INTRODUCING A NOVEL CONCEPT TO OBSERVATIONAL RESEARCH IN THE ASIA-PACIFIC REGION: ENRICHED REAL-WORLD DATA (RWD) STUDIES

Workshop

ISPOR 7th Asia-Pacific, Singapore

6th September 2016

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INTELLIGENCE APPLIED.

Discussion Leaders

Laura Garcia Alvarez
Engagement Manager, Real-World Evidence Solutions at IMS Health

Ong Leong Seng
Chief Architect & Group Director, Integrated Health Information System, Ministry of Health Holdings

Joanne Yoong Su-Yin
Associate Professor, National University of Singapore (NUS)

Josh Hiller
Senior Principal, Real-World Evidence Solutions at IMS Health

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Today’s discussion

16:00	Welcome and introductions	Laura Garcia Alvarez
16:05	How electronic medical record (EMR) systems can be implemented?	Ong Leong Seng
16:20	What research can we do using EMR?	Joanne Yoong Su-Yin
16:35	What´s next? Enriched RWD Studies	Josh Hiller
16:50	Moderated Q&A	Laura Garcia Alvarez

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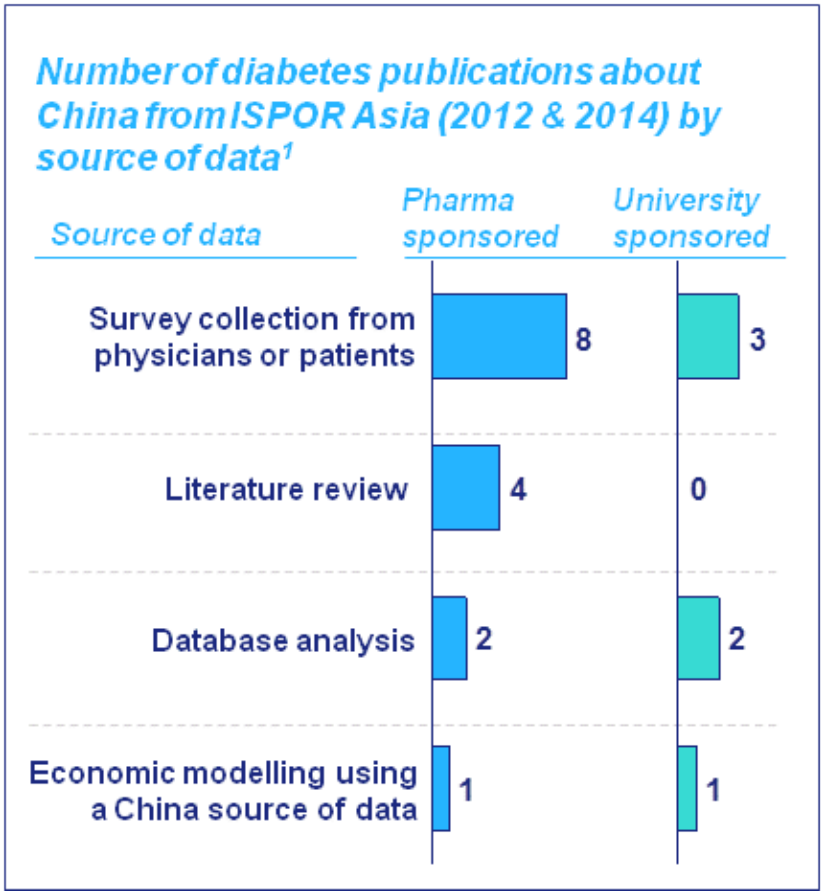
Although the RWE landscape in the Asia-Pac region is currently immature, it has the potential for future evidence generation



Historically, there is heavy reliance in data collected through surveys in observational research.

Current landscape is evolving towards structured data capture providing opportunities for use of RWD in observational studies.

In this workshop, we will cover the following topics:

- EMR infrastructure implementation
- Usage of RWD data in research

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How electronic medical record (EMR) systems can be implemented in Asia?

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EMR/EHR Implementations in Singapore Opportunities, Challenges and Lesson Learnt

Ong Leong Seng
Chief Architect & Group Director
Architecture & Innovation

IHiS
Because IT's in Healthcare

About IHiS

- **Vision:** To be the trusted technology partner in healthcare
- **Mission:** To lead and deliver technology for excellence in healthcare
- **Goals:**
  - Drive Service Excellence and Value at Healthcare Institutions
  - Integrate Care Delivery across Healthcare Continuum
  - Innovate to Transform Healthcare

Key Healthcare Statistics

increasing demands on healthcare

- **population trends**
- **capacity**
- **chronic illnesses**
- **case complexity**

2m >50 by 2020

6.9m by 2030

82yrs in 2011

public sector providers

currently serving

380,000
hospital admissions

970,000
accident + emergency

4,500,000
specialist outpatient clinics

4,650,000
polyclinics

63 percent of all deaths

diabetes
respiratory
heart disease
hypertension
stroke
cancer

Multi-disciplinary care team
clinician, social worker, therapist

Family support
caregiver training
community

Access to facilities
treatment
rehabilitation

requires:

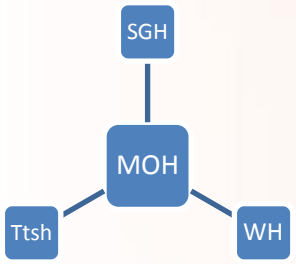
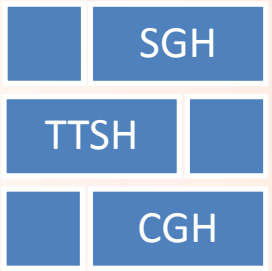
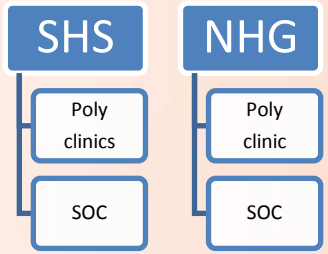
expansion

1,120 more nursing home beds by 2015

3,700 more acute & community hospital beds by 2020

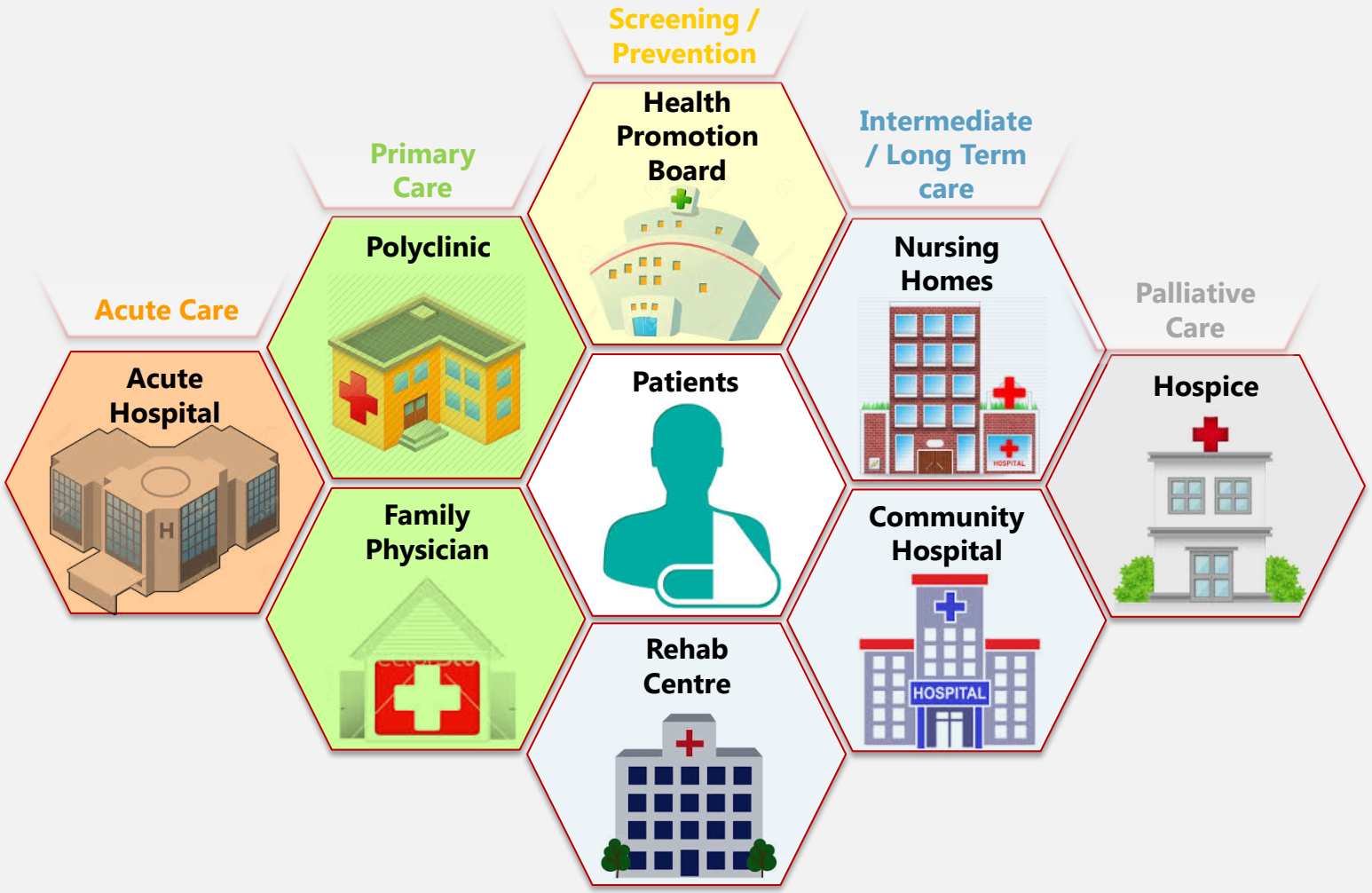
20,000 more healthcare professionals by 2020

Changing Healthcare IT Landscape

Healthcare	Treatment Outcomes	Disease Outcomes	Population Care
			
	Department Centric	Hospital Centric	Hospital SOC, Polyclinic Centric
Healthcare IT	Interfaced Department Systems	Integrated Cluster Systems	Fully Integrated National Systems

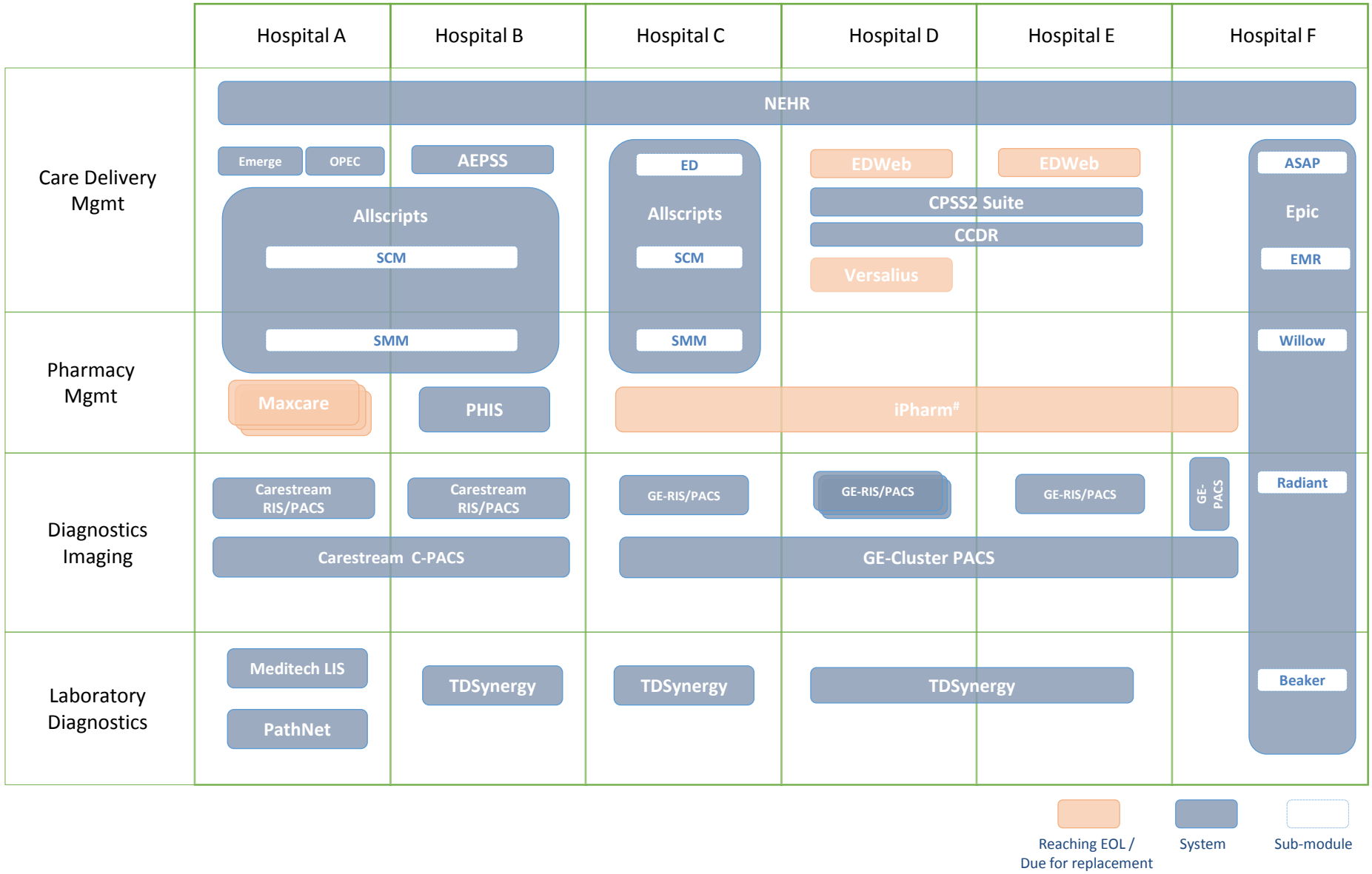
Cluster centric

Singapore Healthcare 2020 and Beyond

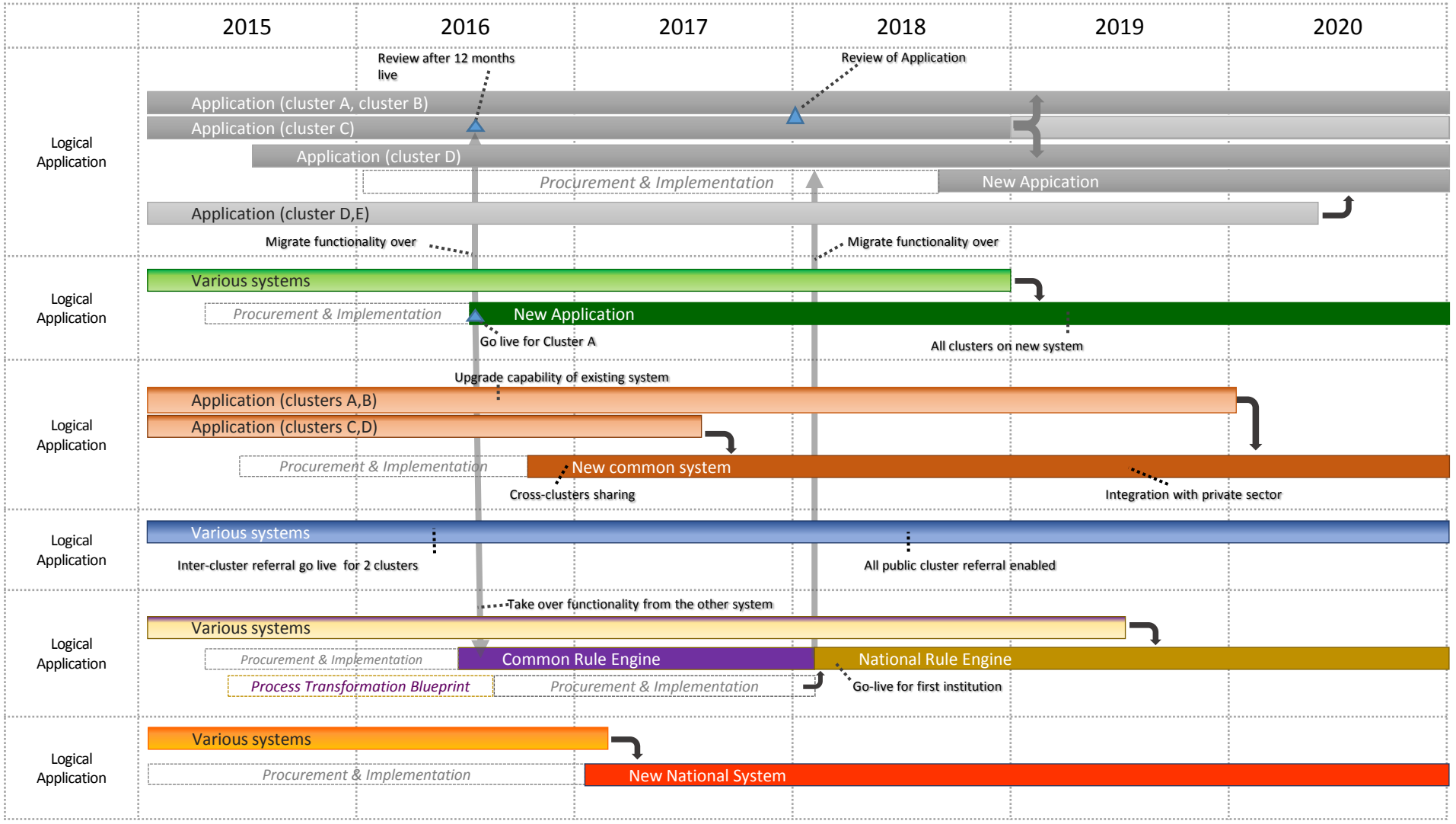


Current IT Architecture – Clinical IT Systems

Increasingly fragmented by independent procurement for new corporate entities. Some aging systems present softer targets for consolidation.



Consolidation Roadmaps with dependencies



Use of process analysis to identify fit with existing/planned IT systems

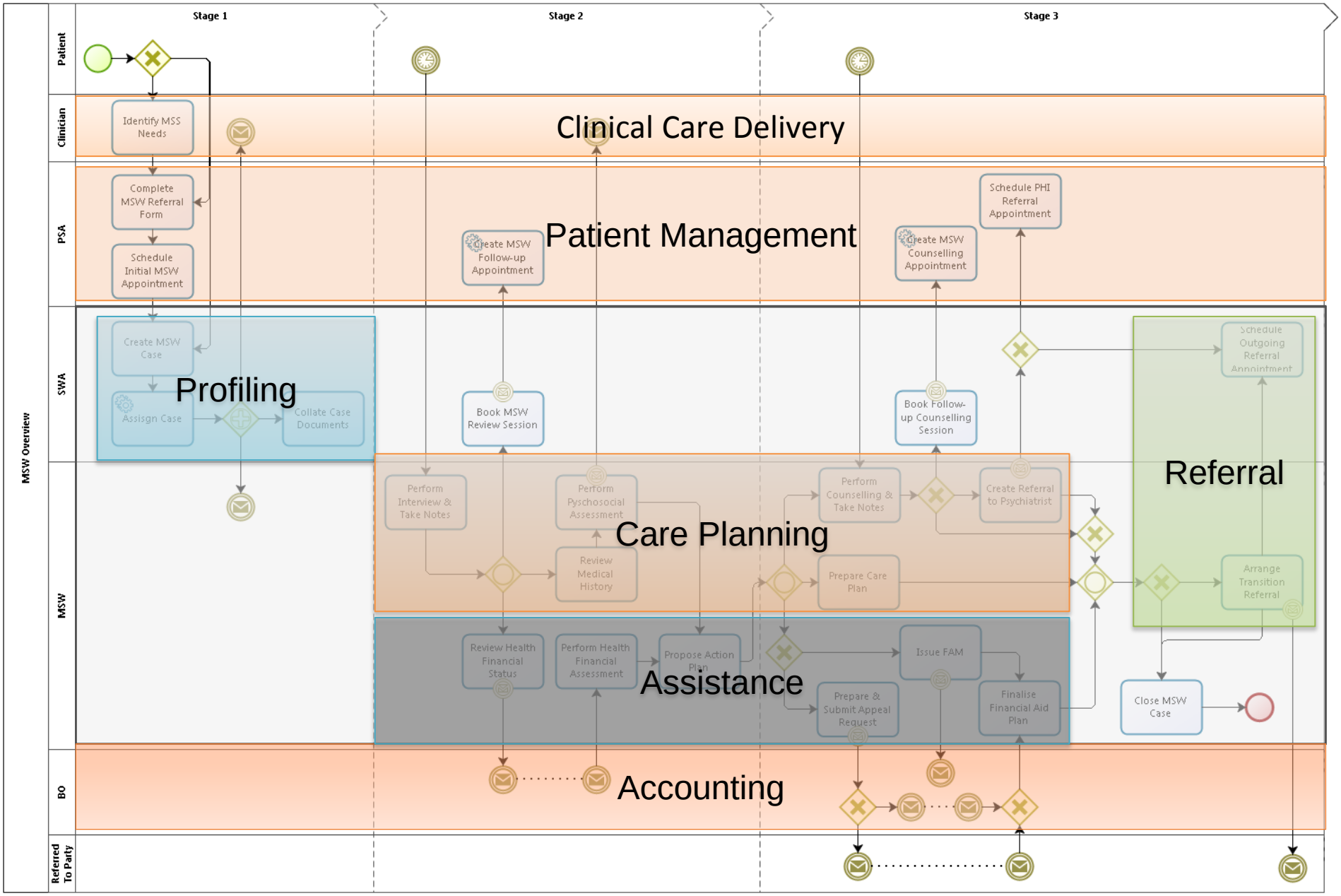
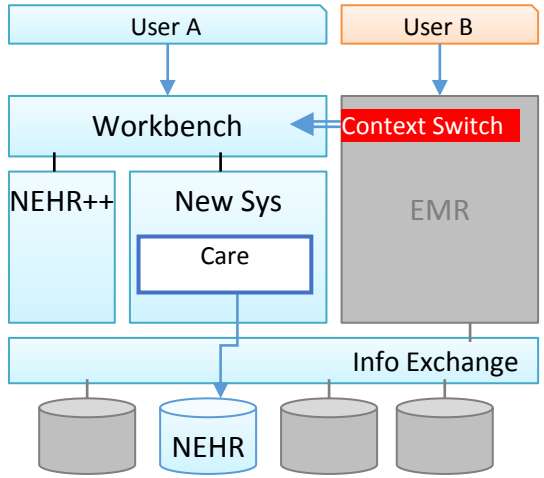
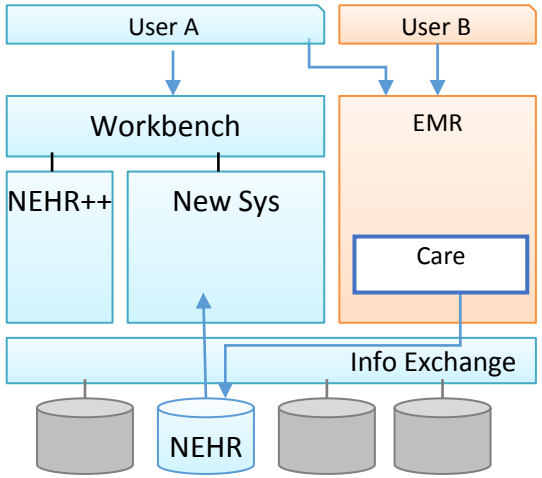
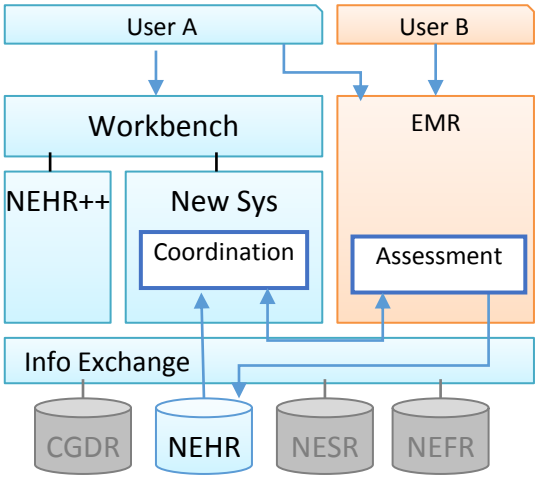


Illustration of architecture options to implement a process

Common System	Distributed/Local System	Hybrid 2-Tier Model
		
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Applying Architecture Trade-off Analysis Method (ATAM)

Attributes	Common System	Distributed/Local System	Hybrid 2-Tier Model
Level of Acceptance	UserB are unwilling to use another system other than their EMR this process	User A are generally neutral regarding whether function is done in local EMR's or on a separate central system.	User A are generally neutral regarding whether function is done in local EMR's or on a separate central system.
Agility	Bla bla bla.	Bla bla bla.	Bla bla bla.
Cost Effectiveness	Bla bla bla.	Bla bla bla.	Bla bla bla.
Data Quality	Bla bla bla.	Bla bla bla.	Bla bla bla.
Maintainability	Bla bla bla.	Bla bla bla.	Bla bla bla.
User Experience	Bla bla bla.	Bla bla bla.	Bla bla bla.
Feasibility	Bla bla bla..	Bla bla bla.	Bla bla bla.

http://www.sei.cmu.edu/architecture/tools/evaluate/atam.cfm

HIMSS EMRAM Stage 6 Hospitals Awards

IHiS Integrated Health Information Systems

Singapore General Hospital SingHealth

KK Women's and Children's Hospital SingHealth

National University Hospital

Tan Tock Seng Hospital

First in Asia
our Public Hospitals

HIMSS ANALYTICS europe

STAGE 6&7 AWARDS

HIMSS EMRAM Stage 6 Hospitals Awards

10-Sep-2014

Khoo Teck Puat Hospital And National Heart Centre Achieve Global Benchmark For Advanced IT To Improve Patient Care

Singapore, September 10, 2014 – HIMSS Analytics Asia Pacific announced today that Khoo Teck Puat Hospital (KTPH) and National Heart Centre Singapore (NHCS) have achieved HIMSS EMRAM Stage 6, an international benchmark for the use of advanced IT to improve patient care.

16-Oct-2013

CGH Achieves Global Benchmark for Advar Hospital IT To Improve Patient Care

Changi General Hospital's Medication Management System with QR Co

Singapore, October 16, 2013 – HIMSS Analytics Asia Pacific announced today that Changi G HIMSS EMRAM Stage 6, an international benchmark for the use of advanced IT to improve

Ng Teng Fong General Hospital Achieves HIMSS Analytics EMRAM Stage 6 Award

24-Aug-2016

Institute of Mental Health Achieves Global Recognition with HIMSS Analytics EMRAM Stage 6

- First Psychiatric Hospital outside of North America to be Awarded Stage 6

Photo: Institute of Mental Health

Singapore, 24 August 2016 – The Institute of Mental Health (IMH), will be awarded Stage 6 under the HIMSS Analytics EMR Adoption Model (EMRAM) later this evening at HIMSS Asia Pacific Awards Dinner at Westin Grande Sukhumvit Bangkok in Bangkok, Thailand. The collaborative efforts of IMH and Integrated Health Information Systems (IHiS) to implement several high performance systems such as the Closed Loop Medication Management (CLMM) and Clinical Documentation (C-Doc) systems enabled the institution to be the first psychiatric hospital outside of North America to achieve this global benchmark.

A/Prof Chua Hong Choon, Chief Executive Officer, IMH said, ""We are honoured to be the first psychiatric hospital outside of North America to receive this recognition. Attaining HIMSS stage 6 has significantly contributed to improving work processes and systems in the hospital which translates to better patient care and improved safety. Leveraging advances in technology has helped us to better allocate precious manpower resources, enjoy cost savings as well as boost the confidence of our staff as they are better equipped to deliver effective and reliable mental healthcare services to our patients."

Critical Success Factors

- Strong leadership and governance
  - Require from all aspects: Clinical, Business, Operations
  - Important for adoption and change management
  - Need to set strategic goals, objectives and direction
  - Need to be actively involved, not just saying it
  - Be prepared to make hard decisions, if necessary
  - EMR implementation is never an IT project

- Objectives of implementing the EMR
  - Need to define upfront with SMART KPIs
  - Use as guidance for decision making, prioritization

Challenges & Lessons Learnt

- Scope of implementation
  - Is it really just the EMR or it extends to the ancillary and supporting systems/capabilities, e.g. Patient Management, Patient Accounting, Pharmacy, ID Admin
  - Do not forget to ensure these areas are able to handle the new capabilities: network, access control, downtime, production support, users roles and workload

- Data governance
  - Is the institution data policy updated to support EMR roll out?
  - Important to ensure every data field has a unique and global definition, e.g. unique lab test code for each test, unique drug code for each drug

- One size does not fit all
  - Harmonize and standardize global definitions, master data, DB schema
  - Allow and plan for localization, e.g. process, workflow, template

Challenges & Lessons Learnt

- Patient safety must be 1st priority
  - Is this function compromising patient safety, e.g. copy and paste
  - How do we ensure sufficient test coverage?

- Do not photocopy the AS-IS UI, processes, workflow, templates
  - Especially true if it is from manual and paper to electronic
  - BPR is required to streamline and optimize how it should work in electronic, which may require right siting of work among roles (e.g. Orders now placed by doctors instead of nurses prior to CCOE roll out), re-define/new user roles access rights (e.g. VVIP access)
  - Every function and report request must have justifications and create value

- Data migration and roll out strategy
  - Do we really need to migrate all past data into the EMR?
  - Should we do a big bang roll out or roll out by specialties, in-patient then out-patient, by user roles, etc?


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What research can we do using EMR?

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USC Dornsife
Dana and David Dornsife College of Letters, Arts and Sciences
Center for Economic and Social Research

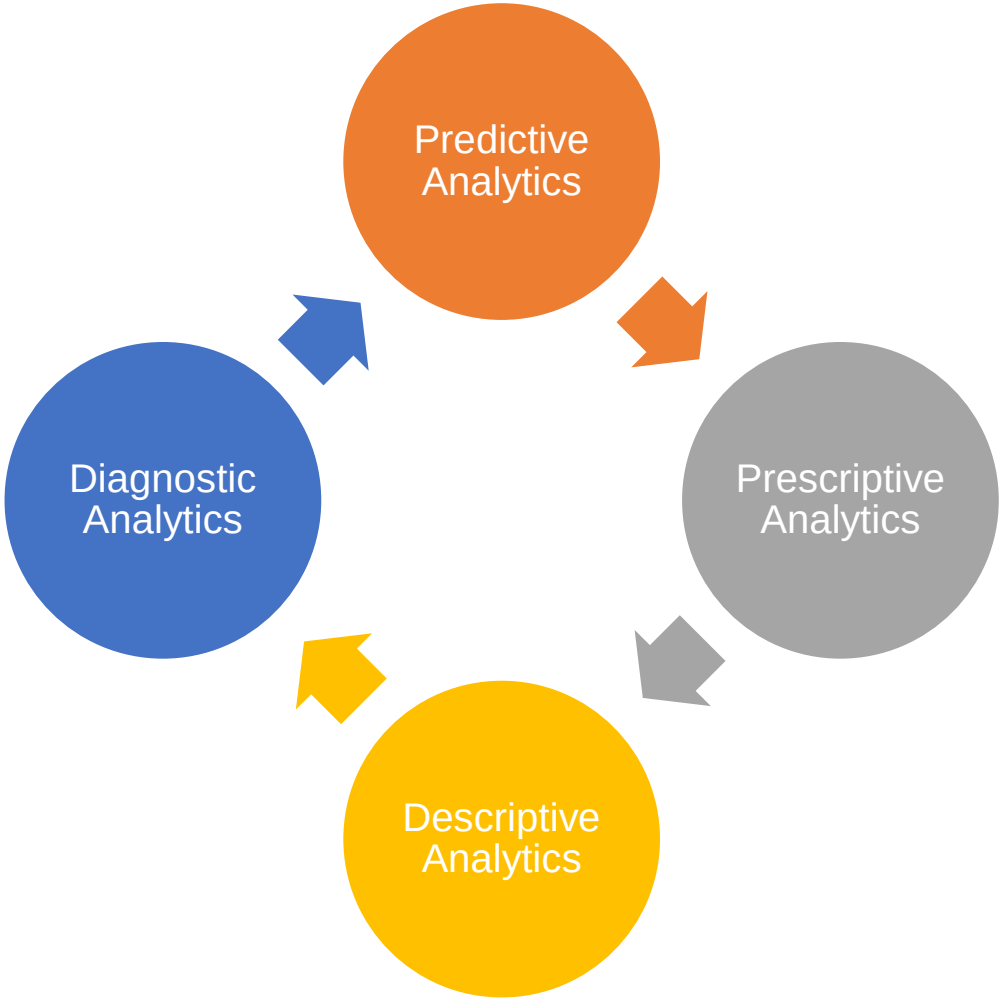
NUS National University of Singapore | Saw Swee Hock School of Public Health

National University Hospital System
Center for Health Services and Policy Research

Using EMR in Health Services Research in Singapore : Lessons and Looking Ahead

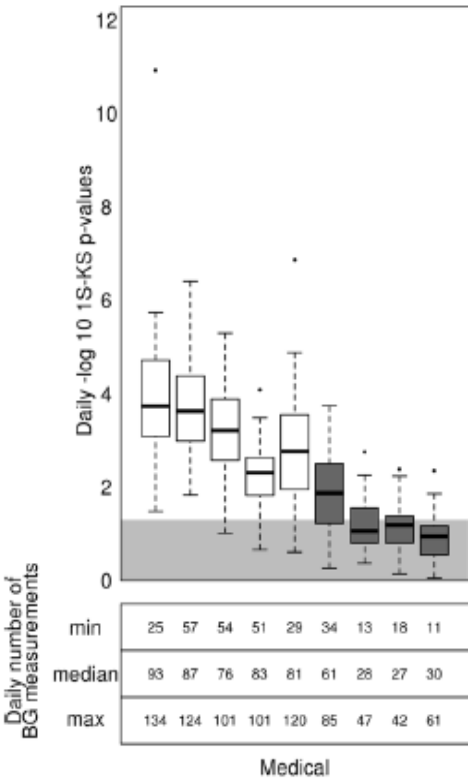
Joanne Yoong
Senior Economist, Center for Economic and Social Research, University of Southern California
Associate Professor, National University of Singapore
Deputy Director, Center for Health Services and Policy Research, NUHS
Honorary Senior Lecturer, London School of Hygiene and Tropical Medicine

Better Analytics, Better Healthcare

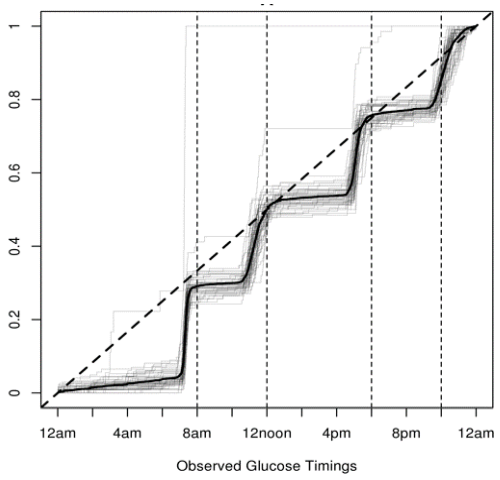


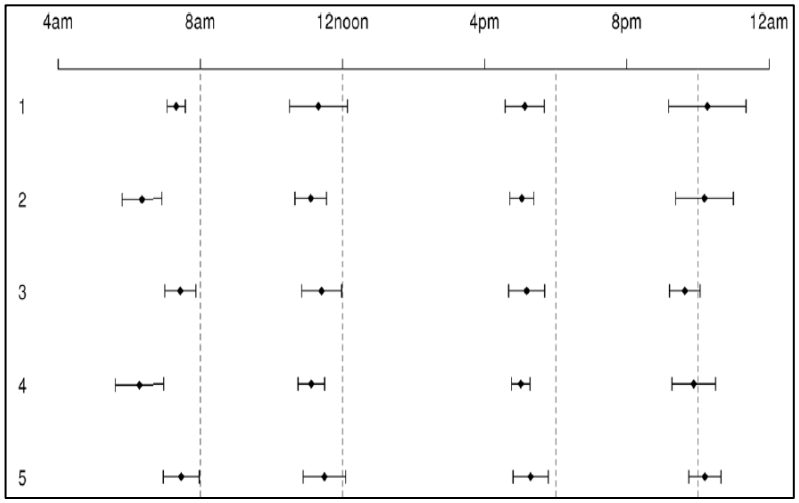
Tom Davenport, Five Types of Analytics for The Internet of Things, Deloitte University Press

Example 1: Descriptive Analytics



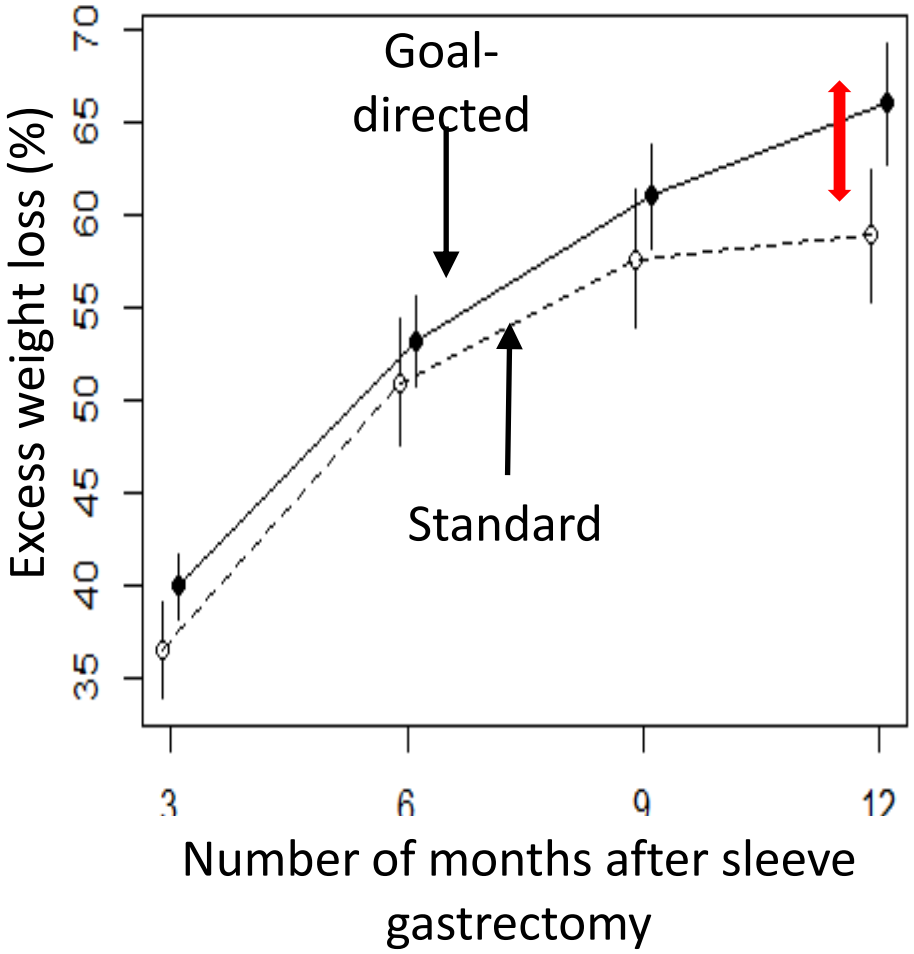
- We used 73182 blood glucose measurements from 3673 patients between November and December 2013 in the EH to monitor adherence to timely measurement protocol.





Chen Y, Kao SL, Tai ES, Wee HL, Khoo EY, Ning Y, Salloway MK, Deng X, Tan CS. Utilizing distributional analytics and electronic records to assess timeliness of inpatient blood glucose monitoring in non-critical care wards. BMC Med Res Methodol. 2016;16:40

Example II: Diagnostic Analytics



- Can a goal-directed program improving weight loss outcome when compared to standard program after sleeve gastrectomy?
- We identified patients from 3 bariatric centers between April 2010 and July 2013 in the electronic health records (EHRs), and compared the center that has a goal-directed program with the other 2 centers.

Kim G, **Tan CS**, Ng JY, Cheng AK, Rao J, Soe KT, Kong LW, Naseer F, Er PS, Lomanto D, So JB, Shabbir A. Goal-directed program after sleeve gastrectomy improves weight loss. Surg Obes Relat Dis. 2016;12(3):518-21.

Example III: Predictive Analytics

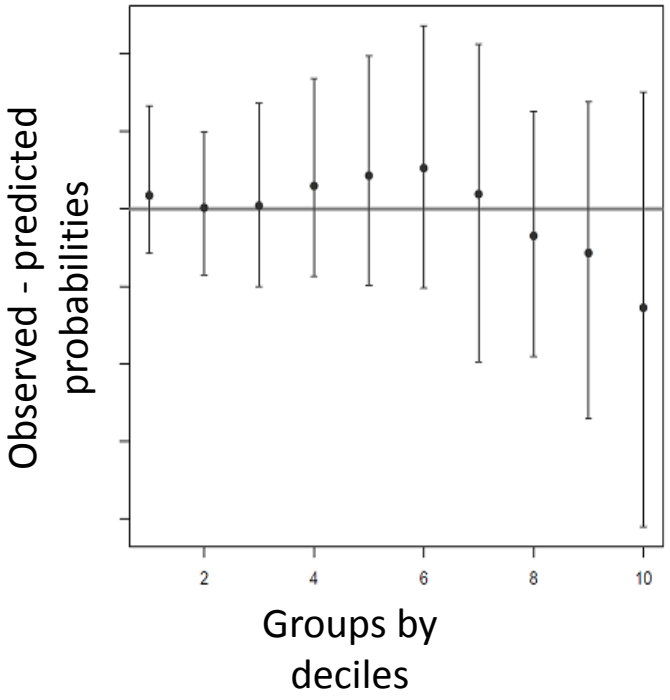
Variables	Odds ratio (95%CI)	p value
Age at enrolment in years		0.250*
First quartile: ≤44	1.00	
Second quartile: 45–56	1.08 (0.47–2.51)	0.854
Third quartile: 57–65	2.17 (0.94–5.04)	0.071
Fourth quartile: ≥66	1.20 (0.51–2.81)	0.677
Gender		
Male	1.00	
Female	1.16 (0.59–2.27)	0.666
Ethnicity		0.113*
Chinese	1.00	
Malay	0.39 (0.16–0.94)	0.037
Indian/Others	0.85 (0.27–2.64)	0.776
Patient class		
Subsidised	1.00	
Private	4.18 (1.49–11.74)	*0.007*
Shared care with FP		
AMC-FP	1.00	
Private FP	4.30 (2.23–8.30)	*<.000*

*Overall *p* value for categorical variables with more than two groups

- Which patients are most likely to enroll into a program to co-ordinate patient care between specialists and family physicians (FPs)?
- We identified 220 patients enrolled into the program between August 2010 to December 2012 in the EHRs.
- Private class patients and patients seeing private FPs are more likely to continue, but diagnosis, comorbidities and meds surprisingly not significant.

Lim AY, **Tan CS**, Low BP, Lau TC, Tan TL, Goh LG, Teng GG. Integrating rheumatology care in the community: can shared care work? Int J Integr Care. 2015; 15:e031.

Example IV: Prescriptive Analytics



Cut-off	Optimal Youden's J statistic	90-th percentile of the risk score
Specificity	69 (9.9)	92.1 (0.2)
Sensitivity	61.6 (10)	29.7 (1.9)
Accuracy	68.3 (7.9)	85.9 (0.4)

- Using EMR of 10678 diabetic patients between January 2010 and December 2011, we proposed a well-calibrated risk score that identifies the top spenders using previous year's records including sociodemographic, biochemistry, comorbidity and healthcare utilization variables.
- Application: Patients to be assigned based on a more refined score to complex case management within a Patient-Centered Medical Home (PCMH) model

Tan CS, Deng X, Tai ES, Khoo YHE, Toh ES, Salloway MK, Koh TW, Wee T, Wee HL. Predicting high cost patients with type 2 diabetes mellitus using hospital databases in a multi-ethnic Asian population, IEEE-EMBS International Conference on Biomedical and Health Informatics (BHI). 2016.

You say EMR, I say HSR …

Striking a balance between EMR to support hospital management and clinical care and the conduct of health services research is challenging

- Rich clinical data versus other information
- Ease of entry and process needs versus ease of use and research needs
- Too little vs too much automation
- Data safety and protection versus facilitation and interoperability

Tantalus in the Age of the EMR- Moving Towards Novel Enriched Studies

What´s next? Enriched RWD Studies

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Historically, researchers must trade-off benefits and limitations based on data collection mechanism

	Retrospective analysis	Prospective data collection
Pros	• Large data sets • Real-life patterns • Analysis can uncover new insights	• Control around collected data, confounders, sample size • Focus on hypothesis
Cons	• Data verification/ quality issues • Incomplete data • Time lags • Coding issues	• Costly, time-consuming • Smaller sample sizes • Delays in initiation due to recruitment

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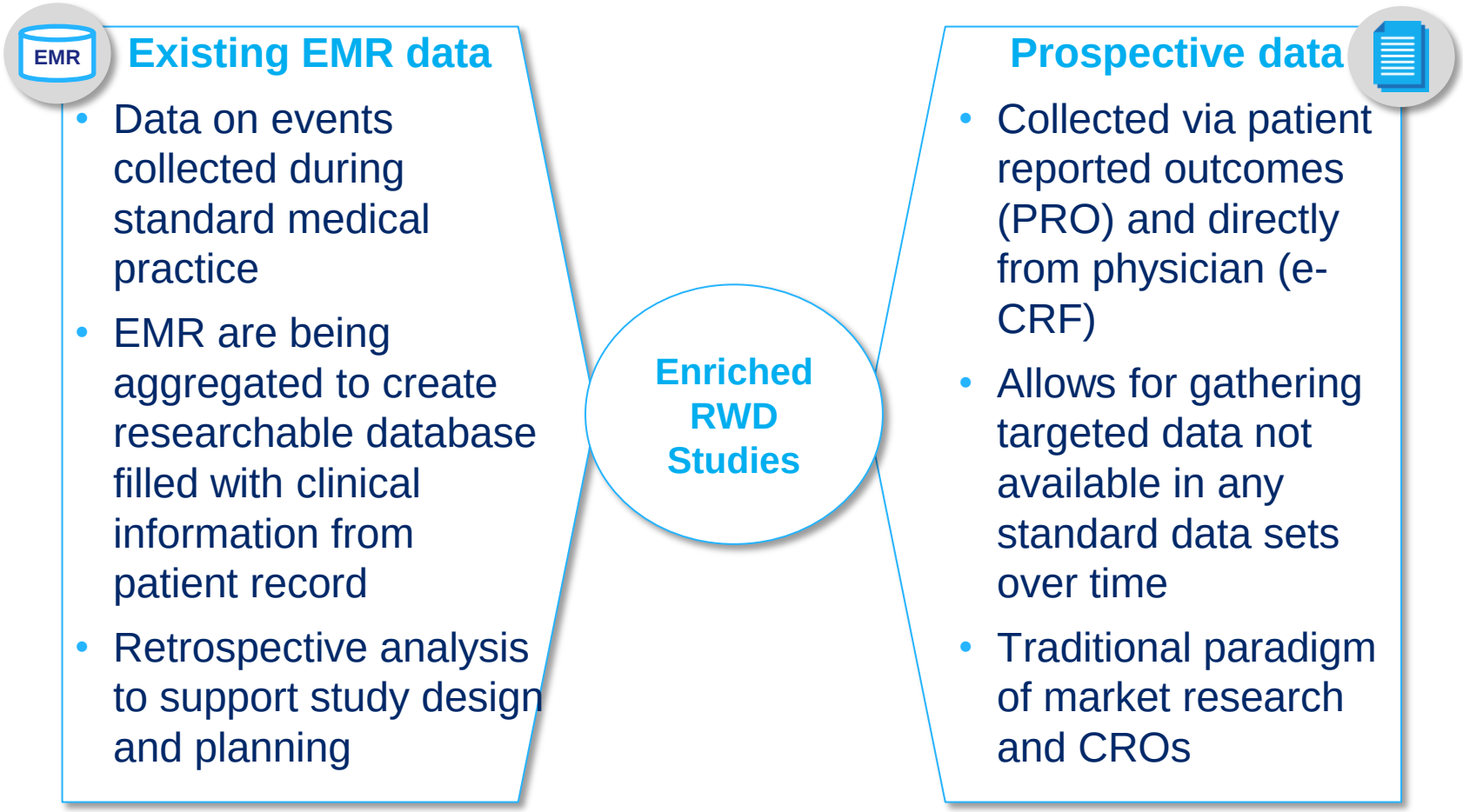
Enriched Real-World Data (RWD) Studies are observational studies that combine existing EMR with prospective data



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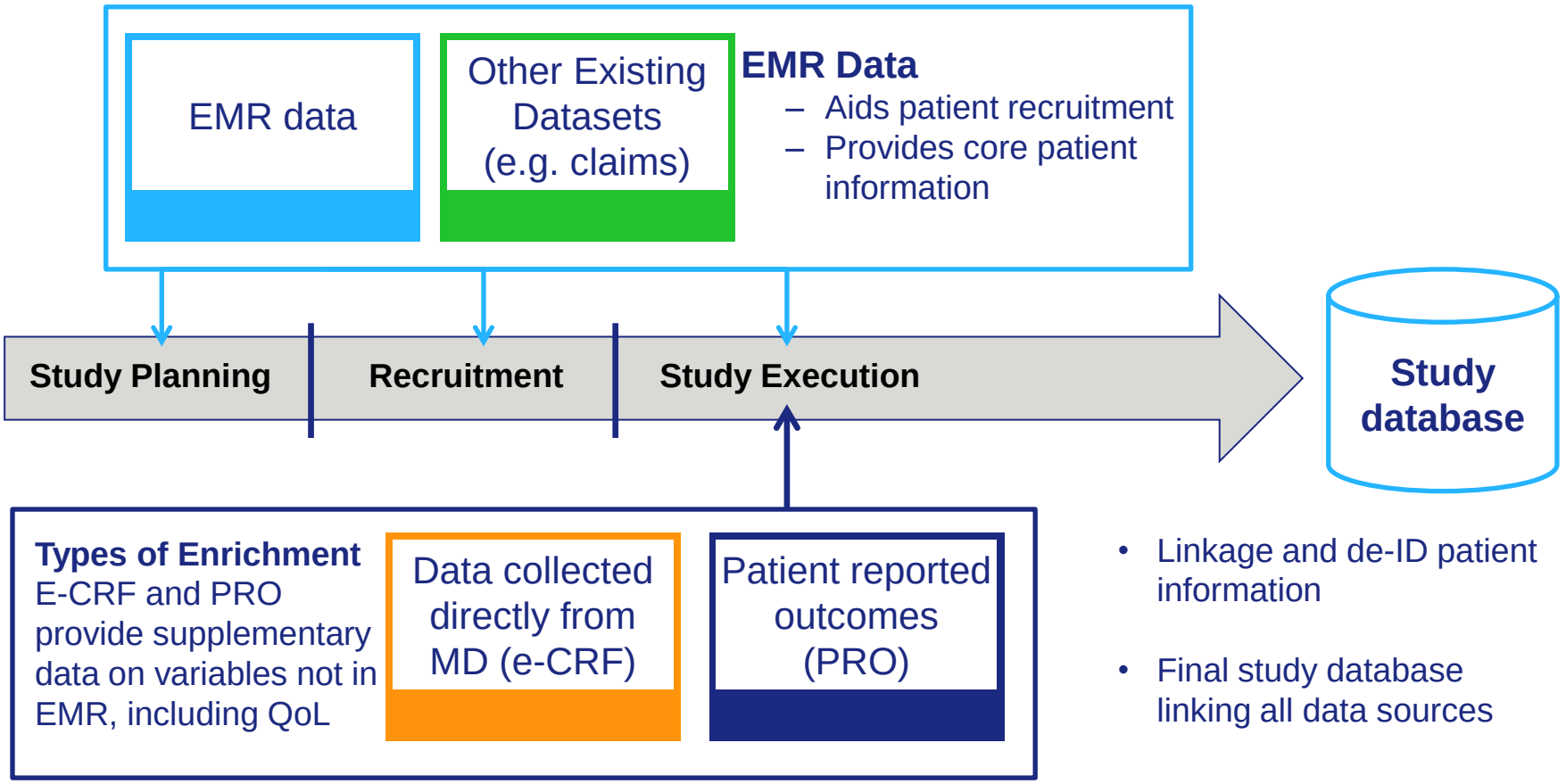
Enriched RWD Studies use integrated multi-source data to provide a comprehensive view of the patient



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Throughout the lifecycle of an observational study, EMR data can enhance the design and delivery of the study

Observational study lifecycle

Traditional Capabilities

Study planning	Identify site & physician	Patient recruitment	Data collection & monitoring	Data integration & analysis
• Clinical expertise • Epidemiology (sample size calculation)	• Site list generation • IRB • Contracting and training physicians • Performance forecast	• Informed consent support • Physician support and motivation • Review patient records	• Electronic data capture tools • Query management • Data validation • Site support	• Data management • Statistical services • Publication services

RWD Driven Enhancements

Study planning	Identify site & physician	Patient recruitment	Data collection & monitoring	Data integration & analysis
• **Study planning** – I/E criteria testing – Routine care evaluation – # sites and time to recruit	• **Targeted physician list** – High patient density based on I/E (EMR) – High likelihood based on Rx	• **Assisted patient identification** – Program to analyze patient data offline (cold) – Pop-up identification real time in EMR (hot)	• **Linkage to EMR** • **Assisted population of CRF** – Reduced physician burden	• **Continued follow-up** – On-going extraction of EMR data – Long-term outcomes

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Applying Enriched RWD Studies

Key Benefits

- Stronger evidence
- Enhanced study value
- Improved probability of success
- Efficiency

Situations where Enriched RWD studies may be applicable:

- **Strong foundational data**, where most of the data is complete but key variables are not collected electronically; can enrich for the last 10-20% of data, rather than gathering all the data through eCRF
- **TAs** where the patient perspective through capture of PROs is critical; enable linkage of PROs to clinical data
- **Chronic diseases** where long-term follow-up is required to evaluate outcomes; electronic follow up reduces drop-out and is less costly
- **Data from disparate sources required**, such as deep clinical information combined with full healthcare resource utilization costs

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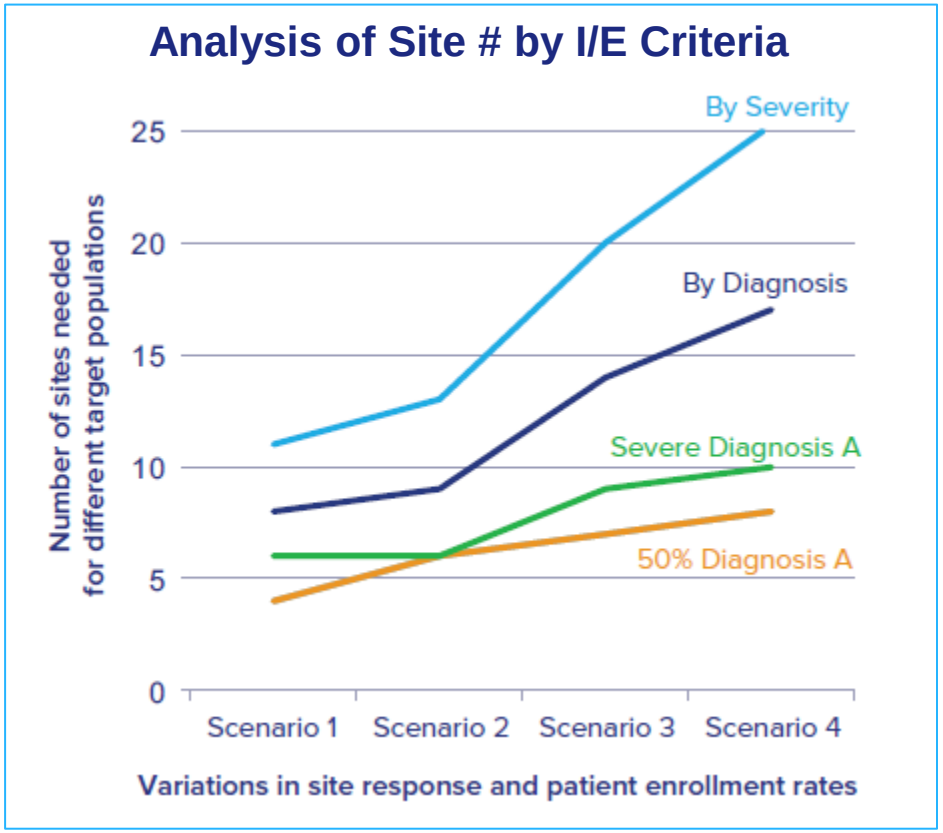
Example 1: Optimizing study design and planning

Challenge: Planning a multi-year observational study there was concerned that some elements in the protocol would make patient recruitment more difficult. To ensure efficient study deployment and generalizable results, it chose to use study planning analysis to inform important decisions around key variables, recruitment timelines and the distribution of physicians to target by specialty.

Approach: Use EMR databases to evaluate inclusion and exclusion criteria to determine number of sites required. Evaluate capture of routine data to determine budget and timelines for ensuring all variables were collected in study

Impact:

- **Ensure accurate budgeting**
- **Informed recruitment planning and forecast**
- **Refined I/E criteria and patient stratification**



Results presented in poster ***PRM20: FEASIBILITY OF ELECTRONIC MEDICAL RECORDS IN AUSTRALIA, CHINA, AND JAPAN TO SUPPORT NOVELTY (A NOVEL OBSERVATIONAL LONGITUDINAL STUDY OF PATIENTS WITH ASTHMA AND/OR COPD***

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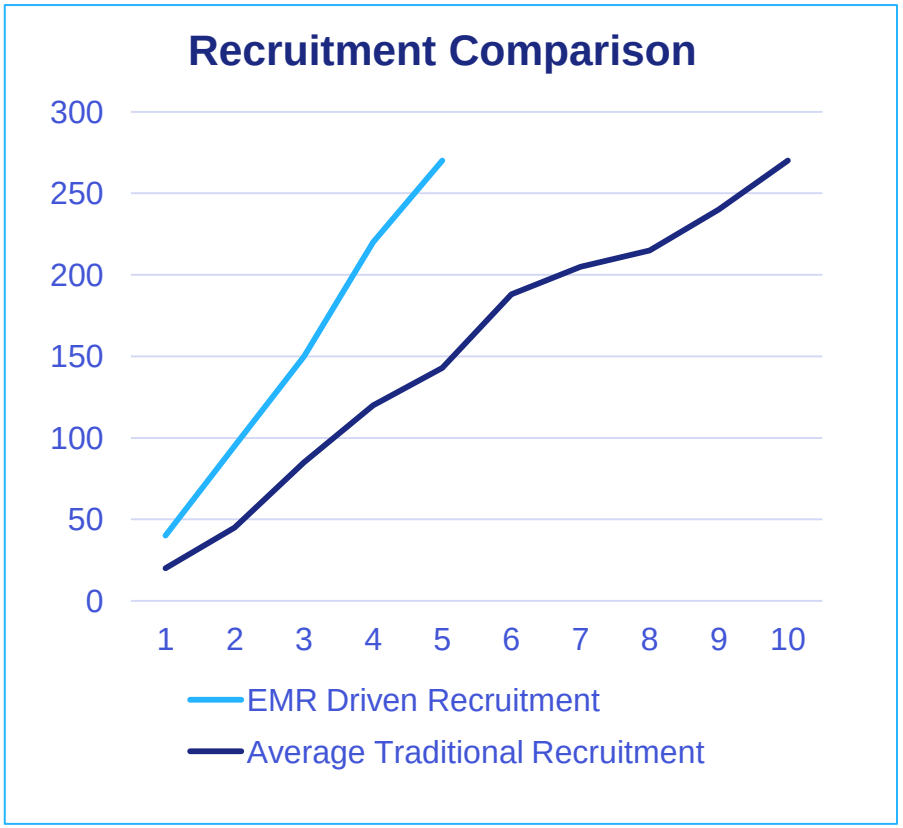
Example 2: Site targeting to drive recruitment

Challenge: Desired patient cohort needed for multi-year observational study in diabetes proved to difficult for investigators to estimate accurate numbers of patient meeting criteria, putting recruitment targets and timelines at risk

Approach: Apply inclusion and exclusion criteria to EMR data bases to identify physicians with high populations of patients meeting study criteria. Prioritise recruitment of physicians with high patient populations for participation in study

Impact: Reduced timeline for recruitment by ~5 months, creating efficiency and reduced resource need to meet target recruitment



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Conclusions

- Real-world data driven approach to study design and planning enables a fact based assessment of study feasibility prior to expensive and time consuming engagement with investigators
- Recruiting investigators (where possible) from a universe that is heavily populated with patients meeting study criteria can greatly reduce recruitment timelines
- Linkage of EMR data to physician or patient collected data enables the creation of a more comprehensive study database to be used for analysis
- As with any design, an Enriched RWD approach provides more benefit in particular situations

If you have any questions, please contact us

Laura Garcia Alvarez
Engagement Manager, Real-World Evidence Solutions
IMS Health

lgarciaalvarez@es.imshealth.com

Ong Leong Seng
Chief Architect & Group Director
Integrated Health Information System

ong.leong.seng@ihis.com.sg

Joanne Yoong Su-Yin
Associate Professor
National University of Singapore (NUS)

joanne.yoong@gmail.com

Josh Hiller
Senior Principal, Real-World Evidence Solutions
IMS Health

jhiller@imshealth.com

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Moderated Q&A

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