



Clinical Trials Research with the Philippines: *Streamlining the Process*

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Focus: Quality & Risk and the Philippines



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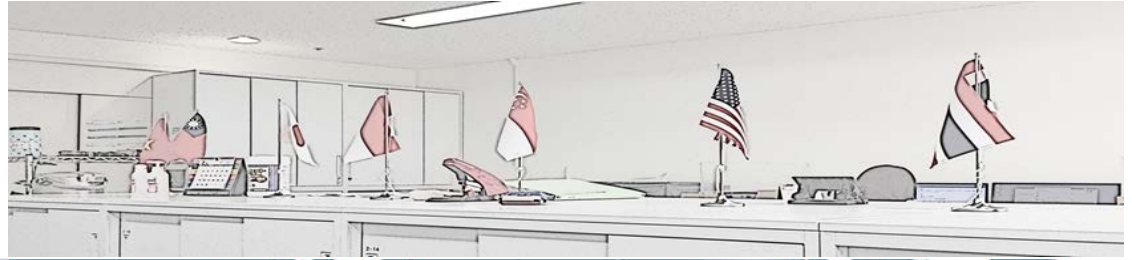


Targets



- 1. from NCGM to the Philippines
- 2. Health conditions in the Philippines
- 3. Roadmap of clinical trials to Philippine sites

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Why connect through DIT?

- GCP (E6), Ethnicity (E5), MRCT (E17)
- PMDA requirements
- WHO PQ standards
- *minimize CQ risk*
- 4 hours, 13 minutes from Tokyo
- 3 h, 48 min from Osaka
- 2 h, 20 min from Okinawa

<https://www.travelmath.com/flying-time/from/Tokyo,+Japan/to/Manila,+Philippines>
<https://www.erinmeyer.com/self-assessment-questionnaire/>

ICH=International Council on Harmonization
 GCP=Good Clinical Practice
 MRCT=Multi-Regional Clinical Trial
 PMDA=Pharmaceutical and Medical Devices Association
 WHO PQ= World Health Organization Pre-Qualifications
 CQ=cultural intelligence quotient: “CQ is the new IQ”

Targets



- 1. from NCGM to the Philippines
- **2. Health conditions in the Philippines**
- 3. Roadmap of clinical trials to Philippine sites

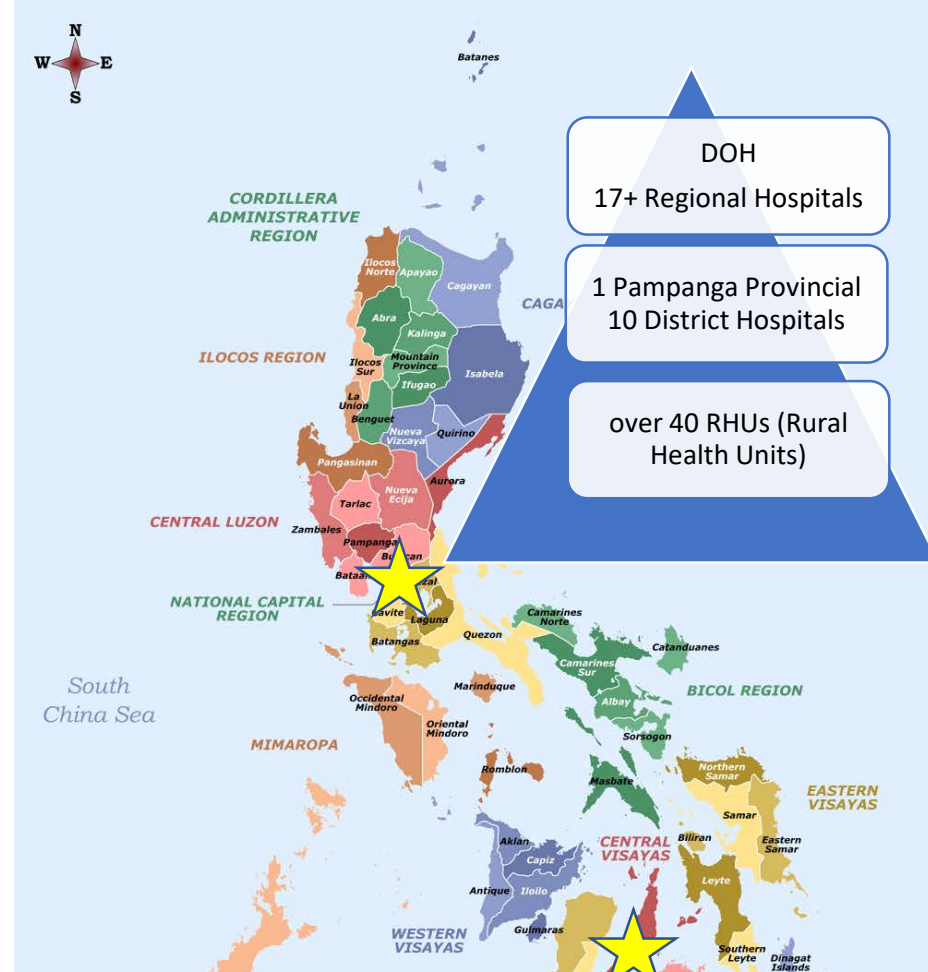
'Maharlika'

- North: Luzon (Manila)
- Central: Visayas (Cebu)
- South: Mindanao (Davao)

- Emerging economy with triple burden of diseases
 - Infectious Diseases (tropical)
 - Non-communicable
 - *Mental health*

<https://www.audleytravel.com/the-philippines/best-time-to-visit>

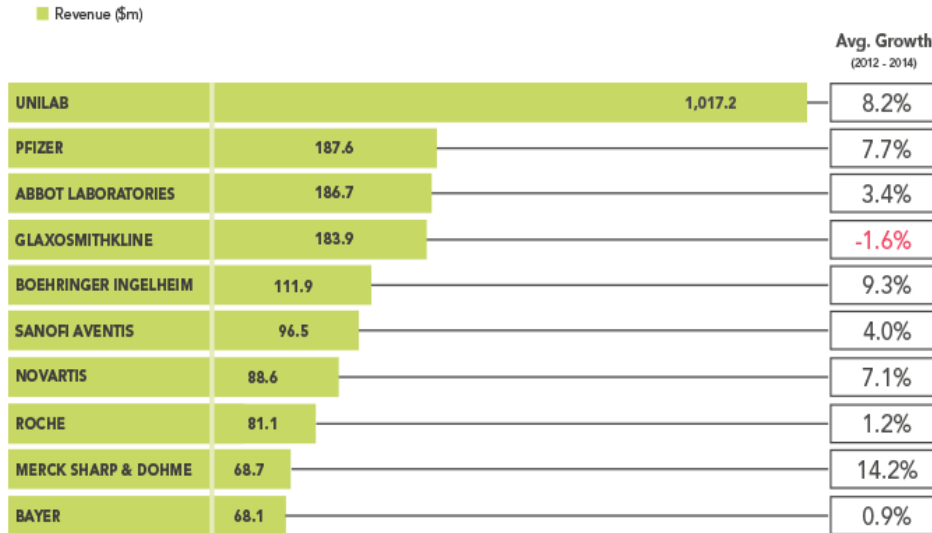
- Wet (JJASON) - mosquitoes
- Dry (DJFMAM)



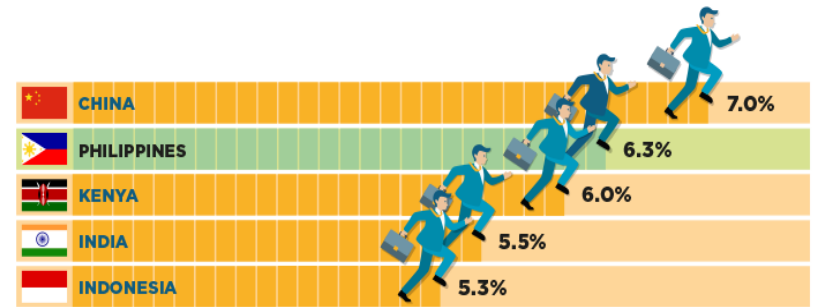
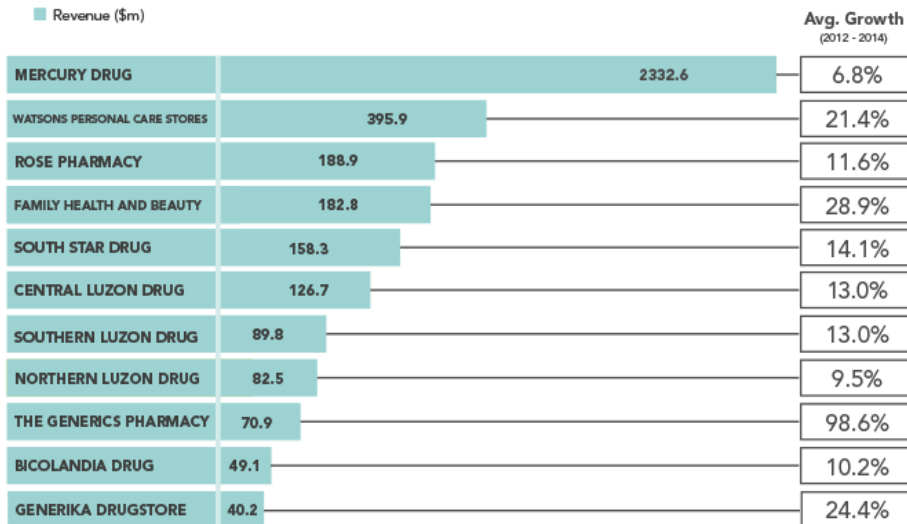
Destination	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Banaue	24°C 45mm	25°C 27mm	26°C 78mm	27°C 129mm	27°C 231mm	26°C 249mm	25°C 326mm	25°C 376mm	25°C 315mm	25°C 255mm	25°C 266mm	24°C 114mm
Bohol & Panglao Island	30°C 133mm	30°C 99mm	31°C 92mm	32°C 70mm	33°C 99mm	32°C 159mm	32°C 142mm	32°C 128mm	32°C 139mm	31°C 197mm	31°C 222mm	31°C 151mm
Boracay	29°C 152mm	30°C 74mm	31°C 51mm	32°C 67mm	33°C 264mm	32°C 334mm	31°C 614mm	31°C 506mm	31°C 440mm	31°C 448mm	30°C 387mm	29°C 253mm
Cebu	30°C 104mm	30°C 80mm	31°C 59mm	33°C 65mm	33°C 115mm	32°C 175mm	32°C 191mm	32°C 162mm	32°C 174mm	32°C 193mm	31°C 166mm	31°C 122mm
Manila	30°C 16mm	31°C 7mm	32°C 11mm	34°C 23mm	34°C 124mm	32°C 268mm	31°C 387mm	31°C 431mm	31°C 335mm	31°C 32mm	31°C 133mm	30°C 64mm
Palawan	31°C 41mm	31°C 21mm	32°C 35mm	33°C 46mm	32°C 153mm	31°C 175mm	31°C 192mm	31°C 197mm	30°C 203mm	31°C 227mm	31°C 234mm	31°C 165mm
Southern Luzon	27°C 46mm	28°C 24mm	29°C 30mm	31°C 50mm	30°C 199mm	29°C 293mm	28°C 446mm	27°C 451mm	28°C 356mm	28°C 240mm	28°C 203mm	27°C 128mm



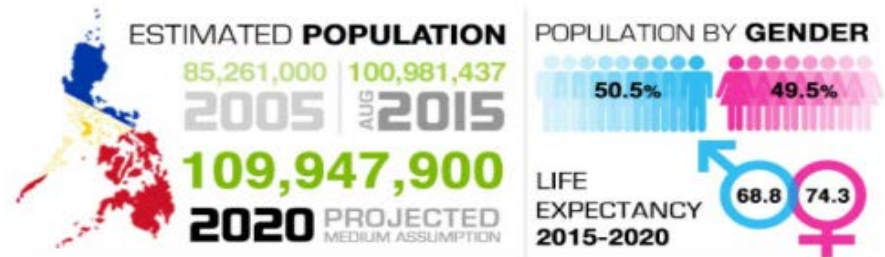
TOP PHARMACEUTICAL COMPANIES IN THE PHILIPPINES BY REVENUE, 2014



TOP DRUG RETAILERS IN THE PHILIPPINES BY REVENUE, 2014

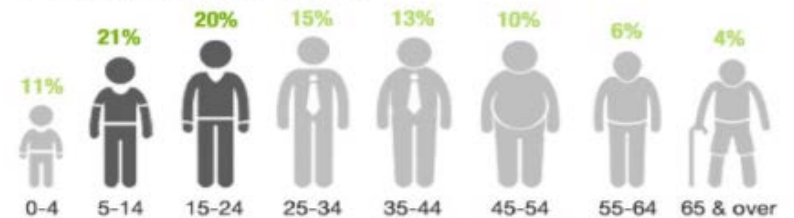


Philippine Healthcare Economics



PHILIPPINES

POPULATION BY AGE GROUP



Philippine Healthcare Economics

Philippine Healthcare Market Trend Analysis:

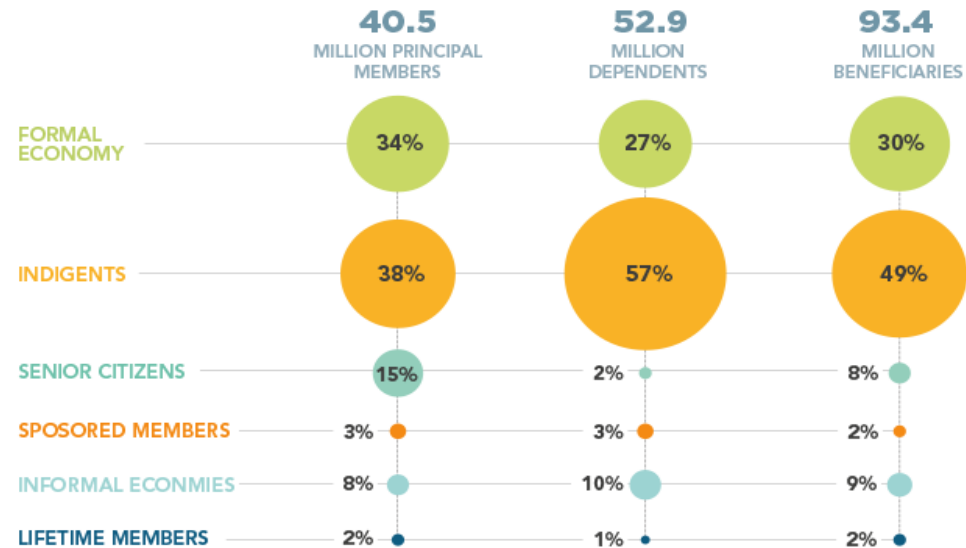
- DOH outreach to all areas through RHUs
- Tropical infections and NCDs
- In need of improved maternal and child care
- Aging and psychiatry are upcoming concerns
- Note: DOH procurement of drugs & devices relies heavily on WHO PQ
- If there is no WHO guideline, then approvals from the Specialty Societies are important

http://www.wpro.who.int/philippines/areas/communicable_diseases/continuation_communicable_diseases/en/
<https://www.cdc.gov/globalhealth/countries/Philippines/>
<https://www.doh.gov.ph/population>
<https://www.doh.gov.ph/mortality>
<https://www.doh.gov.ph/morbidity>
https://pharmaboardroom.com/country_reports/philippines-pharma-report/

Philippine health research registry



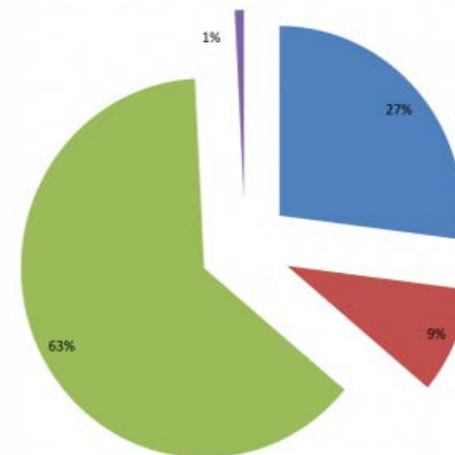
PHILIPPINES HEALTH COVERAGE AS OF DECEMBER 31, 2015



Source: PhilHealth

Philippines health expenditure broken down by source (2011)

■ Government
 ■ Social Insurance
 ■ Private sources
 ■ Rest of the World

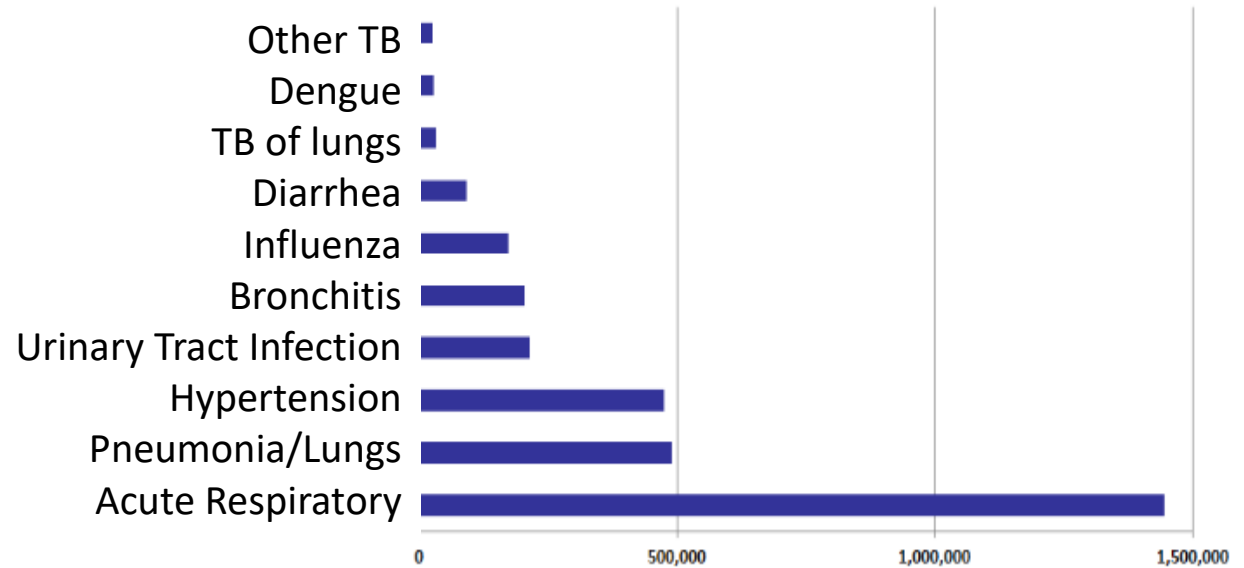


Source: National Statistical Coordination Board

Philippine Healthcare Indicators

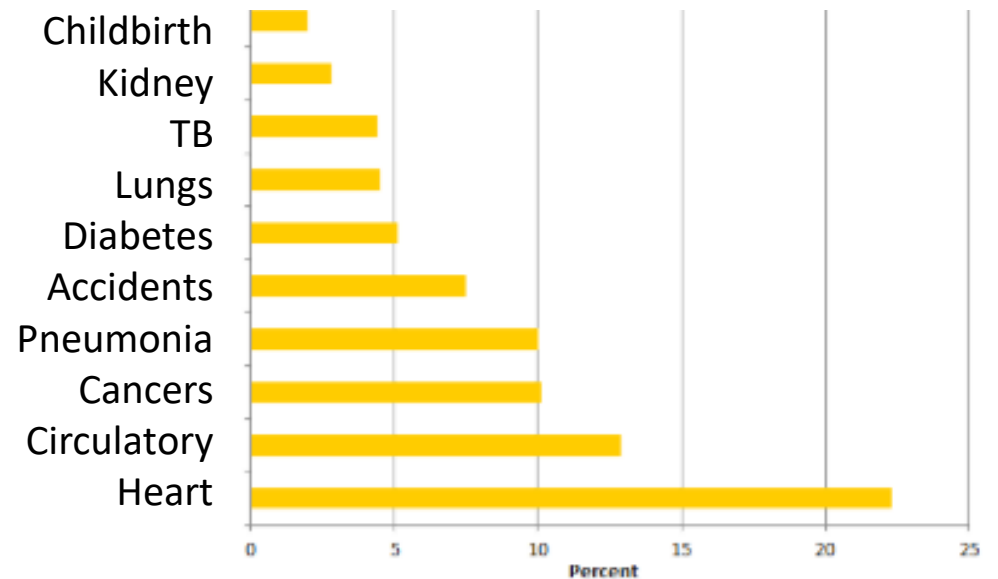
MORBIDITY: TOP 10, Philippines

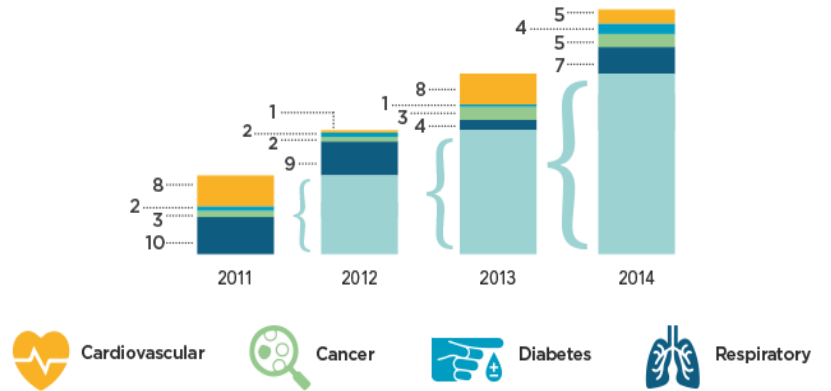
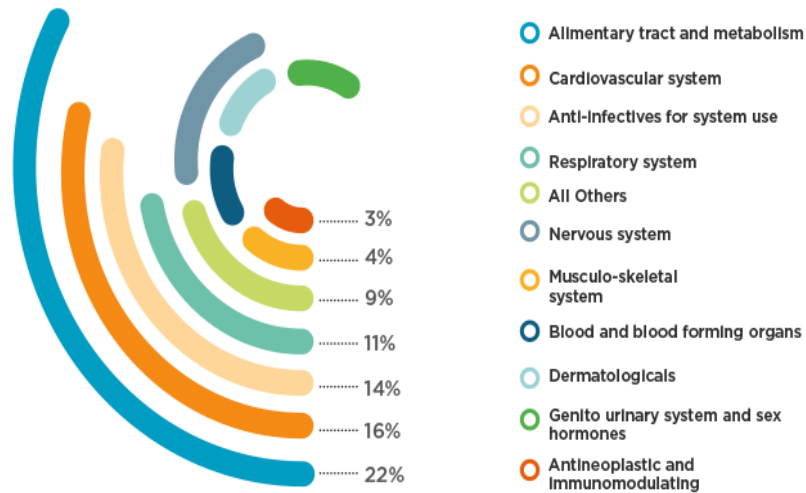
- Department of Health (2014)



MORTALITY: TOP 10, Philippines

- Department of Health (2013)



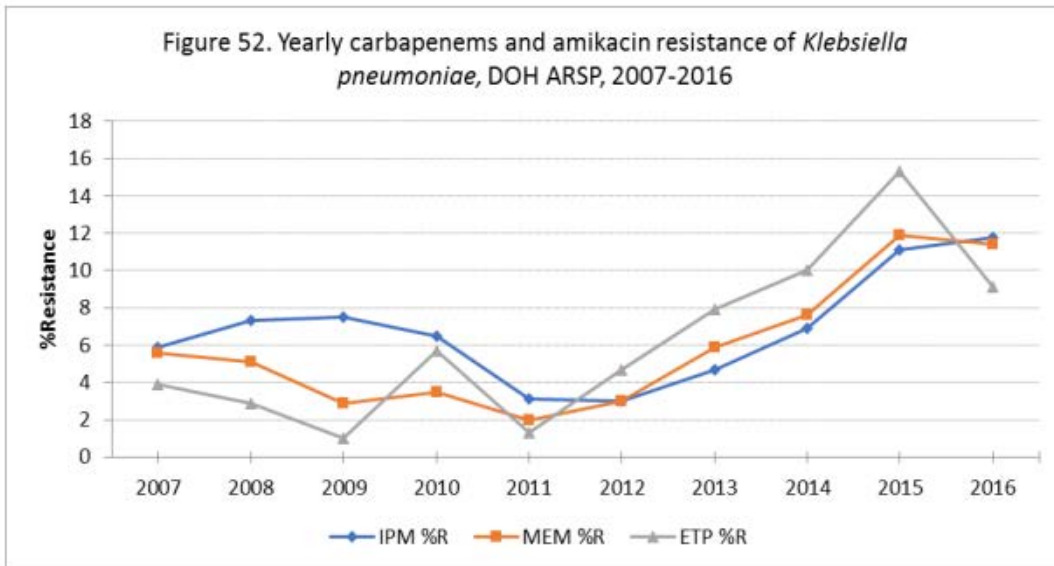
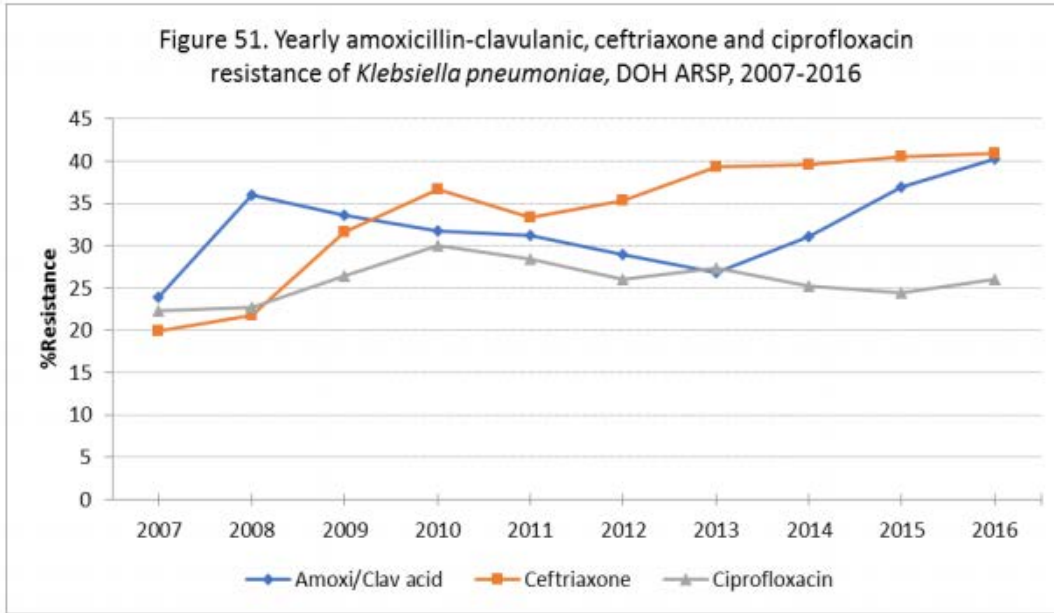


Philippine Healthcare Indicators

Philippine General Healthcare Market Gap:

- High morbidity due to infections, therefore need improved screening, diagnosis, and prevention
- Cardiovascular reach does not match mortality rank

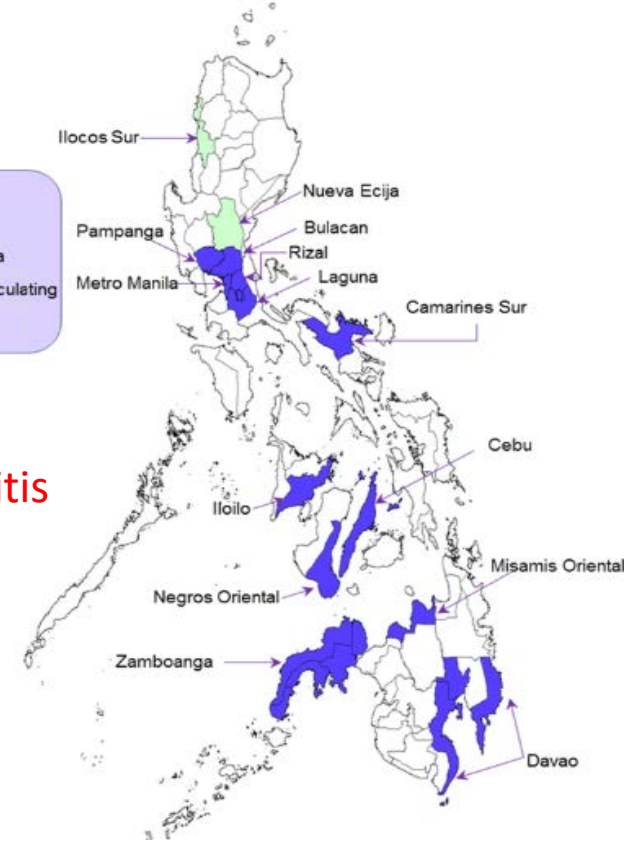
http://www.wpro.who.int/philippines/areas/communicable_diseases/continuation_communicable_diseases/en/
<https://www.cdc.gov/globalhealth/countries/Philippines/>
<https://www.doh.gov.ph/population>
<https://www.doh.gov.ph/mortality>
<https://www.doh.gov.ph/morbidity>
https://pharmaboardroom.com/country_reports/philippines-pharma-report/
 Philippine health research registry



LEGEND:

- JE infection in animals (swine and monkeys) & mosquitoes
- No animal, no mosquito data
- JEV infected mosquitoes circulating
- JEV seropositive animals

Japanese Encephalitis



Philippine ID

http://www.wpro.who.int/philippines/areas/communicable_diseases/continuation_communicable_diseases/en/

<https://www.cdc.gov/globalhealth/countries/Philippines/>

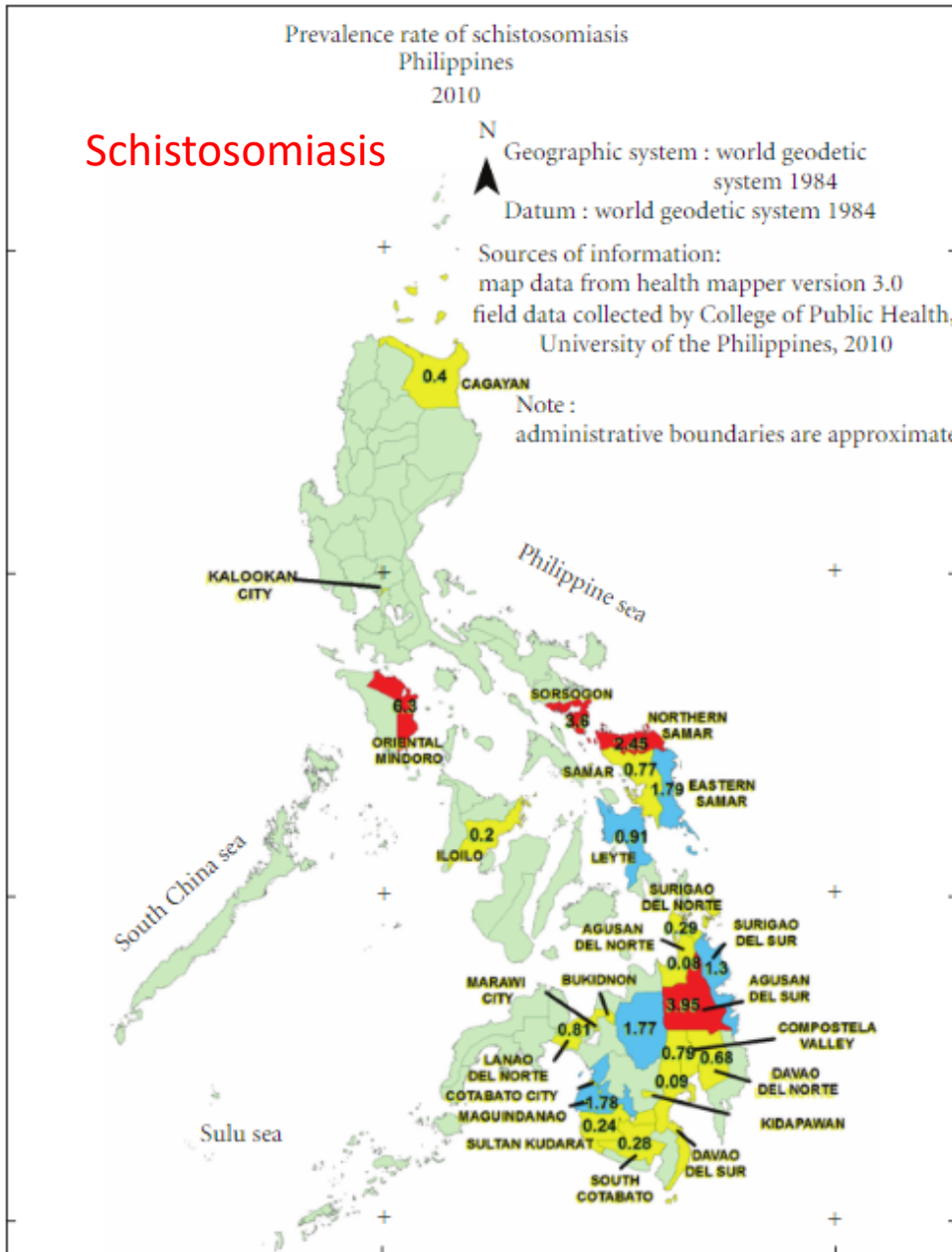
Research Institute of Tropical Medicine (2016). *Antimicrobial Resistance Surveillance Program Data Summary Report*. Available at: http://arsp.com.ph/wp-content/uploads/2017/06/2016_annual_report_summary.pdf

Schistosomiasis

Prevalence rate of schistosomiasis
Philippines
2010

Geographic system : world geodetic system 1984
Datum : world geodetic system 1984
Sources of information:
map data from health mapper version 3.0
field data collected by College of Public Health,
University of the Philippines, 2010

Note :
administrative boundaries are approximate.



Legend

Rabies Free zone



Rabies

MDR-TB/HIV

Philippine ID

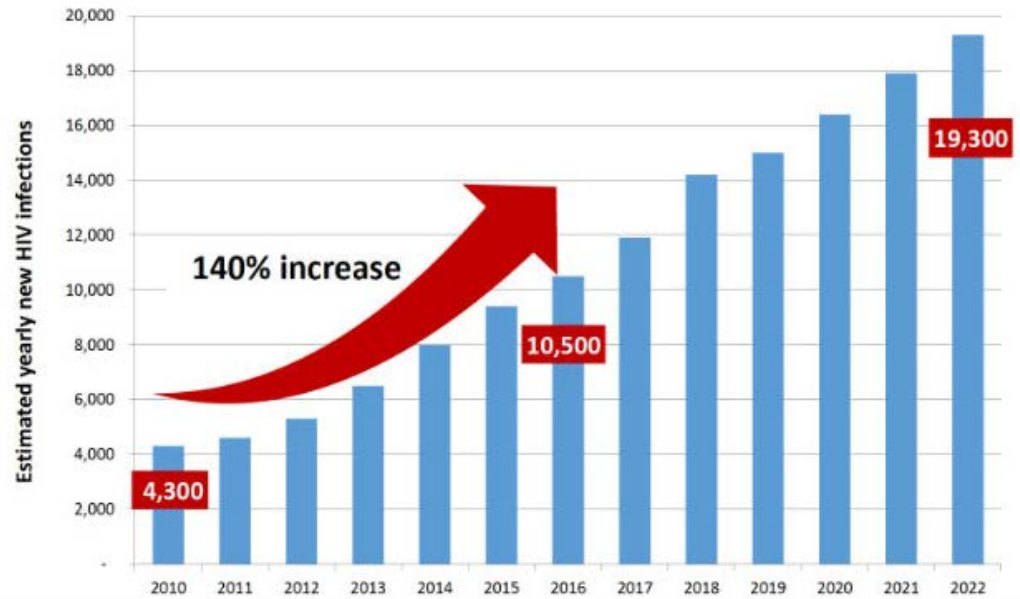


MOQA-VS	2013			2014	
	Oct	Nov	Dec	Jan-Mar	Total
Measles admissions	121	481	1099	3908	5,509
desired sample size*	26	105	240	831	1,202
actual IgM-tested†	46	152	415	922	1,535
Negative	14	18	19	37	
Positive	32	134	396	885	
% accuracy	69.6	88.2	95.4	96.0	
Pre-QA1 %	69.6				
Post-QA1 %	88.2				
improvement	(+18.59%)				
P	<0.0001				
significance	extremely				
Pre-QA2 %	88.2				
Post-QA2 %	95.4				
improvement	(+7.2%)				
P	<0.001				
significance	Very				

- 2015 ← MERS CoV, Ebola Reston
- 2014 ← Measles, MERS CoV, Henipah
- 2013 ← Pertussis, Measles
- 2012 ← Leptospirosis
- 2011 ← Chikungunya
- 2010 ← Dengue
- 2010 ← Pandemic A H1N1
- 2009 ← Ebola Reston in pigs and humans/ Leptospirosis/ Salmonella typhi
- 2007 ← Resistant *Shigella flexneri* 2a in Cavite, Bohol and Cotabato
- 2004 ← Meningococemia outbreak in CAR
- 2003 ← SARS Outbreak
- 2002 ← West Nile Virus Pseudo outbreak (RITM as Referral Laboratory)
- 2001 ← Bioterrorism threat using *Bacillus anthracis* as biological weapon
- 1998 ← Serological Surveillance ABLV
- 1996 ← Ebola Reston in monkeys (US)
- 1992 ← Ebola Reston in monkeys (Sienna, Italy)
- 1989 ← Ebola Reston in monkeys (Resto)

Emerging/Re-emerging

140% increase in yearly new HIV infections from 2010 to 2016



Source: Philippine Spectrum Projections, May 2017

- The Philippines remains highly endemic to many seasonal, epidemic-prone, as well as neglected tropical diseases
- AMR: Gonorrhoea, Klebsiella, E. coli, and more

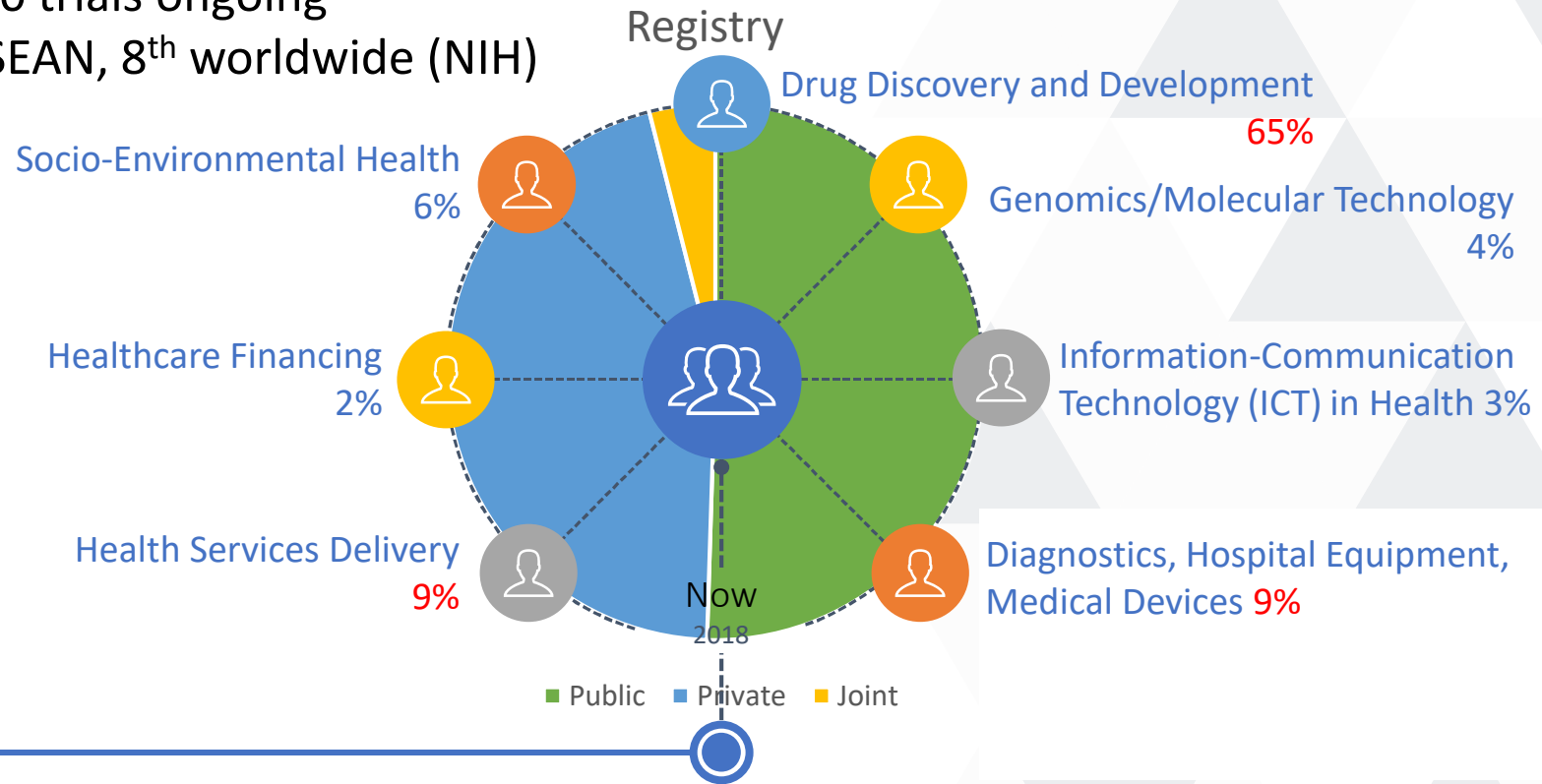
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Current Clinical Trials in the Philippines

51 new trials registered last year
 Over 500 trials ongoing
 3rd in ASEAN, 8th worldwide (NIH)



PCHRD=Philippine Council for Health Research Development

Philippine Health Research Registry (2017).

http://registry.healthresearch.ph/index.php?option=com_healthregistry&controller=registry&task=result_list

<http://blog.credev.com/2018/04/30/philippines-clinical-trial-regulatory-process/>

Php 194-M govt-funded (PCHRD) [Y 398-M]
 Php 3-B private (CROs, Pharma) [Y 6.1-B]
 Php 3.2-T joint [Y 6.5-T]



Registered Clinical Trials

Public	#	Private	#
General	160	St Luke's	155
PCHRD	130	Parexel	059
UP Diliman	067	IQVIA	057
UP Manila	063	Novartis	050
NIH	062	Merck	040
Trop Med	057	AZ/PPD/Pfizer	030 each
Veterans	047	Takeda	009
Lung	046	SDP/Otsuka	003 each
Heart	042	Shionogi	002



PCHRD=Philippine Council for Health Research Development
 NIH=National Institutes of Health

Philippine Health Research Registry (2017).

http://registry.healthresearch.ph/index.php?option=com_healthregistry&controller=registry&task=result_list

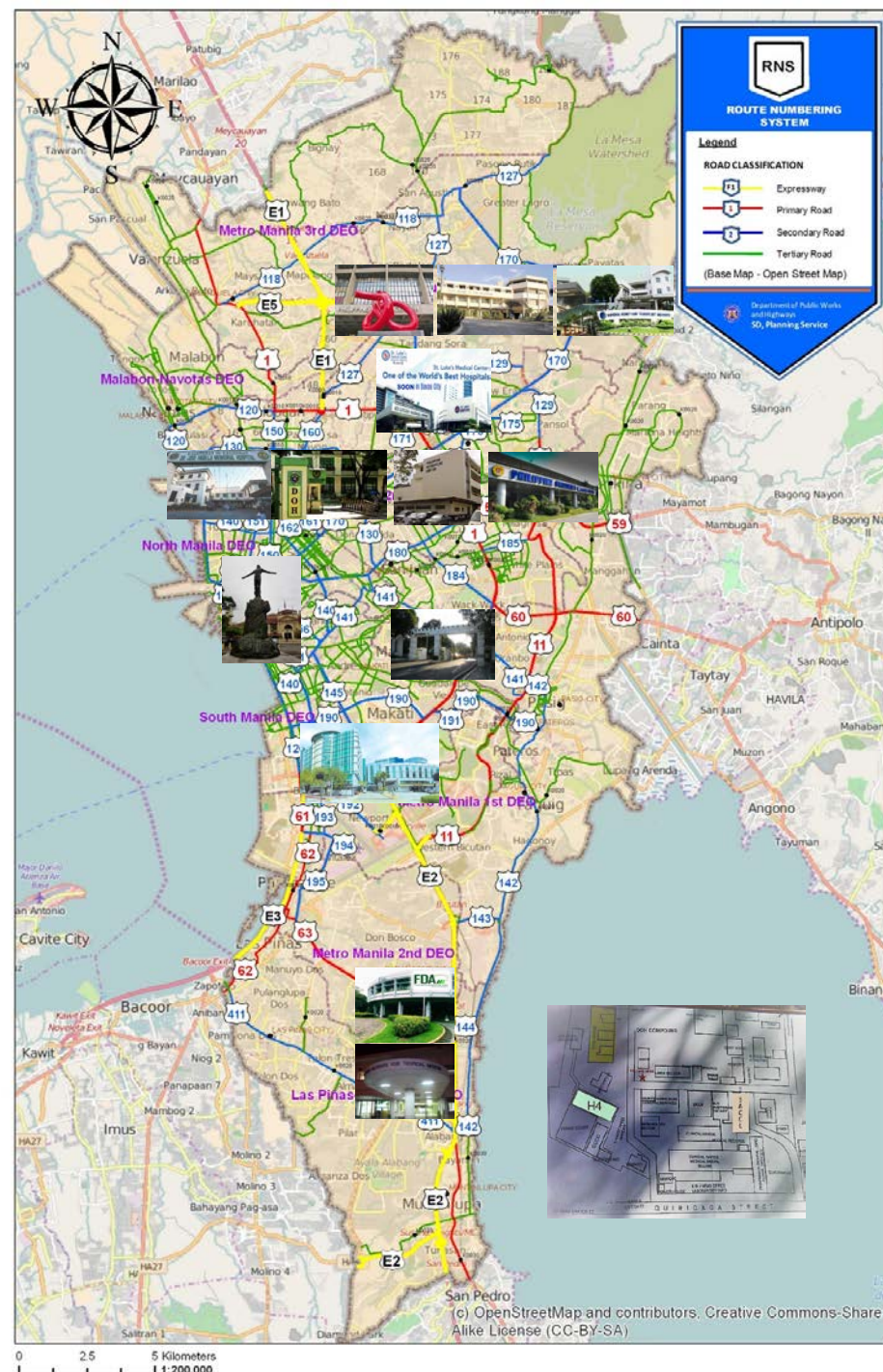


Roadmap 1. *Drug*

- Courtesy call at Department of Health (DOH)
- Submission of dossier at **CDRR with local partner** (FDA Center for Drug Regulation & Research)
- Site selection + local PI and IRB
 - Phase I
 - Phase II-III
 - vaccines
- Online registration
- Research grants



IRB=Institutional Review Board (Ethics)



Roadmap 2. *Device*

- Courtesy call at Department of Health (DOH)
- Submission of dossier at **CDRRHR with local partner** (FDA Center for Device Regulation, Radiation Health, and Research)
- Site selection + local PI and IRB
 - Phase I
 - Phase II-III



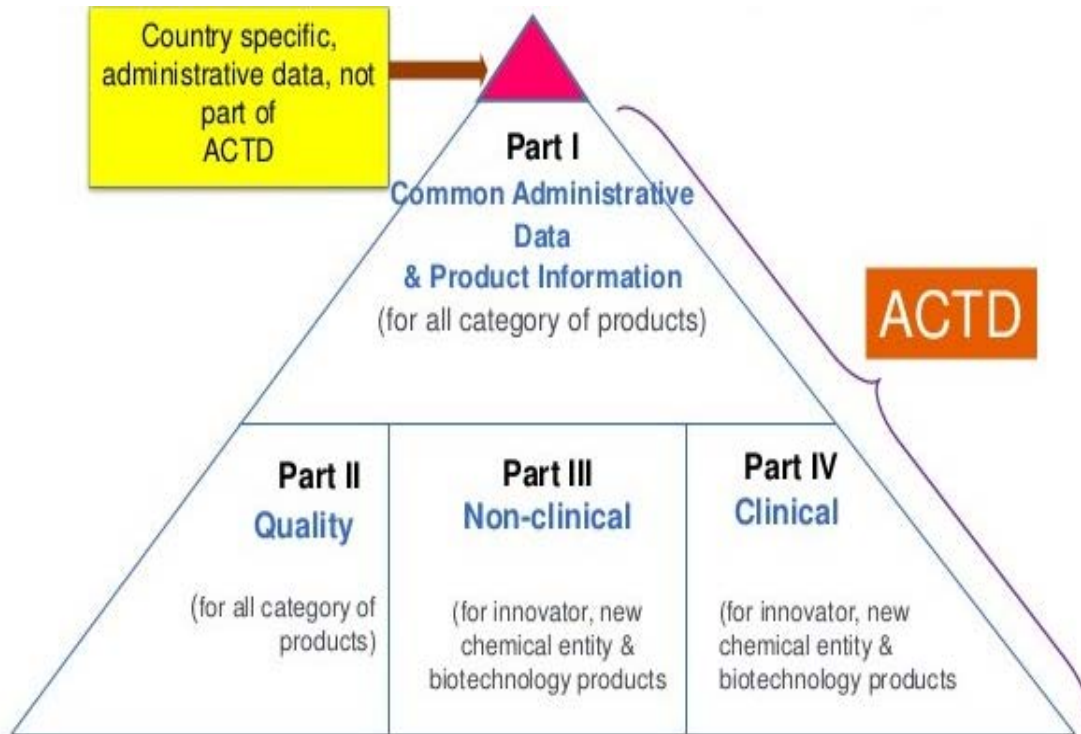
- Online registration
- Research grants



IRB=Institutional Review Board (Ethics)



ACTD Harmonization



ASEAN Healthcare Market		
<i>(in USD)</i>		
Country	Pharma	Devices
Japan	\$104-B	\$29-B
China	\$65-B	\$13-B
India	\$20-B	\$4.2-B
Korea	\$15-B	\$5-B
Indonesia	\$5.9-B	
Thailand	\$4.8-B	
Philippines	\$3.4-B	
Vietnam	\$3.2-B	
Malaysia	\$3.1-B	
Singapore	\$840-M	
ASEAN	>\$21-B	>\$5-B

ACTD=ASEAN Common Technical
 ASEAN=Association of South East
 GCP=Good Clinical Practice
 IB=Investigator's Brochure
 CPR=Certificate of Product I
 PCIU=Permit for Clinical Inv
 IRB=Institutional Review Board (E
 LTO=License to Operate
 Contracts: MOU=Memorandum o
 MOA=Memorandum o
 MTA=Material Transp

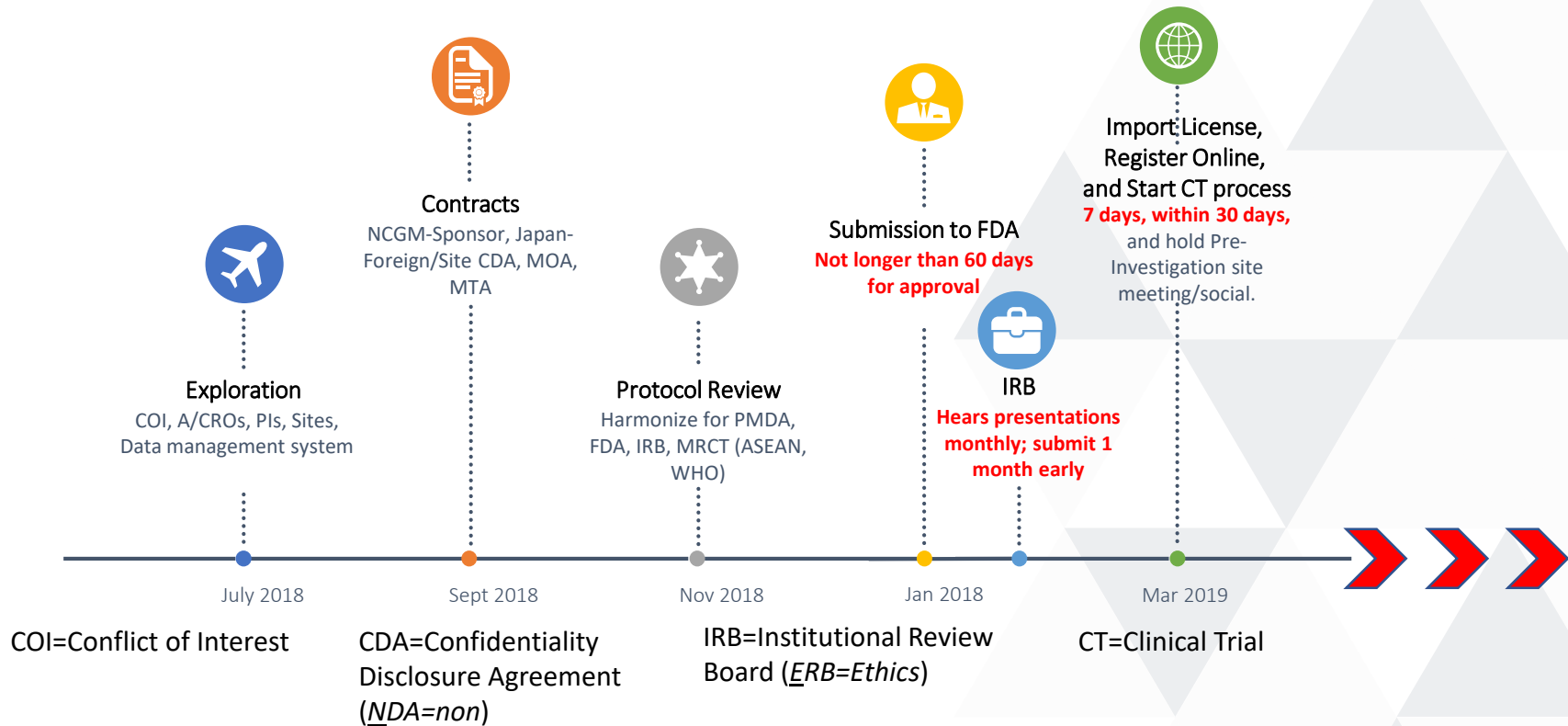


- ASEAN market
- ASEAN Common Technical Dossier (template) and IB
- Country-specific:
 - Application:
 - LTO GCP Risk Sites IRB Pilipino (Informed Consent)
 - IB: CPR PCIU Import Permit
 - (MOU) MOA MTA
 - Fees: FDA Php 2500, IRB Php 15-60k or %

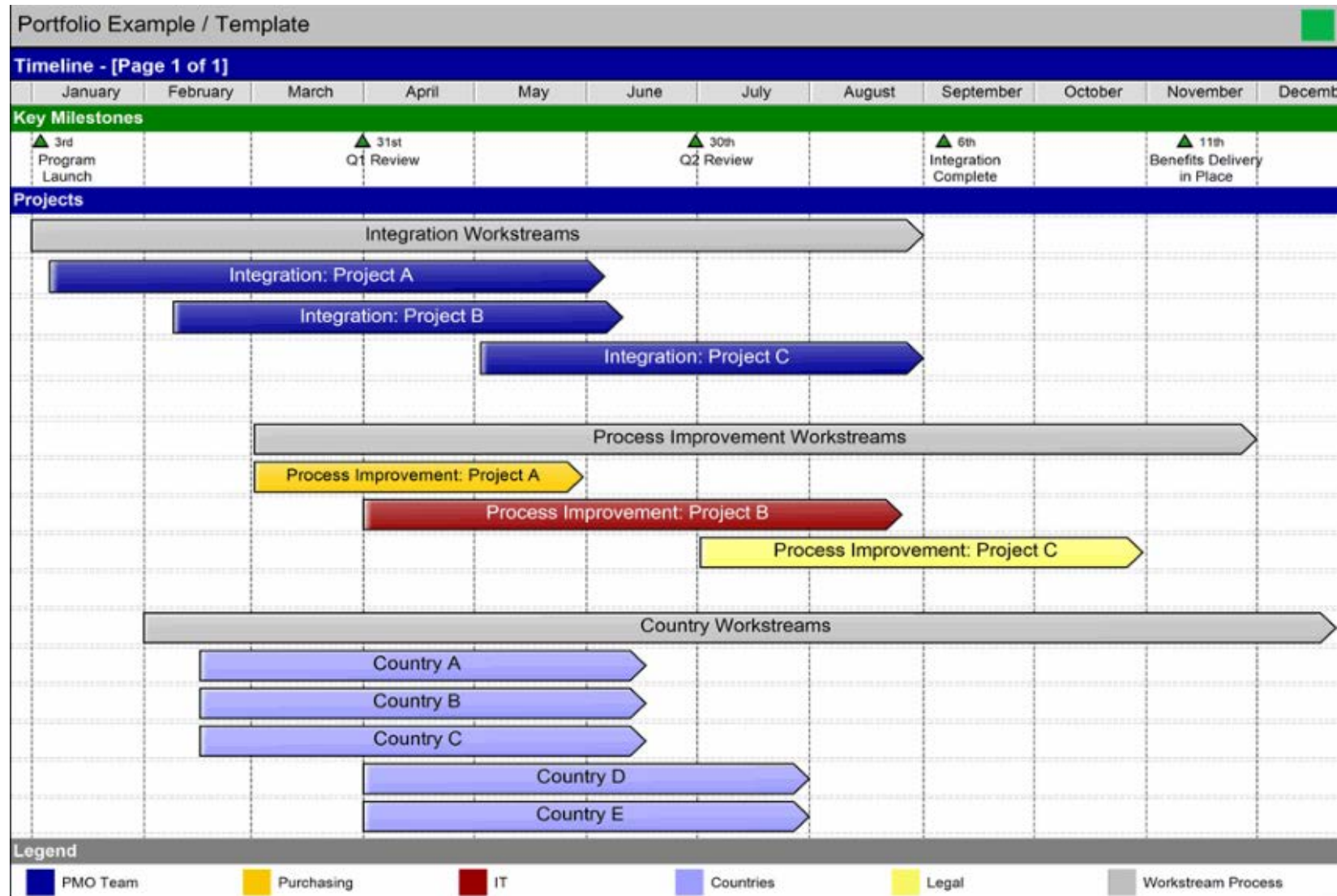
- Regional funding network: e-Asia

Pacific Bridge Medical (2014).

Standard Timeline *toward* Clinical Trials (FDA-Philippines)



Overall target: MRCT Project Portfolio Gantt



Arigatō gozaimasu!
ありがとうございます！



Maraming salamat po