

INFECTIOUS DISEASES DATA OBSERVATORY

# Building a visceral leishmaniasis data-sharing platform to optimise treatment and inform future research

Philippe Guerin on behalf of the VL Data Platform

**ASTMH 2017** 

www.iddo.org Twitter: @IDDOnews

#### Public **Data sharing requirements** Health agencies Funders Journals World Health EUROPEAN MEDICI Publications Countries Programmes Governance About WHC MRC 24 June 2013 EMA/240810/2012 Executive Director Media centre Publication and access to clinical Medical Major research funders and international NGOs to implement WHO standards on reporting clinical Research World Health POLICY/0070 trial results Status: Draft for public consultation Council Effective date: E D С News release Review date: Organization Supersedes: N.A 18 MAY 2017 LIGENEVA - Some of the world's largest funders of medical research 1. Introduction and purpose and international non-governmental organizations today agreed on new standards The aim of the European Medicines Agency ("the Agency") that will require all clinical trials they fund or support to be registered and the results ansparency is a key consideration for the Agency in deliv disclosed publicly here is prowing demand from external stakeholders for f BILL&MELINDA eliberations and actions, but also about the data and res thebmj egulatory decisions are based. Following consultations wit In a joint statement, the Indian Council of Medical Research, the Norwegial GATES foundation nd European bodies, including the European Ombudsman BioMed Central The Open Access Publisher Research Council, the UK Medical Research Council, Médecins Sans Frontières and upervisor, the Agency has drafted this policy, which con Epicentre (its research arm), PATH, the Coalition for Epidemic Preparedness cuments (related to medicinal products for human and y EMA/110196/2006), which came into effect in December Innovations (CEPI), Institut Pasteur, the Bill & Melinda Gates Foundation, and the olicy on access to documents and this policy on publicatio Wellcome Trust agreed to develop and implement policies within the next 12 months Inalised, will be aligned. that require all trials they fund, co-fund, sponsor or support to be registered in a lowing external parties access to CT data held by the Ap publicly-available registry. They also agreed that all results would be disclosed within akeholders' rights, interests and values. In addressing m e following views and positions, which inform the policy: specified timeframes on the registry and/or by publication in a scientific journal. nabling public scrutiny and secondary analysis of CTs: A enefit public health in future. It will make drug developm Today, about 50% of clinical trials go unreported, according to several studies, ofter playing field that allows all drug developers to learn from g because the results are negative. These unreported trial results leave an incomplete e wider scientific community to make use of detailed and nowledge in the interest of public health. The Agency also and potentially misleading picture of the risks and benefits of vaccines, drugs and ansparency will take regulatory decision-making one ster medical devices, and can lead to use of suboptimal or even harmful products med use of medicines. Independen Research funders are making a strong statement that there will be no more excuses Editorial **Annals of Internal Medicine** on why some clinical trials remain unreported long after they have completed," said Dr Marie-Paule Kieny, Assistant Director-General for Health Systems and Innovation wellcome Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors



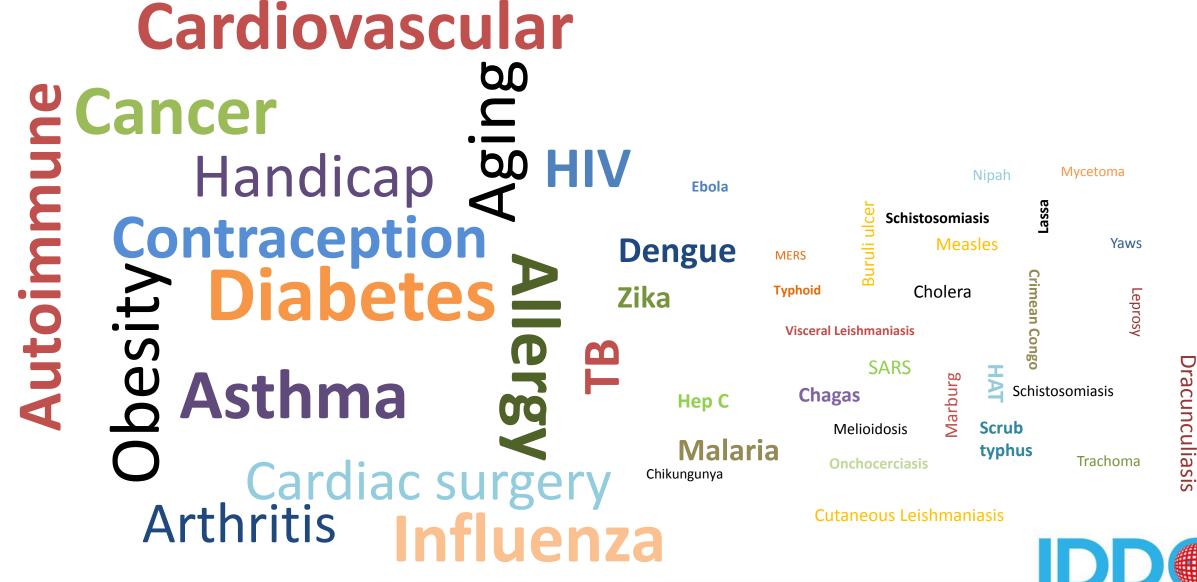




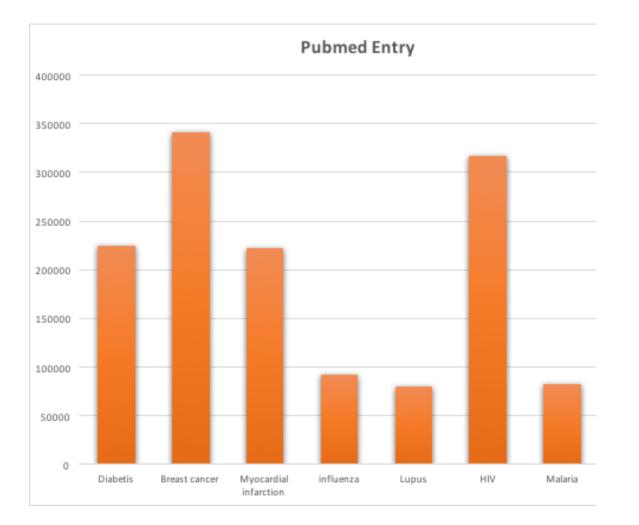
#### In VL



# **Data reality check**



## **Proxy of "Interest"**



INFECTIOUS DISEASES DATA OBSERVATORY

## **Proxy of "Interest"**





#### **Proxy of "Interest" & Resources**





#### **Data Imbalance**

- Poverty-related & emerging infections vs other diseases
  - Lower data volume, variable in quality
  - Scattered geographically
  - Challenges in patient recruitment
  - Limited commercial interest
- Challenges of funder and journal data-sharing policies
  - Disadvantages for developing country investigators
  - Ethical challenges: Benefits vs risks
  - Data security and privacy protection
  - Cost



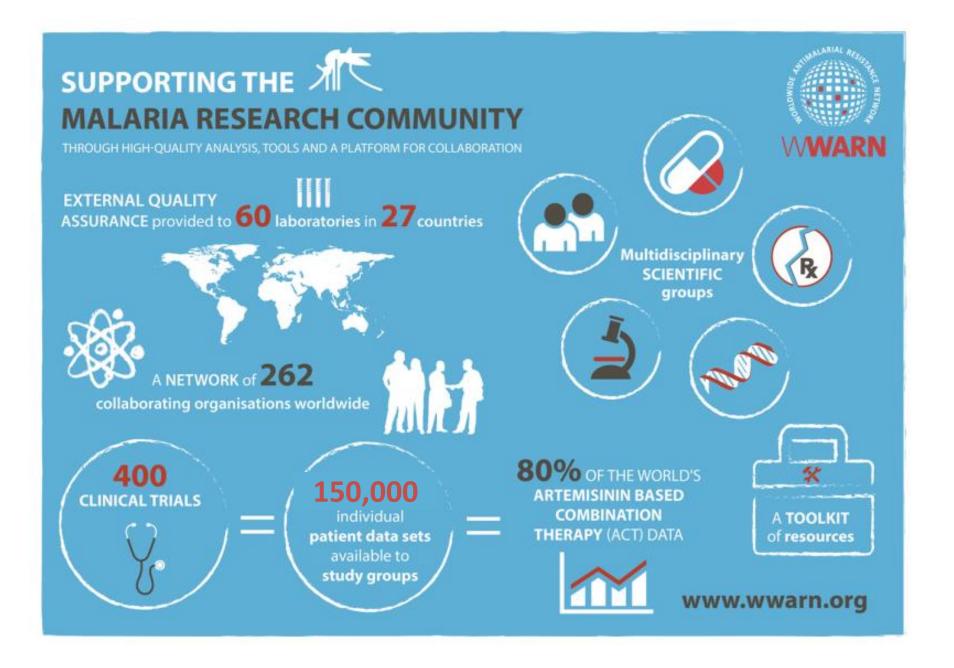
#### **Understanding factors affecting efficacy**

Drugs	SSG	Ampho B Liposomal	Ampho B deoxycholate	MIL	PM sulphate	SSG+PM	LAB+SSG	LAB+MIL	PM+MIL
Clinical efficacy									
Asia	35-95% (depending on areas)	> 97% all regions	> 97%; single dose: > 96%	94-97% (India)	94% (India)	93,8% (India)	> 97%	> 97%	> 97%
Africa	93%	33 - >97% (depending on areas)	Not fully established	72%	84%	91%	87%	79%	Not documented
Resistance	As high as 60% (India)	Not documented	Not documented	20% (Nepal)	Lab isolates (easily)	Lab isolates (easily)	Lab isolates	Lab isolates	Lab isolates (easily)

Extreme variations in treatment response observed by drugs and regions

Source DND*i* 









#### Could available data be used to optimise treatment outcome?



**RESEARCH ARTICLE** 

Systematic review of clinical trials assessing the therapeutic efficacy of visceral leishmaniasis treatments: A first step to assess the feasibility of establishing an individual patient data sharing platform

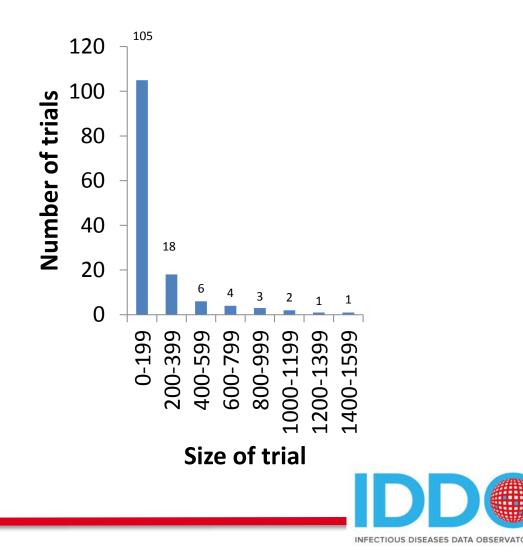


Jacob T. Bush<sup>1,2</sup>, Monique Wasunna<sup>3</sup>, Fabiana Alves<sup>4</sup>, Jorge Alvar<sup>4</sup>, Piero L. Olliaro<sup>1,5</sup>, Michael Otieno<sup>1,2,3</sup>, Carol Hopkins Sibley<sup>1,2,6</sup>, Nathalie Strub Wourgaft<sup>4</sup>\*, Philippe J. Guerin<sup>1,2</sup>\*

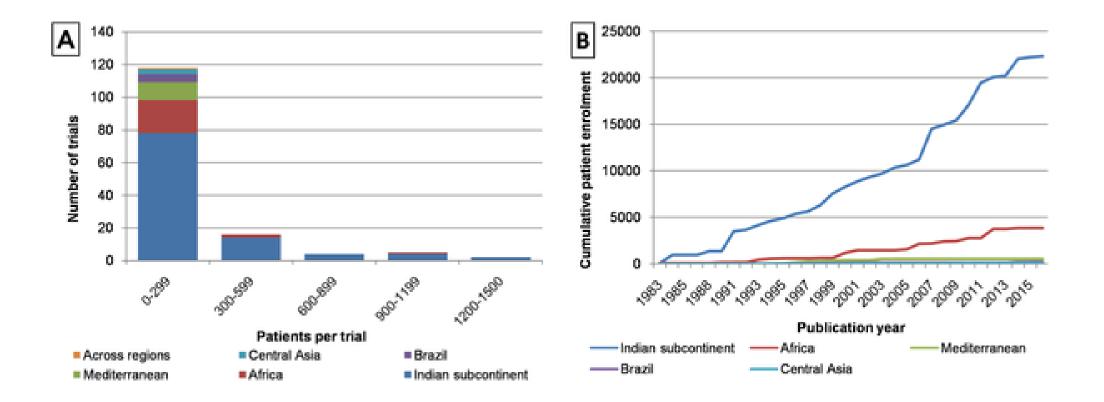


# **Clinical trials landscape**

- 141 clinical studies on VL drugs
  - 25,865 patients
  - Most trials enroll less than 200
- 1,379 patients in completed, unpublished trials
- 9,802 in active trials
  - Total > 37 000 patients



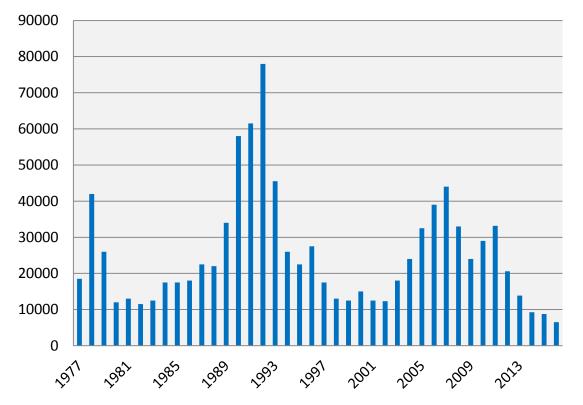
#### A perishable but transferable knowledge





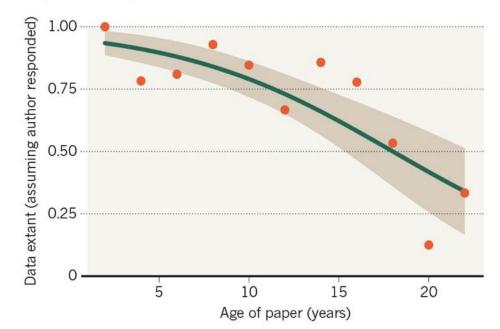
### Guarding the value of data: lesson learned in Asia

India VL trend (1977-2016)



#### **MISSING DATA**

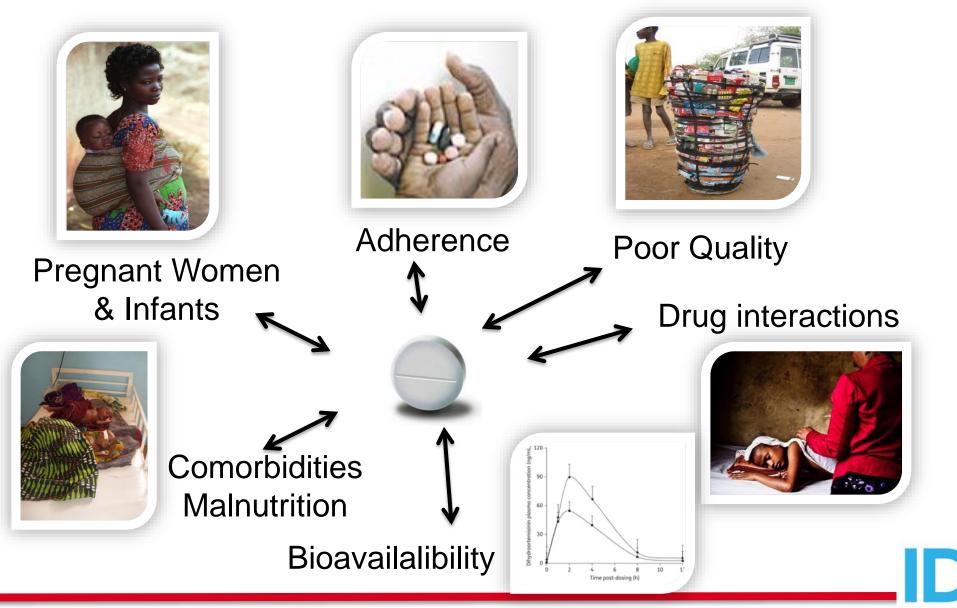
As research articles age, the odds of their raw data being extant drop dramatically.



Vines et al. Current Biology 2014



### **Identifying factors affecting drug efficacy**



#### **Benefits of data platforms**

- Larger patient numbers allow for greater power
- Sufficient size to examine **sub-populations** 
  - Infants, pregnant women, malnourished children
- Better historical baseline for evaluating treatments
- Increased validity of findings
- Provide the forum for standards development for prospective studies
- Inform new drug development



The Infectious Diseases Data Observatory (IDDO) assembles clinitation in the second s



#### VL data platform - Scientific Advisory Committee

- Defining the governance
- Developing research agenda with the scientific research community



Prof. Simon Croft



**Prof. Shyam Sundar** Banaras Hindu



**Prof. Marleen Boelaert** Institute of Tropical Medicine



**Dr. Jorge Alvar** DND*i* 



**Dr. Koert Ritmeijer** MSF



**Prof. Ahmed Mudawi Musa** Institute of Endemic Diseases



Dr. Dinesh Mondal



Observer

**Prof. Hannah Akuffo** Karolinska Institutet



Developing a Data Platform which makes sense for the VL scientific community requires dialogue and innovation



Image: Anita Khemka/DNDi

www.iddo.org/vl

#### In partnership with

Drugs for Neglected Diseases *initiative* 







Thank you

