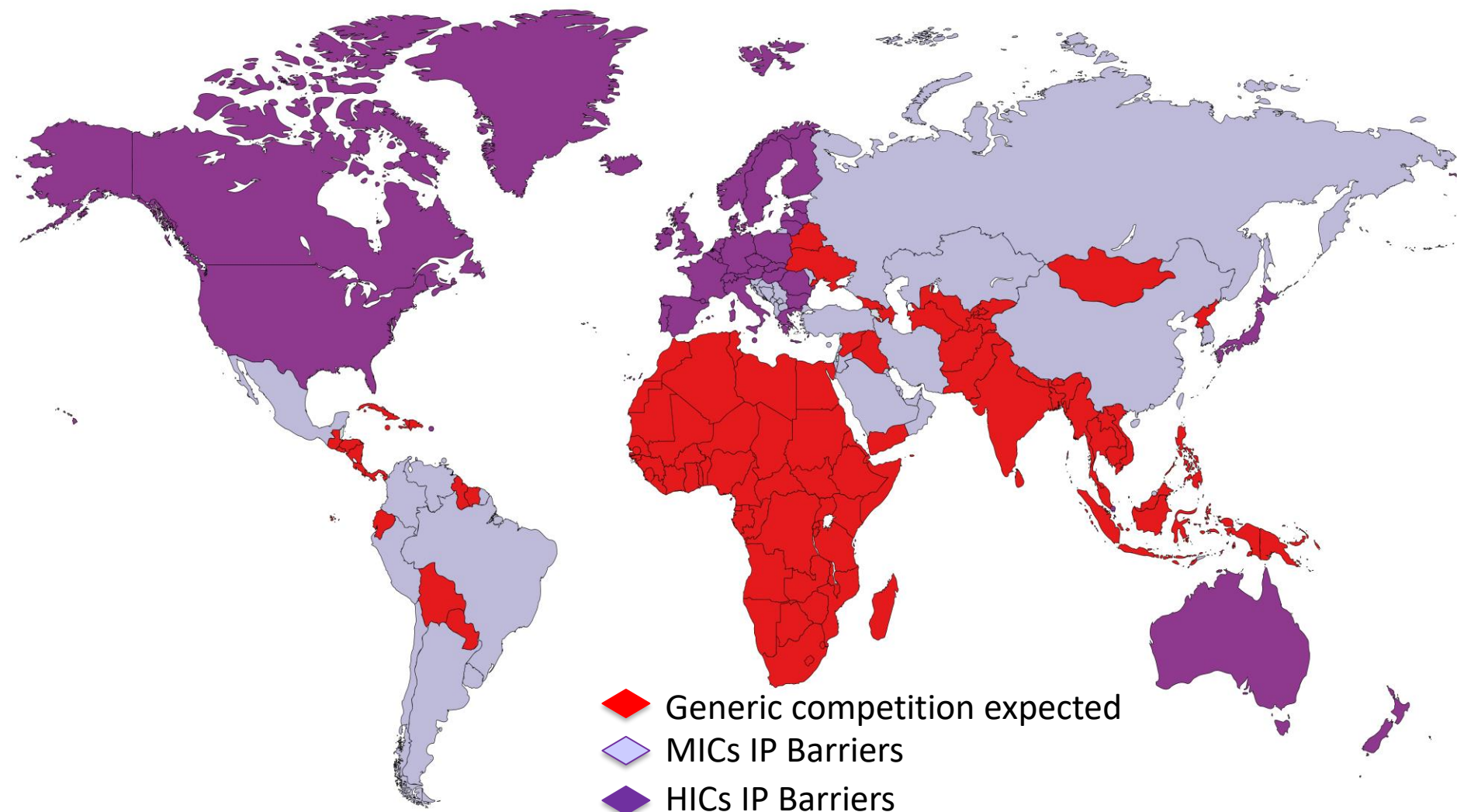
API/Original manufacturer	US FDA	EMA	Pan genotypic	Patents (1st & last expiration date)
sofosbuvir-Gilead	12-2013	1-2014	Combined	✓(2024-2032)
simeprevir-Janssen	11-2013	5-2014	No	✓(2026-2032)
sofosbuvir+ledipasvir-Gilead	10-2014	11-2014	No	✓(2030-2034)
ombitasvir+paritaprevir+dasabuvir+ritonavir-AbbVie	12-2014	1-2015	No	✓(2030-2034)
daclatasvir-BMS	07-2015	8-2014	Combined	✓(2027-2033)
sofosbuvir+velpatasvir-Gilead	06-2016	7-2016	Yes	✓(2031-2034)
elbasvir +grazoprevir-Merck	01-2016	7-2016	No	✓(2032-2035)
sofosbuvir+velpatasvir+voxilaprevir-Gilead	07-2017	6-2017	Yes	✓(2031-2034)
glecaprevir/pibrentasvir-AbbVie	08-2017	7-2017	Yes	✓(2031-2034)

12 weeks of sofosbuvir 400 mg: range of prices



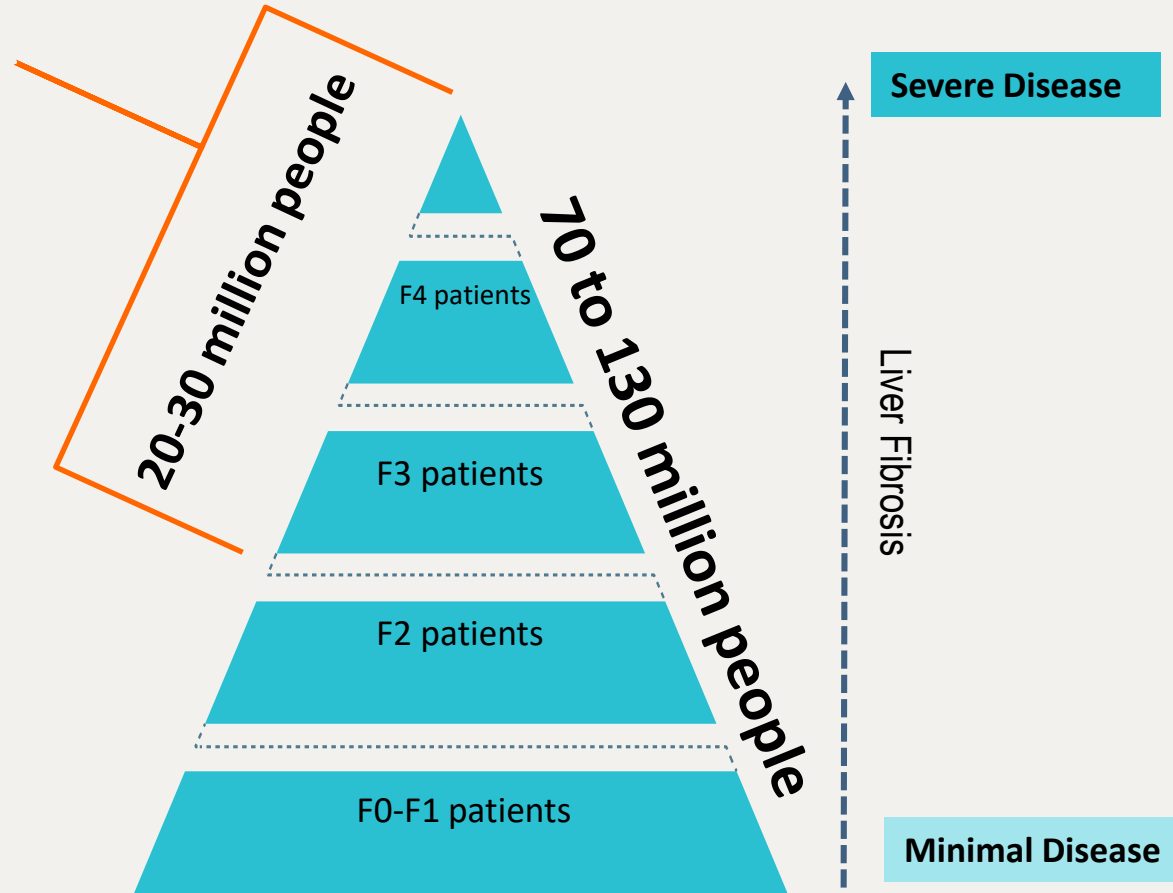
Malaysia & Thailand added to Gilead Voluntary Licensing by Sep 2017...at which prices?

Access to HCV Treatments and IP barriers



Hepatitis C: Problem statement

RATIONING TREATMENT

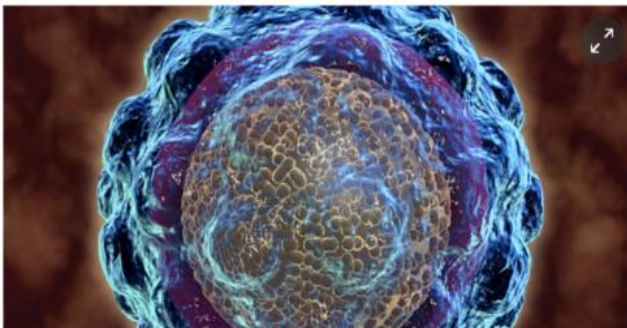


April 2016, launch DNDi-HCV program

the guardian

Hepatitis C treatment for under \$300 coming soon

Drugs for Neglected Diseases initiative says drug successfully tested in Egypt could be available within 18-24 months



Le Monde.fr

Santé

Hépatite C : un traitement à moins de 300 dollars à l'étude

Un essai clinique va débiter en Thaïlande et en Malaisie pour tester une nouvelle combinaison thérapeutique à prix abordable.

LE MONDE | 20.04.2016 à 20h06 • Mis à jour le 20.04.2016 à 20h47 |

Par Paul Benkimoun

Abonnez vous à partir de 1 €

Réagir Ajouter

Partager (552) Tweeter



LesEchos.fr

Hépatite C : bientôt un traitement à moins de 300 dollars

CATHERINE DUCRIET - CATHÉRIE DUCRIET | LE 15/04/16 À 15H03

DNDi, une ONG spécialisée dans le développement à bas coût de produits pour les pays pauvres, relève le défi. En France, le traitement de Gilead est vendu 41.000 euros.

Un traitement contre l'hépatite C à moins de 300 dollars c'est possible. C'est le défi lancé par la structure à but non lucratif DNDi (Drug For Neglected Diseases), spécialiste du développement de médicaments pour les pays du sud, associée aux gouvernements malaisiens et thaïlandais. L'annonce a été faite ce mercredi dans le cadre du Congrès international sur les maladies du foie qui se déroule à Barcelone. En France, le Sovaldi, de Gilead, est vendu 41 000 euros. « Un essai clinique de Phase III, incluant un millier de participants en Malaisie et en Thaïlande démarrera d'ici à juillet prochain » explique Bernard Pécoul, directeur exécutif

NOTRE PARTENAIRE : Bureaux Locaux

LesEchos

DOSSIER :

Spécial ETI,
innover pour trouver
ses relais de croissance



EL PAÍS

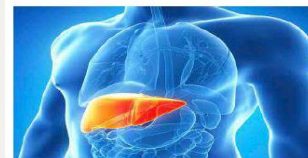
ACCESO A MEDICAMENTOS

Una ONG impulsa tratamientos contra la hepatitis C de menos de 300 euros

La mayoría de los afectados por la enfermedad vive en los países más pobres, donde los precios actuales son imposibles de asumir

EMILIO DE BENITO

Madrid 13 ABR 2016 - 17:21 CEST



Unos 150 millones de personas en el mundo tienen hepatitis C.

La Iniciativa para el Desarrollo de Medicamentos para Enfermedades Olvidadas (DNDi) ha llegado a un acuerdo con el laboratorio egipcio Pherco para desarrollar un tratamiento de la hepatitis C que costará 300 dólares (unos 265 euros al

Rationing of the most expensive treatments has also become reality in the richer countries

Autorizados 15 mil tratamentos para hepatite C. Mais dois mil que o acordado



A 6 de fevereiro de 2015 o então ministro da Saúde Paulo Macedo anunciou o acordo para o tratamento da hepatite C. | PEDRO ROCHA / GLOBAL IMAGENS

quotidianos**sanità**.it

Venerdì 17 FEBBRAIO 2017

Epatite C. Ultimatum a Gilead, Aifa: “Non pagheremo più di 4mila euro a trattamento. Altrimenti produrremo da soli il farmaco”



Hépatite C : forte réduction du prix et remboursement sans restriction pour un premier médicament

Berne, 26.06.2017 - A partir du 1er juillet 2017, l'assurance obligatoire des soins remboursera sans restriction le ZEPATIER. L'Office fédéral de la santé publique (OFSP) a pu faire baisser le prix de ce médicament de 35 %. Ainsi, le traitement profitera à un plus grand nombre de personnes infectées par le virus de l'hépatite C.

Publié le 31/03/2017 à 08:01, Mis à jour le 31/03/2017 à 10:29

Hépatite C : Gilead baisse les prix en France

Actu Santé

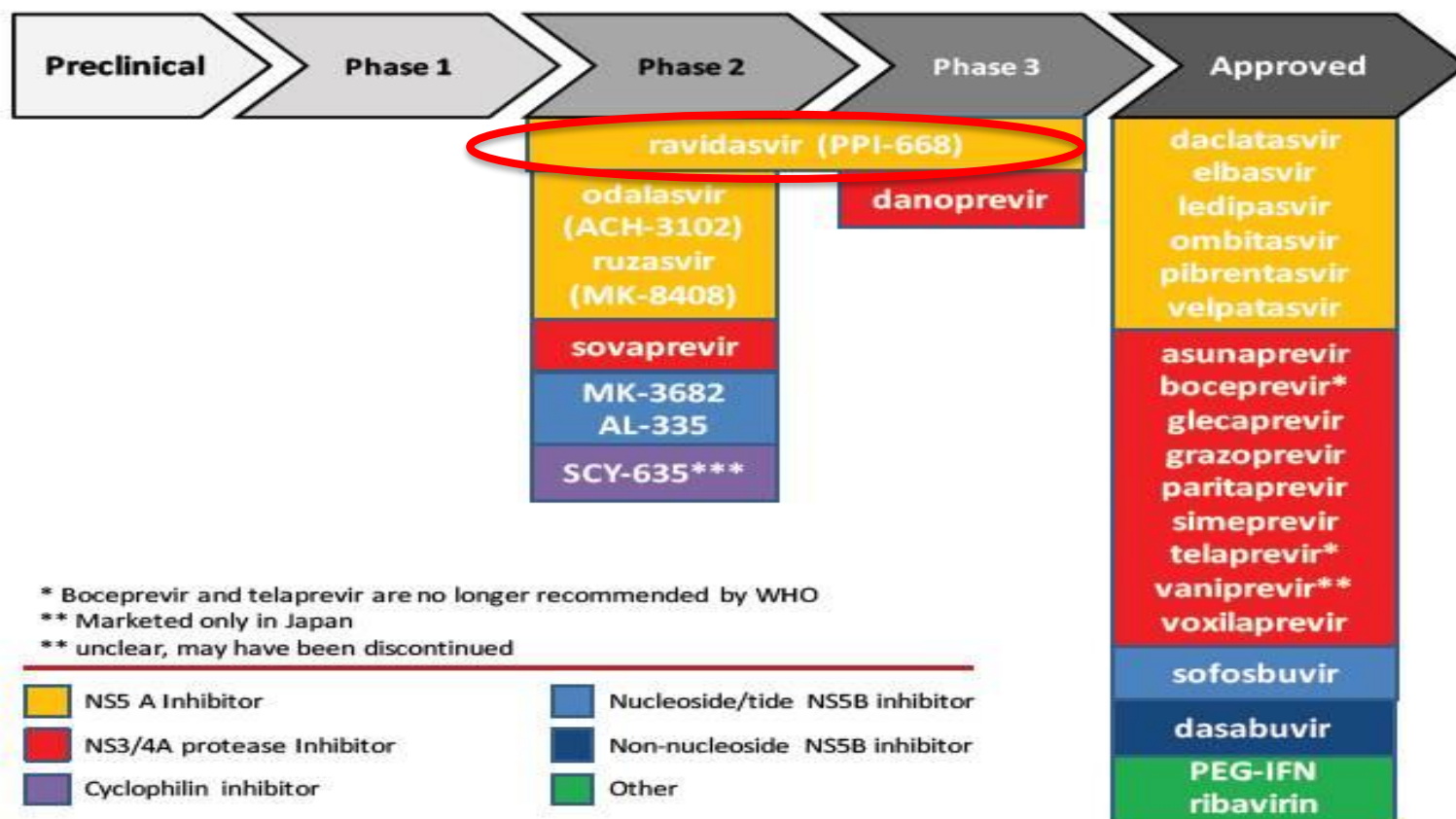
LADEPECHE.fr

HCV Public health challenges in the short to middle term

- Urgent need of simplified models to Dx & Treat HCV, including decentralization, task shifting and community involvement
- Wide availability of affordable, easy-to-use, all-oral pan-genotypic regimens that can enable a public health approach
- Overcome IP & regulatory barriers to expand access to HCV treatment for all

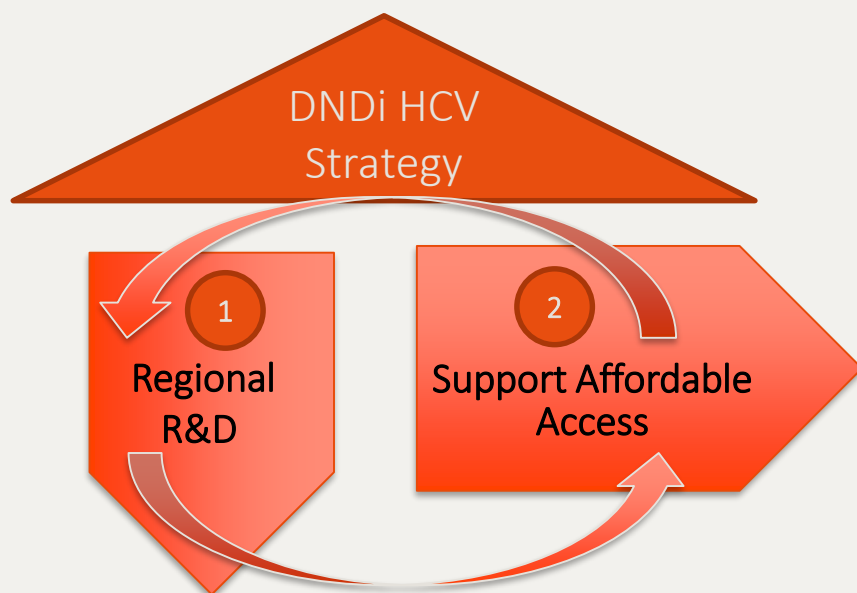
HCV: Rapidly evolving pipeline

FIGURE 14.
OVERVIEW OF HCV MEDICINES ON THE MARKET
AND IN THE PIPELINE (PHASES II & III)



Source: Unitaid.

The DNDi-HCV public health approach



- Complete development of ravidasvir 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 Public Health approach and reduction of Access barriers

- Political commitment & accountability
- Policy change for the sustainable adoption of test & treat with DAAs
- Promote access to affordable, safe, quality and efficacious DAA's
- Address regulatory and intellectual property barriers for access to HCV diagnostics & medicines
- Need of simplified test & treat HCV models of care, scalable to different countries

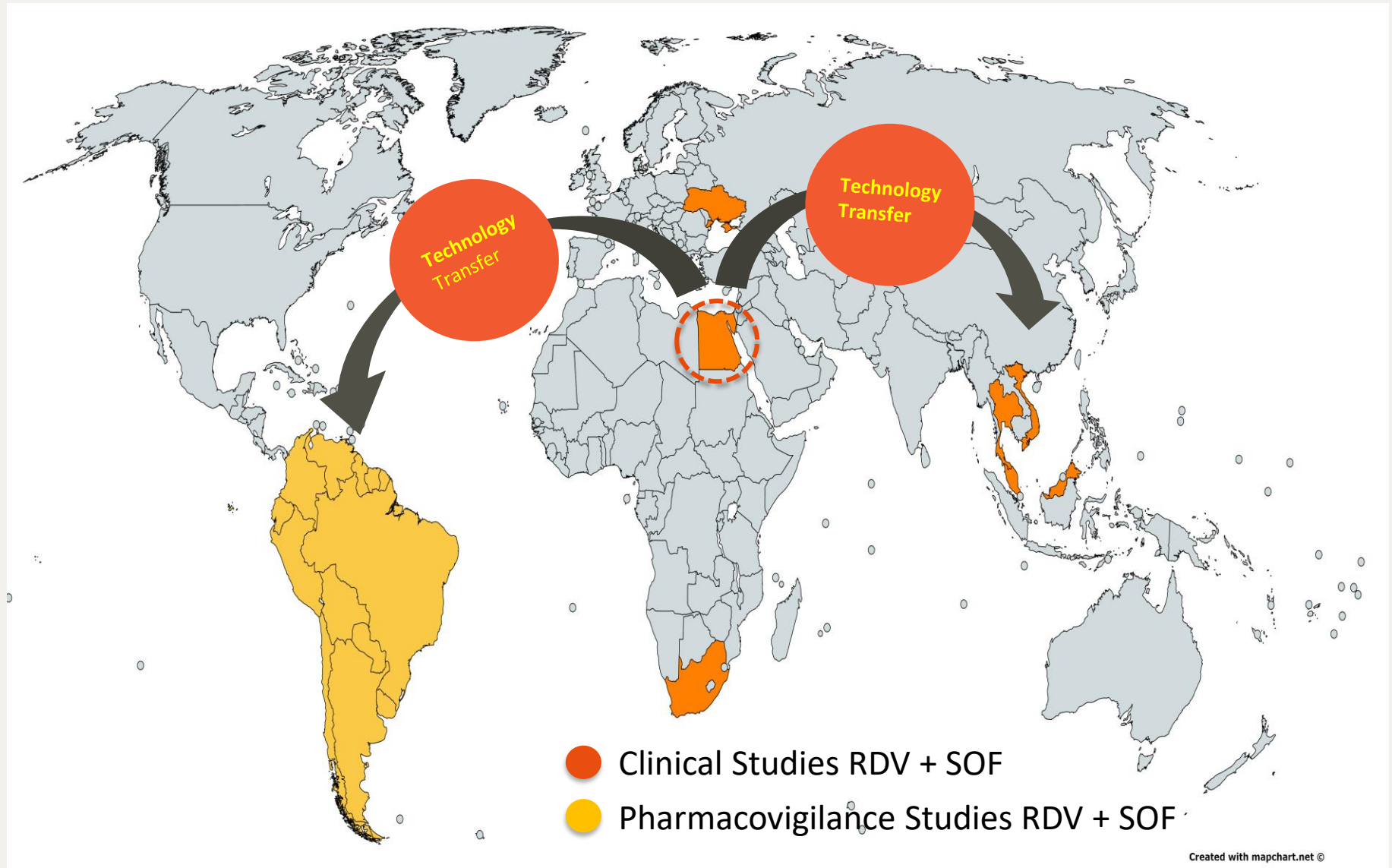
March 2016



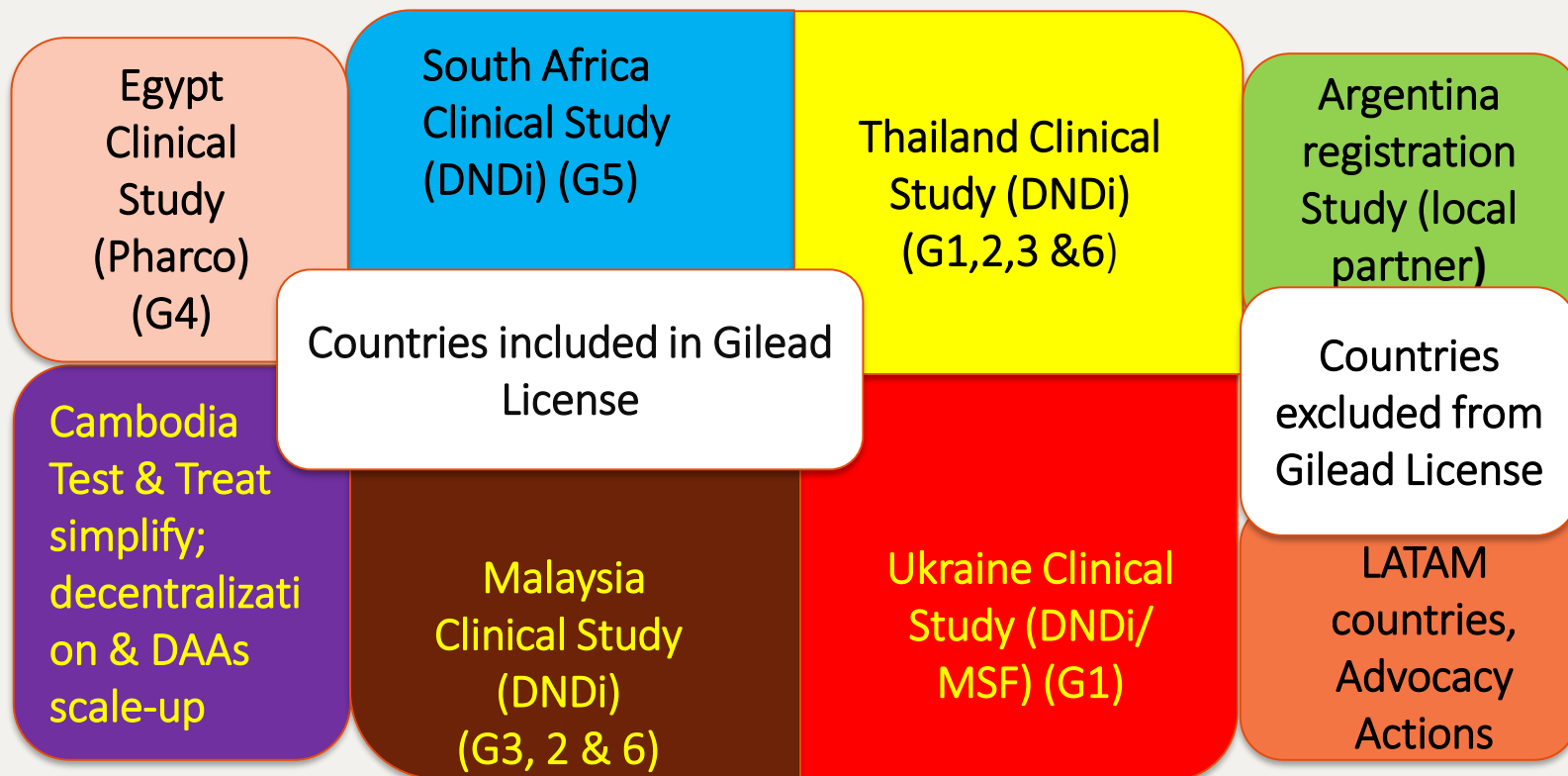
DNDi-HCV Strategic Objectives

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

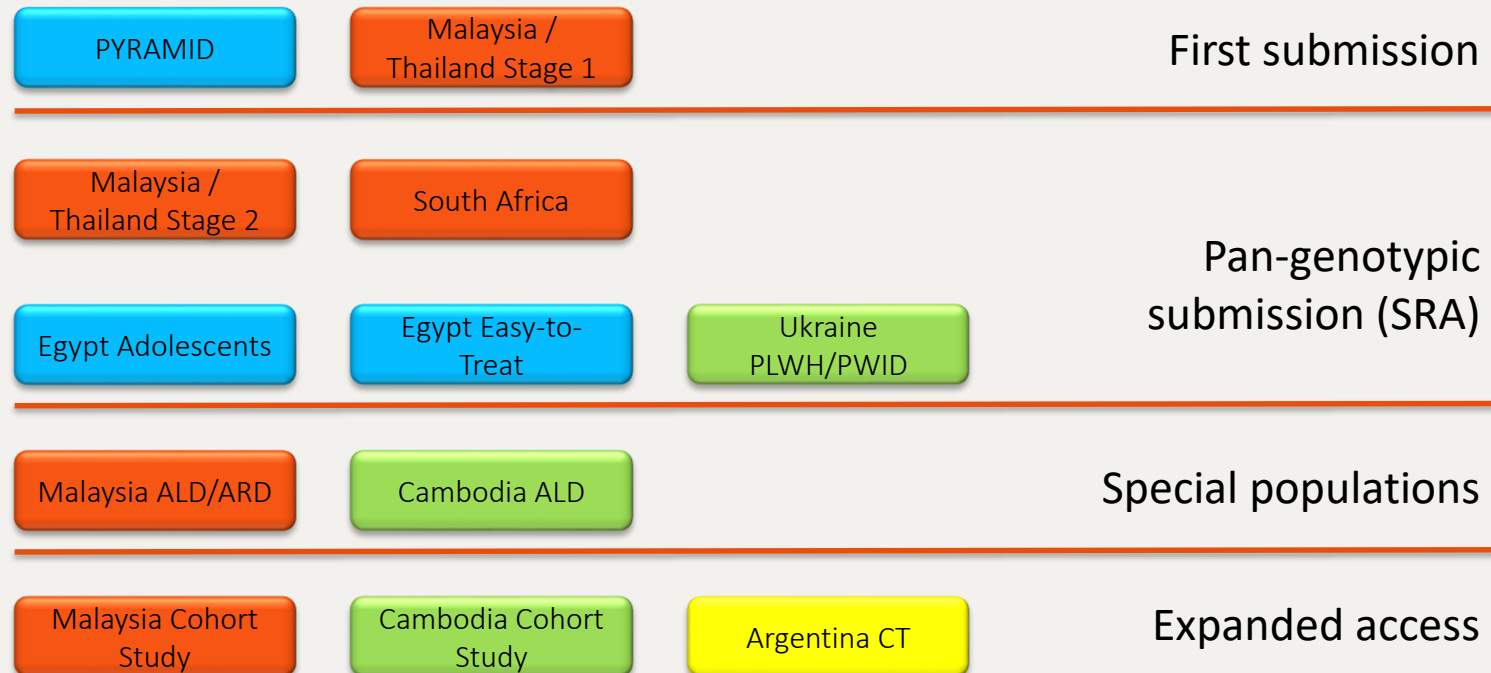
Focus on key countries to influence regions



DNDi HCV program & field work with partners

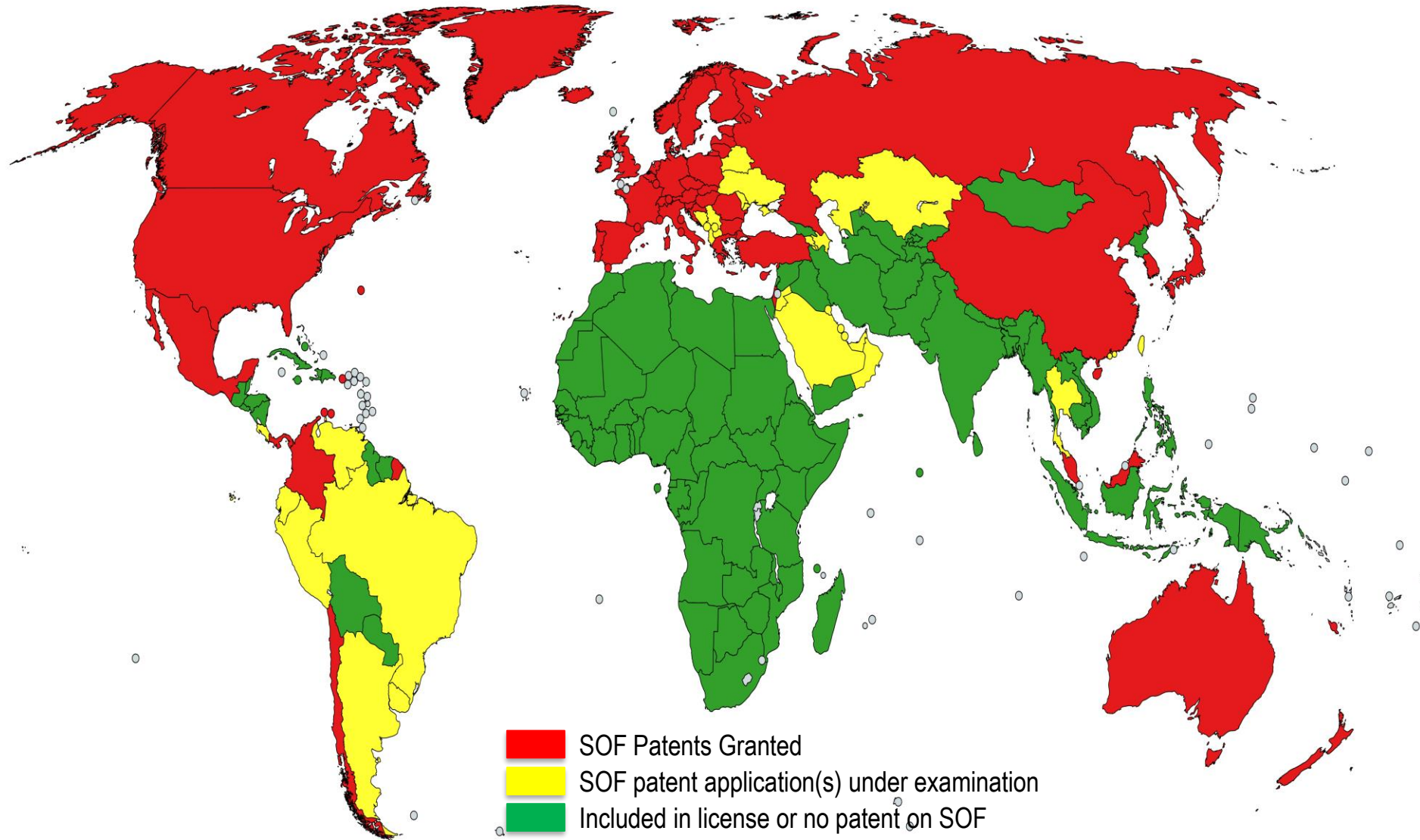


Outline of RDV clinical program



Designed to meet SRA requirements and secure early access to treatment through expanded access programs

RVD must be used in combination with sofosbuvir (relevance of Sof IP landscape)



Created with mapchart.net ©

Partners engaged with DNDi to implement the HCV strategy

**MoHs: Malaysia,
Thai, CBD,
Ukraine, Egypt,
and South
Africa**

**WHO, PQ &
EML, Global
Fund ERP**

**Research
partners:
CRM, Chiang
Mai & Cairo
Univ**

**IP partners:
South Centre
& MdM**

**MSF & DNDi
OCP,
OCG, SAMU, EPICE
NTRE & ACCESS
CAMPAIGN**

FIND

**Generic
manufacturers
for DAA supply**

**Regulatory
authorities:
Malaysia, Thai,
CBD, Ukraine,
Egypt & South
Africa**

**CSOs & patient
groups: C+, TWN,
MAC, MTAAG+,
TTAG, OZONE,
TreatAsia, Ukr Net**



THANK YOU

TO ALL OUR

PARTNERS &

DONORS

DNDi
Drugs for Neglected Diseases initiative



THE STARR FOUNDATION