

R&D Priorities using the TDR Health Product Profile Directory

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70th World Health Assembly (agenda item 13.5 Paper A70-22)

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What is TDR?

The Special Programme for Research and Training in Tropical Diseases

- TDR is co-sponsored by:



- TDR's mission:

To foster an effective global research effort on infectious diseases of poverty and promote the translation of innovation to health impact in disease endemic countries.

World Health Organization Request to TDR

2015 World Health Assembly requested TDR to explore a financing mechanism for product R&D in line with the following principles (CEWG follow up):

- Role of Member States in Governance of coordination mechanism
- Access & affordable products
- Delinkage of R&D costs from final price
- Support for open innovation
- Voluntary pooled fund
- To cover neglected diseases and R&D needs of products suitable for developing countries

TDR report March 2016: Health Product R&D Financing

- Three areas of work:
 - Modeling \$ for a pooled fund
Managing an R&D portfolio
 - Developing a product profile directory for portfolio management
 - **NEW: Operational Plan** with case studies examples: schistosomiasis and cutaneous leishmaniasis. With WHO NTD dept.
- Discussion at 70th WHA
Agenda 13.5 Paper A70-22



http://www.who.int/tdr/capacity/gap_analysis/en/

How much funding would make an impact?

The Portfolio-To-Impact (P2I) model

FIG. 2.3 CONCEPTUAL OVERVIEW OF FINANCIAL MODEL

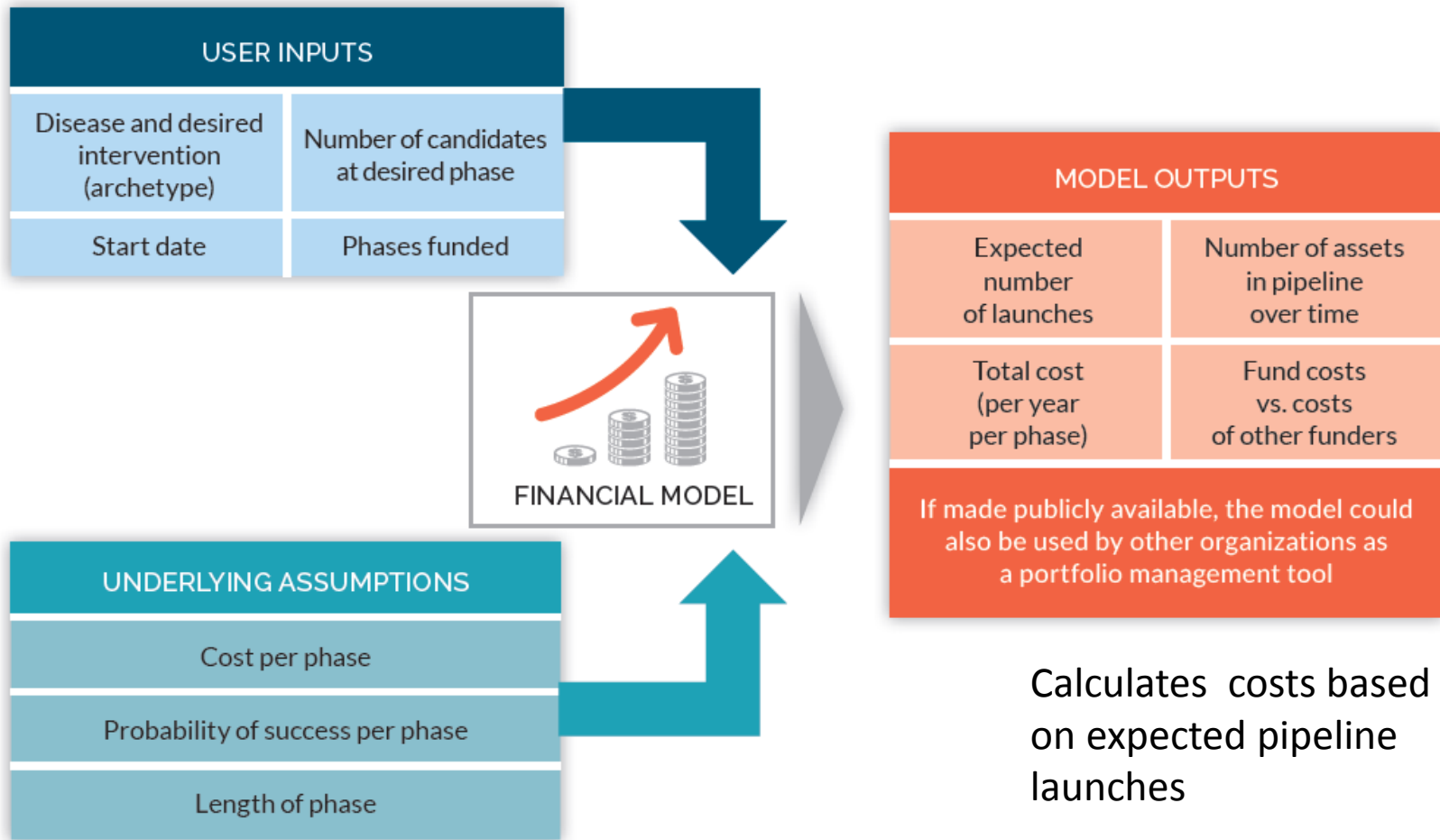


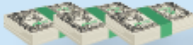


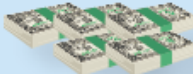







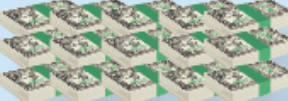






FIG. 5.1 OVERVIEW OF FUND OPTIONS AND MECHANISMS

	ANNUAL FUND SIZE US\$ millions (m) ^a	STEADY STATE PROJECTS/YEAR	ESTIMATED STAFFING NEEDS (FULL-TIME EQUIVALENT)	IF DEVELOPMENT STARTS IN 2017, WHAT IS EXPECTED BY 2030?
1	Passive coordination Up to US\$ 1 m	Define and communicate global priorities across diseases	1	
2	Prioritization Forum Up to US\$ 5 m	Review funding directions with donors and evaluate if funding is aligned with global priorities	3	
3	~US\$ 15 m (small) 	Fund 3-4 projects (no innovation- focused projects)	3 	3 repurposed drugs - simple
4	~US\$ 50 m (PDP size) 	Fund 15-20 projects (few innovation-focused projects)	9  + 	1 new chemical entity (NCE) - simple
5	~US\$ 100 m (medium) 	Fund 25-40 projects (including ~5 innova- tion-focused projects)	14  +  + 	1 repurposed drug - complex
6	~US\$ 300 m (large) 	Fund 80-100 projects (a novel intervention to approval)	26  +  + 	1 simple biologic
7	>US\$ 500 m (global) 	Fund 140-160 projects (can fund many projects in priority areas)	40  +  +  + 	1 NCE - complex

^a Costs shown represent annual amount of funds for disbursement to support R&D from preclinical to phase III. Costs related to management, infrastructure and fund hosting are not shown.

TOOLKIT for identifying and communicating PRIORITIES

1. Develop a directory of health product profiles

- Many organizations produce these ≠ Not many published
- Public health need and access as top line requirements
- Address a public health failure

2. Use of product profiles in portfolio management + R&D mapping

Product profiles mapped against:

- Is there R&D to meet the needs expressed in a product profile?
- Stage of development against milestone agreements
- Funding requirements / shortfall
- Greater precision in articulating priorities
- Better understanding of global efforts
- Identification of gaps – i.e. no agreed profile
- Steps towards ‘global coordination’

The key problems today are missing overviews of product profiles and inconsistency in terminology

What we heard

“During the Ebola crisis, Ministries of Health were swamped with suggestions of products. A **single source of high-quality guidance** would have been extremely **helpful**.”

“The entire health community displays a very inconsistent use of designations for research guidance. For example, there is **no common understanding** of what a profile consists of.”

“Even within WHO, we don’t have a generally accepted and applied rule on **how to label guidelines**.”

“Many guidelines are too detailed and might stifle innovation. We need to provide **higher-level guidance than most profiles** which go very much into technical details.”

Key insights

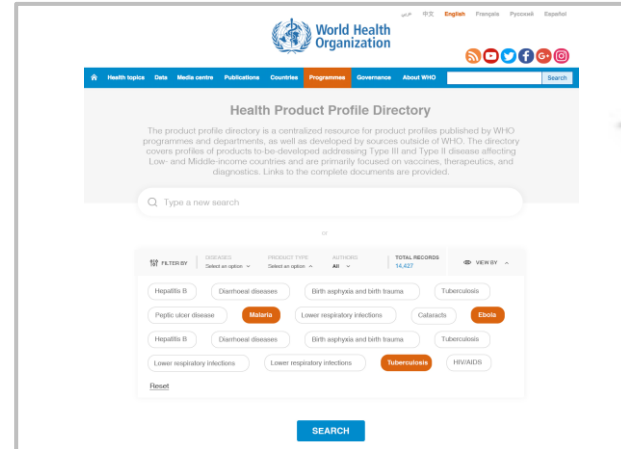
- There are numerous **different sources** for product development guidelines
- **Lack of clarity** whether product profiles available are **WHO endorsed**
- A **variety of labels** are in use for such guidance
- The global health community would **benefit** from more **high-level guidance** describing needed product profiles without technical details
- A **clear separation** of **strategic vs. technical goals** of a product profile would be beneficial

SOURCE: WHO expert panel workshop December 5, team analysis

Overview of directory

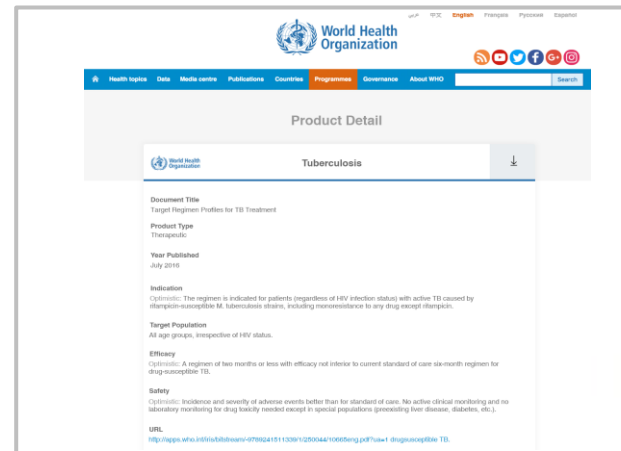
Searchable database

- Ability to search database of product profiles
- Filter profiles by various criteria (e.g., originator, publishing year, disease area, product type)
- See all the product profiles for particular diseases types
- Download overview of profiles for individual analysis



Directory of product profiles

- Provides pre-defined details of product profiles (e.g. indication, target population)
- Standardized reporting fields and level of detail
- Provides hyperlink to original document for full details







Health Product Profile Directory

The product profile directory is a centralized resource for product profiles published by WHO programmes and departments, as well as developed by sources outside of WHO. The directory covers profiles of products to-be-developed addressing neglected diseases affecting Low- and Middle-income countries and are primarily focused on vaccines, therapeutics, and diagnostics. Links to the complete documents are provided.

or

 FILTER BY	DISEASES Select an option ▾	PRODUCT TYPE Select an option ▾	AUTHORS All ▾	ORGANISATIONS Select an option ▾	STATUS Select an option ▾	TOTAL RECORDS 141	 VIEW BY ▾
				<input type="checkbox"/> Select All			
				<input type="checkbox"/> WHO			
				<input type="checkbox"/> External			



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OF

FILTER BY

DISEASES

Select an option

PRODUCT TYPE

Select an option

AUTHORS

All

ORGANISATIONS

Select an option

STATUS

Select an option

TOTAL RECORDS

141

VIEW BY

Select All (80)

Active

Inactive

SEARCH

Directory Coverage



Indication	Number of profiles in directory
Tuberculosis	16
Malaria	8
Ebola	4
Taenia solium taeniasis/cysticercosis	4
HIV	3
Chagas Disease	3
Hookworm Disease	2
Pneumococcal	2
Zika Virus	2
Hepatitis B	1
Onchocerciasis	1
MERS-CoV	1
Hepatitis C	1
Cutaneous Leishmaniasis	1
HIV+Syphilis	1
Paediatric HIV	1
Rift Valley fever	1
Schistosomiasis	1
Dengue	1
Sleeping Sickness	1
Visceral Leishmaniasis	1
Bacterial vs non-bacterial	1
Japanese encephalitis	1
Lassa fever	1
Lymphatic Filariasis	1

HIV+Syphilis	1
Paediatric HIV	1
Rift Valley fever	1
Schistosomiasis	1
Dengue	1
Sleeping Sickness	1
Visceral Leishmaniasis	1
Bacterial vs non-bacterial	1
Japanese encephalitis	1
Lassa fever	1
Lymphatic Filariasis	1
Blinding Trachoma	1
Trachoma	1
Soil-Transmitted Helminths	1
Nipah Virus	1
Crimean Congo haemorrhagic fever	0
Ascariasis	0
Trichuriasis	0
Meningitis	0
Maternal sepsis	0
Marburg	0
SARS coronavirus diseases	0

Sources:

Product profiles contained in this directory are obtained from the following sources:

- WHO
- Acambis
- Anlylam
- CADO
- CAMI
- Centers for Disease Control & Prevention, Kenya
- DNDi
- EMVDA
- The George Washington University Medical Cent
- Janssen
- malERA
- MMV
- PATH
- Sabin Vaccine Institute
- Murtagh Group
- TOVA
- UNICEF



Search Results (11)

Select upto 3 results to compare



DATE



Tuberculosis

Target regimen profiles

Published in July 2016



Janssen

Tuberculosis

The challenge of new drug discovery for tuberculosis

Published in 2011



FIND

Tuberculosis

Target product profile of a Molecular drug-susceptibility Test for Use in Microscopy centers

Published in July 2015

The challenge of new drug discovery for tuberculosis

Published in 2011



FIND

Tuberculosis

Target product profile of a Molecular drug-susceptibility Test for Use in Microscopy centers

Published in July 2015



FIND

Chagas Disease

Point-of-Care Diagnosis and Assessment of Response to Treatment

Published in 2015



Zika

WHO Zikv TPP

Published in Jan 2016

1 2

[VIEW / COMPARE](#)

Product Detail



Tuberculosis



Document Title	Target Regimen Profiles for TB Treatment
Product Type	Therapeutic
Published by	World Health Organisation
Year Published	Jun 2016
Indication	Optimistic: The regimen is indicated for patients (regardless of HIV infection status) with active TB caused by rifampicin-susceptible <i>M. tuberculosis</i> strains, including monoresistance to any drug except rifampicin.
Target Population	All age groups, irrespective of HIV status.
Efficacy	Optimistic: A regimen of two months or less with efficacy not inferior to current standard of care six-month regimen for drug-susceptible TB.
Safety	Optimistic: Incidence and severity of adverse events better than for standard of care. No active clinical monitoring and no laboratory monitoring for drug toxicity needed except in special populations (preexisting liver disease, diabetes, etc.).
URL	https://www.finddx.org/wp-content/uploads/02/2016/Porras-TPP-PoC-ChD-DX-ToC2015-.pdf

Product Detail



Chagas Disease



Product Type	Diagnostic
Document Title	eHEALTH Portal
Published by	FIND
Year Published	Jun 2015
Indication	Chagas Disease
Target Population	Serodiagnosis of pregnant women and women admitted at delivery living or born in endemic
Sample type and volume	Ideal: urine sample
User setting	(i) Ideal: processing at point of care; (ii) Less desirable: samples processed in a reference laboratory transported
Performance	Sensitivity: >%95 Specificity: %100. Ideal: integrated into routine health care screening (e.g., metabolic screening)
URL	https://www.finddx.org/wp-content/uploads/02/2016/Porras-TPP-PoC-ChD-DX-ToC2015-.pdf

There are several gaps in product development guidance for type III diseases


✓ WHO product profile available
 ✓ Product profile outside WHO
 Research priorities by WHO
 Research priorities outside WHO









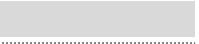



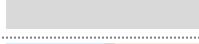


























Disease- Type III	Therapeutic	Vaccine	Diagnostic
Chagas disease		✓	✓ ✓
Trachoma			✓
Trypanosomiasis	✓		
Lymphatic filariasis			✓
Diphtheria		✓ ✓	
Measles			
Tetanus			
Malaria	✓	✓ ✓	✓
Onchocerciasis		✓	✓
Leishmaniasis	✓		
Leprosy			
Syphilis			✓ ✓
Hypertensive disorders of pregnancy			
Japanese Encephalitis		✓	
Ascariasis	✓ ✓		✓
Schistosomiasis			✓
Pertussis			✓

Note: Analysis is based only on profiles easily accessible profiles and/or shared during initial landscape screening

1 Results based upon analysis of 119 documents, 87 of which were classified as WHO documents; 11 WHO documents contain product profiles, 21 documents describe product profiles developed outside of WHO (for type III and type II diseases)

There are several gaps in product development guidance for type II diseases

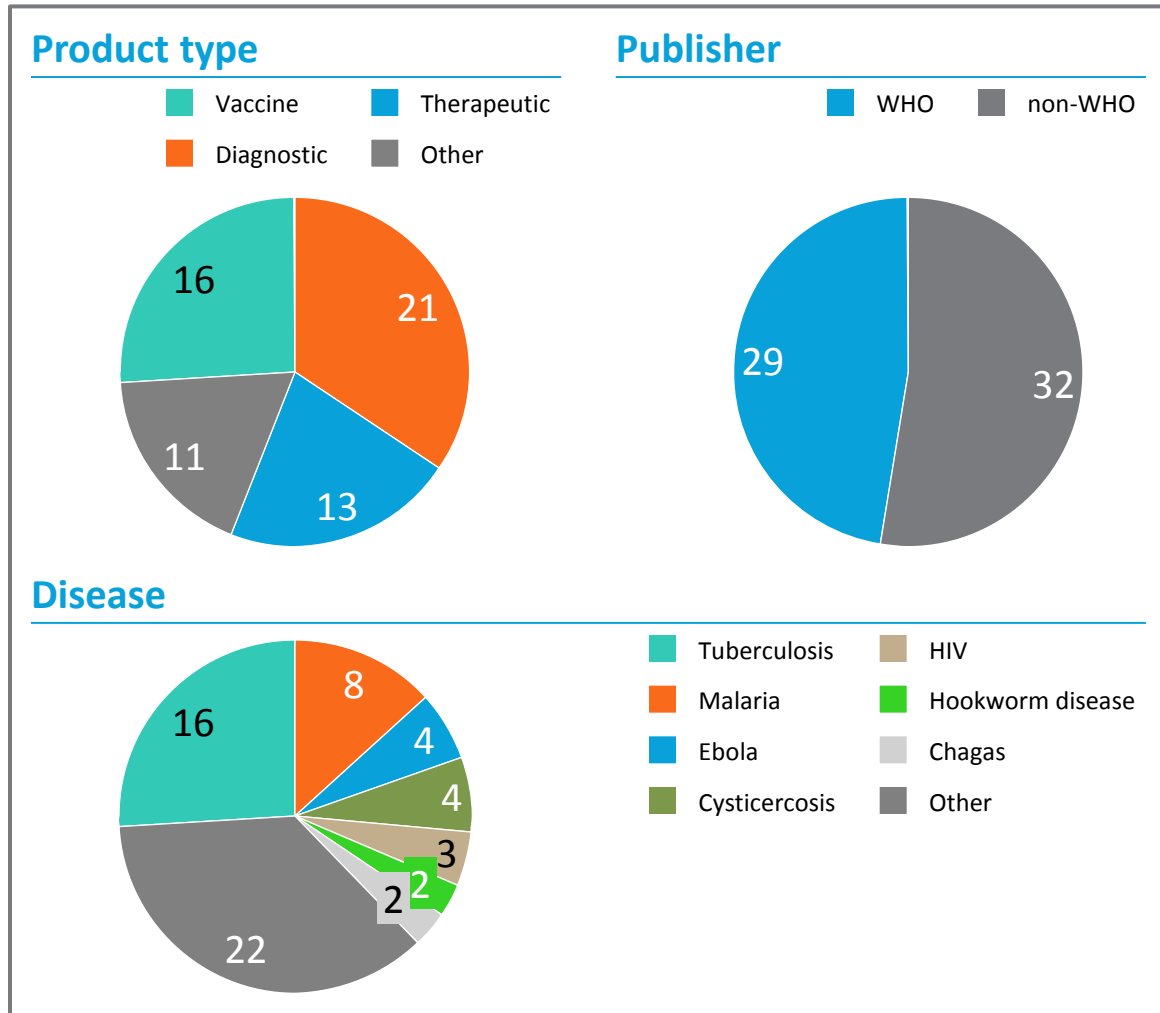
 WHO product profile available
  Product profile outside WHO
  Research priorities by WHO
  Research priorities outside WHO

Disease- Type II	Therapeutic	Vaccine	Diagnostic
Trichuriasis			
Tuberculosis (incl. multi-drug resistant TB)			
Diarrhoeal diseases			
Dengue			
Meningitis			
Hookworm disease			
HIV/AIDS			
Lower respiratory infections			
Maternal sepsis			
Rheumatic heart disease			
Upper respiratory infections			
Peptic ulcer disease			
Hepatitis B			

Note: Analysis is based only on profiles easily accessible and/or shared during initial landscape screening

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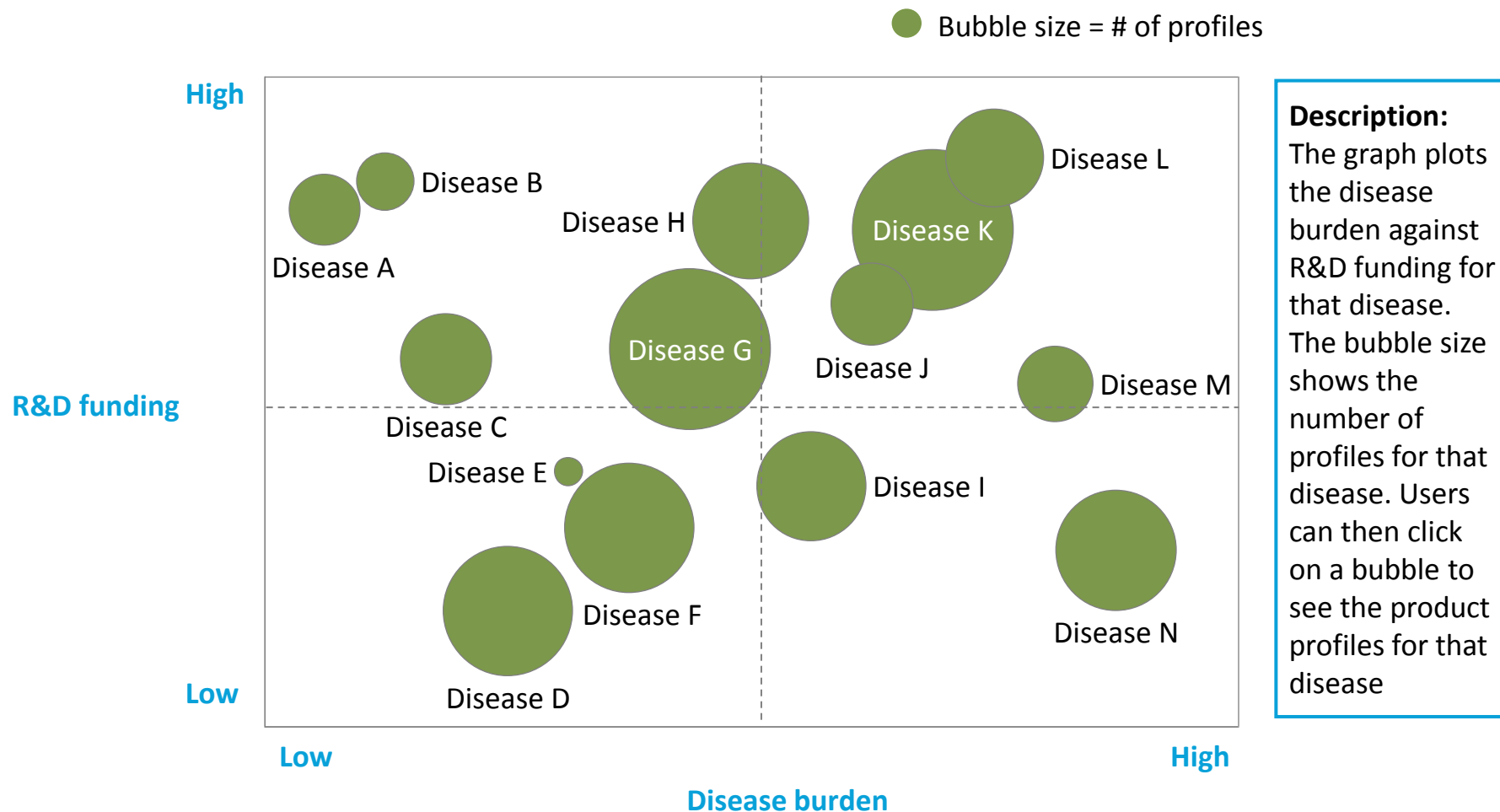
Potential Analysis with the Product Profile Directory¹



¹ There are 61 profiles represented here. There are an additional 80 documents with more high-level guidance not included in the statistics above

Potential Analysis

Visualising funding, disease burden and profiles



ILLUSTRATIVE

Purpose of the directory

The directory is



- A collection of links and descriptions of product profiles currently available
- A single, searchable, online database to provide simple access to current product profiles
- A tool to highlight gaps and guide future profile and product development by linking development programs to unmet public health needs

The directory is not



- An endorsement of every profile by the public health community
- A complete view of all product profiles across the whole market
- A repository of the complete profiles
- Linked to procurement policies or payment terms (UNICEF....)

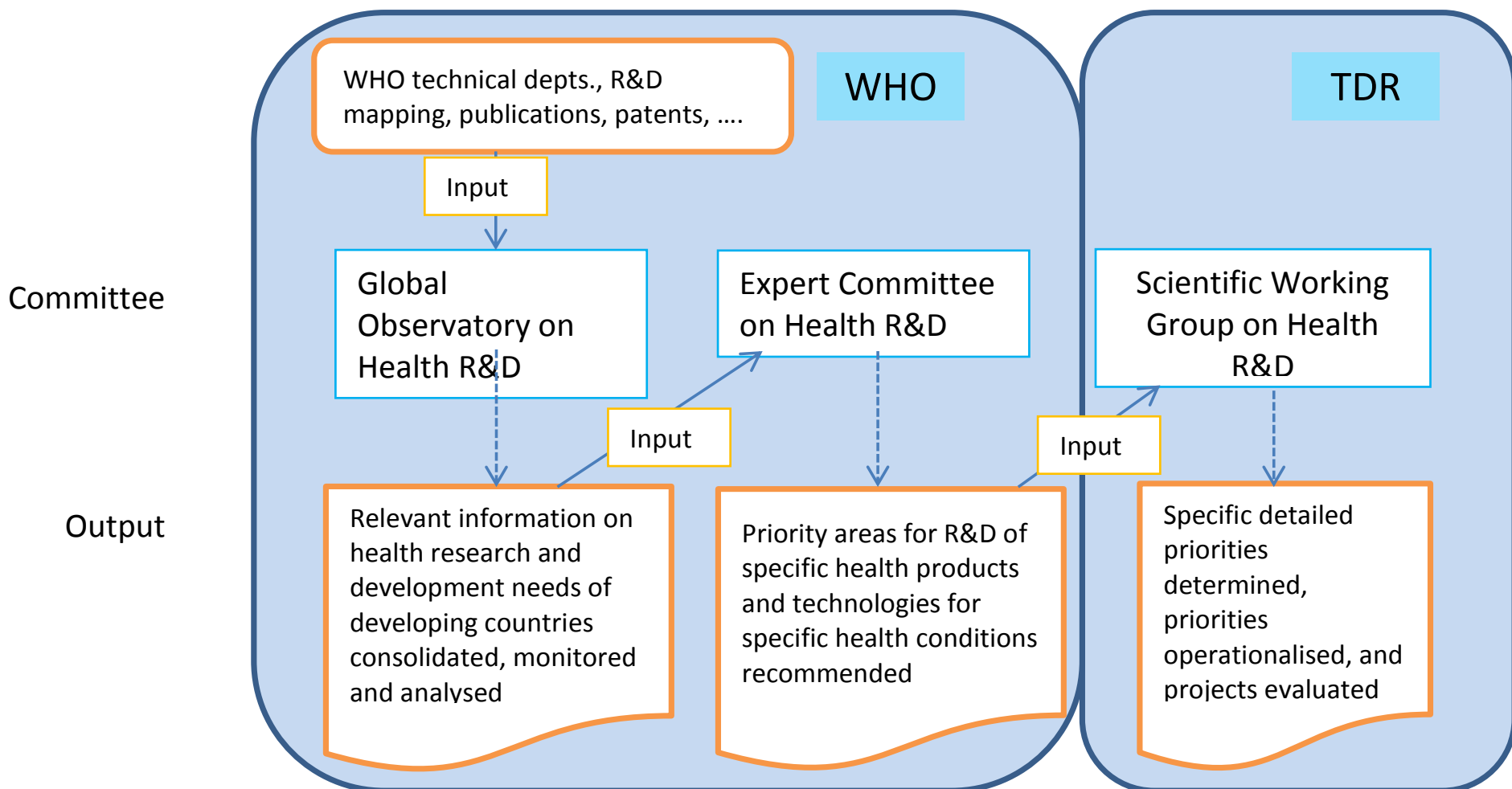
Future considerations for the Product Profile Directory

Considerations:

- 1 Critical mass of information*
- 2 A common **nomenclature** for guidance documents
- 3 The **level of detail** used for guidance at each level
- 4 The level of **standardization of processes** used in developing
- 5 product profiles
- 6 The **governance** model to keep the **data up to date**

*Inputs: WHO, UNICEF, UNDP, Global Fund, BMGFDPs, industry (+/-)
Expand to medical devices, equipment, treatment regimens.

CEWG follow up: A WHO R&D Fund – a credible and effective funding mechanism



responsibilities between WHO and TDR.

Characteristics of the proposed WHO financing mechanism

- ✓ Role for disease endemic & donor countries
- ✓ Meets the G20 commitment on neglected diseases
- ✓ Links global targets / priorities with a mechanism to take action
- ✓ Focus for global R&D means steps towards better coordination
- ✓ Many potential donors but *ONE* funding process (improves efficiency)
- ✓ Pooled fund mean shared risk and shared success
- ✓ Use of existing mechanism plus build on TDR experience and networks
- ✓ Proposed financial mechanism applicable for product R&D for emerging infectious diseases, AMR.

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