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## MALAYSIA TAKES THE LEAD ON A PUBLIC HEALTH APPROACH TO HEPATITIS C WITH NEW INITIATIVE TO ENHANCE DIAGNOSIS & TREATMENT

- **Foundation for Innovative New Diagnostics (FIND) and Clinical Research Malaysia (CRM) sign Memorandum of Understanding to collaborate in the research and development of an innovative Hep C diagnostic testing strategy.**
- **Initiative conducted is in continuation of partnership with the Drugs for Neglected Diseases initiative (DNDi) and in collaboration with the Ministry of Health in Malaysia, underscoring the government's world-leading efforts to tackle the disease**

PUTRAJAYA, 6 August 2018 – The Foundation for Innovative New Diagnostics (FIND) and Clinical Research Malaysia (CRM) today signed a Memorandum of Understanding (MOU) to collaborate in the research and development of an innovative Hep C diagnostic testing strategy.

CRM is a non-profit company owned by the Ministry of Health in Malaysia, and this work underscores the importance of research and development in the government's pioneering efforts to tackle the disease. The initiative is being conducted in continuation of a partnership with the Drugs for Neglected Diseases *initiative* (DNDi) and forms part of a larger FIND project known as *Hepatitis C Elimination through Access to Diagnostics (HEAD-Start)*, supported by Unitaid. Malaysia is the only high-middle-income country included in the project.

***"It is a great honour to be part of this research and development effort with FIND, that will eventually lead to more cost efficient and earlier detection of the Hepatitis C. In line with our effort to be a globally trusted organization and participate in research that matters to the Malaysian population we will continue to strive our best to deliver together with our partner FIND"*** said Dr. Akhmal Yusof, Chief Executive Officer of Clinical Research Malaysia

Although the World Health Organization (WHO) has prequalified different types of HCV tests, screening vulnerable and hard-to-reach populations remains a challenge due to centralized health services, making it difficult to identify those with the disease who need to be linked to care and treatment. FIND will demonstrate the feasibility of using rapid diagnostic tests (RDTs) in decentralized primary healthcare facilities and provide technical assistance to the Ministry of Health in Malaysia to support the project.

***"The introduction of RDTs and simpler diagnostic pathways is a critical step in scaling up hepatitis C care,"*** said Catharina Boehme, CEO of FIND. ***"This MOU with CRM allows us to work closely with the Malaysian government and ensure that the evidence generated can be used to inform national policy so that more people can know their status and enter the care cascade."***

All patients screened during the study with World Health Organization pre-qualified diagnostic tests and confirmed as having active HCV (viraemia) will be linked to care. Treatment will be provided:

- either as part of an ongoing DNDi clinical trial, which is co-sponsored by the Malaysian Ministry of Health and designed to assess the efficacy and safety of a new, alternative treatment regimen combining sofosbuvir with the investigational drug ravidasvir. Results from the first stage of the trial published in April 2018 show this drug combination to be safe and effective, with extremely high cure rates for patients, including hard-to-treat cases;<sup>1</sup>
- or by the Malaysian national HCV programme, which, following an ambitious treatment strategy to overcome the prohibitively high cost of HCV treatment in the country, now offers free hepatitis C treatment (sofosbuvir/daclatasvir) in 21 government hospitals.

The MoU was signed by Dr. Akhmal Yusof, Chief Executive Officer of CRM and Mr. Zachary Katz, Chief Access Officer of FIND and witnessed by the Minister of Health, YB Dr. Dzulkefly Ahmad, the Director-General of Health, YBhg Datuk Dr. Noor Hisham, the Deputy Director-General of Health (Research & Technical Support), YBhg. Datuk Dr. Shahnaz Murad, the Director of National Clinical Research Centre (CRC), YBhg Dato Dr. Goh Pik Pin and the Head of HCV & HIV Unit, FIND, Dr. Francesco Marinucci.

<sup>1</sup> DNDi press release, 12 April 2018. <https://www.dndi.org/2018/media-centre/press-releases/new-affordable-hepatitis-c-combination-treatment-shows-97-cure-rate/> (accessed 18 July 2018)

## About Hepatitis C

HCV is one of the world's most common infectious diseases, usually contracted through unsafe healthcare and injection drug use. Globally, more than 71 million people are chronically infected, over 80% of whom live in low- and middle-income countries (LMICs) – but only one in five people know they have the disease.<sup>2</sup> Around 400,000 people die every year, and the mortality rate is increasing, making it a global health priority: the World Health Organization (WHO) has set an ambitious target of viral hepatitis elimination by 2030.<sup>3,4</sup> In Malaysia, HCV disease burden is high and predicted to rise steeply over the coming decades, leading to a projected 63,900 HCV-related deaths by 2039.<sup>5</sup>

## About CRM

Established by the Malaysian Ministry of Health in 2012, CRM exists to advance global health solutions for a brighter, more hopeful future for the people by providing speedy and reliable end-to-end clinical research support for quality studies. CRM's innate understanding of the local clinical research landscape with the international standards of operations coupled with fundamental backing of the government ministries provide us an incomparable advantage to work with partners from the nascent stages of development to materialisation of the end product, in order to deliver better treatment and high skilled job opportunities. For further information, please visit [www.clinicalresearch.my](http://www.clinicalresearch.my)

## About FIND

FIND was established in 2003 as a global non-profit dedicated to accelerating the development, evaluation and delivery of high-quality, affordable diagnostic tests for poverty-related diseases, now including malaria, tuberculosis, HIV/AIDS, sleeping sickness, hepatitis C, leishmaniasis, Chagas disease, Buruli ulcer, non-malarial fever and diseases with outbreak potential, such as Ebola. FIND has partnered in the delivery of 20 new diagnostic tools and created an enabling environment for numerous others through the provision of specimen banks, reagent development and better market visibility. FIND also supports better access to new diagnostics through implementation, quality assurance and lab strengthening work. FIND has nearly 200 partners globally, including research institutes and laboratories, health ministries and national disease control programmes, commercial partners, bilateral and multilateral organizations, especially WHO, and clinical trial sites. For further information, please visit [www.finddx.org](http://www.finddx.org)

## [Photos Available Here](#)

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<sup>2</sup> World Health Organization. Global hepatitis report 2017. [www.who.int/hepatitis/publications/global-hepatitis-report2017/en/](http://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/) (accessed 27 June 2018)

<sup>3</sup> World Health Organization. Disease burden and mortality estimates, 2000–2015. [http://www.who.int/healthinfo/global\\_burden\\_disease/estimates/en/index1.html](http://www.who.int/healthinfo/global_burden_disease/estimates/en/index1.html) (accessed 27 June 2018)

<sup>4</sup> World Health Organization. Combating hepatitis B and C to reach elimination by 2030, May 2016. [http://apps.who.int/iris/bitstream/handle/10665/206453/WHO\\_HIV\\_2016.04\\_eng.pdf;jsessionid=0B0881916BBD9F9E2B47D4B004DB7969?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/206453/WHO_HIV_2016.04_eng.pdf;jsessionid=0B0881916BBD9F9E2B47D4B004DB7969?sequence=1) (accessed 5 July 2018)

<sup>5</sup> Raihan R, et al. *Euroasian J Hepato-Gastroenterol* 2017;7(1):65–67