Accelerating the Development of Relevant Evidence in Healthcare

Effectively Defragmenting the View of the Patient

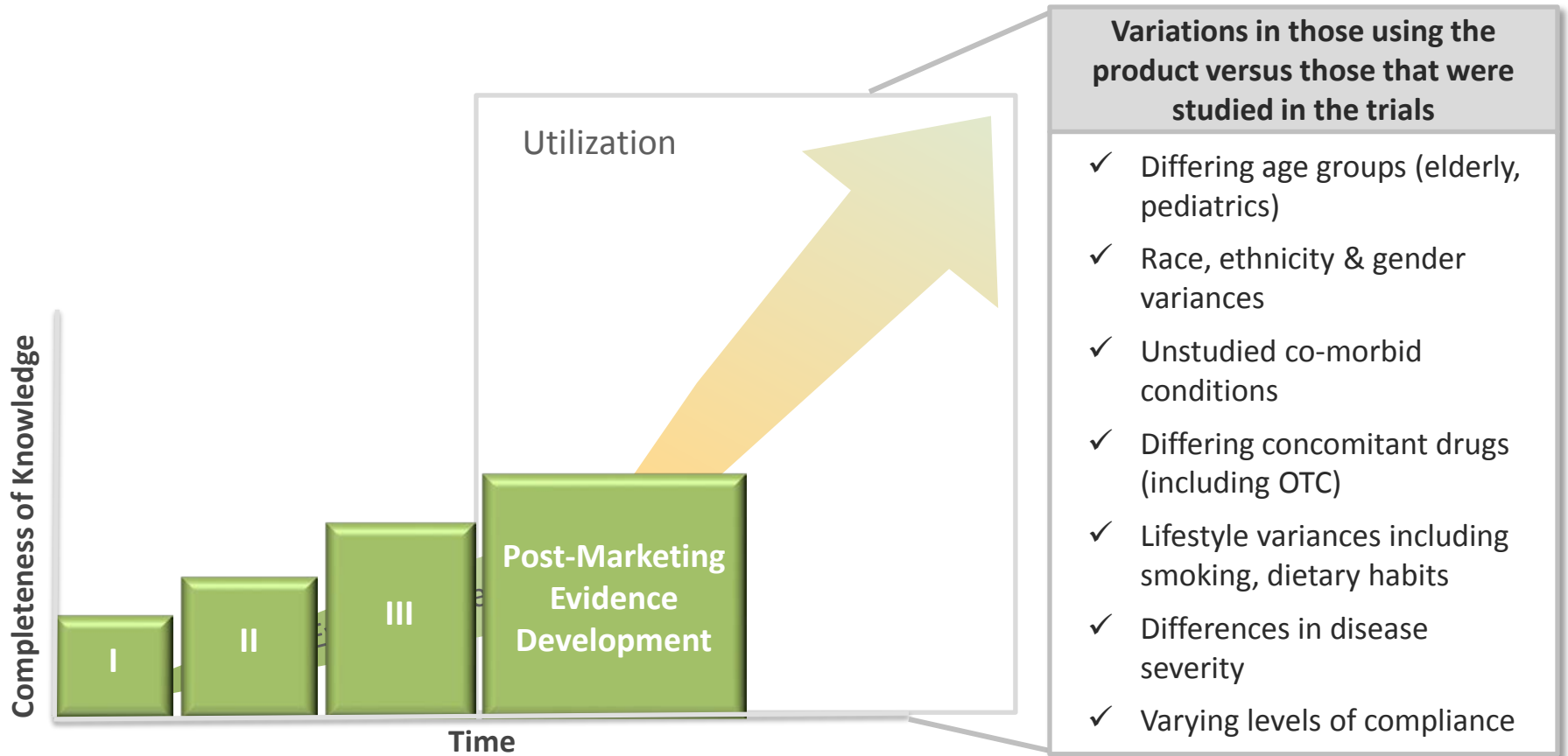**Marcus D Wilson, Pharm.D.**
President

Clinical Trials Leave Us with a Lack of Clarity
Utilization versus Evidence

Utilization

Completeness of Knowledge

I

II

III

Post-Marketing Evidence Development

Time

Variations in those using the product versus those that were studied in the trials

✓ Differing age groups (elderly, pediatrics)

✓ Race, ethnicity & gender variances

✓ Unstudied co-morbid conditions

✓ Differing concomitant drugs (including OTC)

✓ Lifestyle variances including smoking, dietary habits

✓ Differences in disease severity

✓ Varying levels of compliance

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Clinical Trials Leave Us with a Lack of Precision
Hindrances to Effective Clinical Decision Support

Effective Decision Support helps the decision-maker assemble and weigh evidence on Benefit vs Risk for a given population or individual

Clinical trials tell us *if* a product works or *if* a product is safe, just not in *whom*
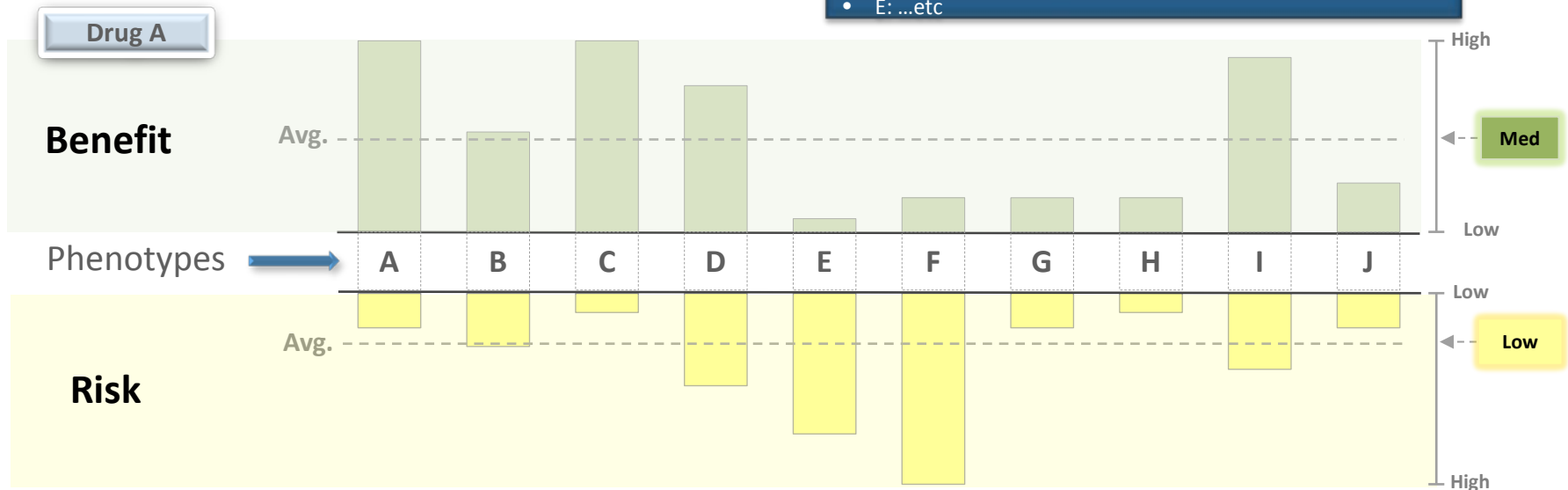
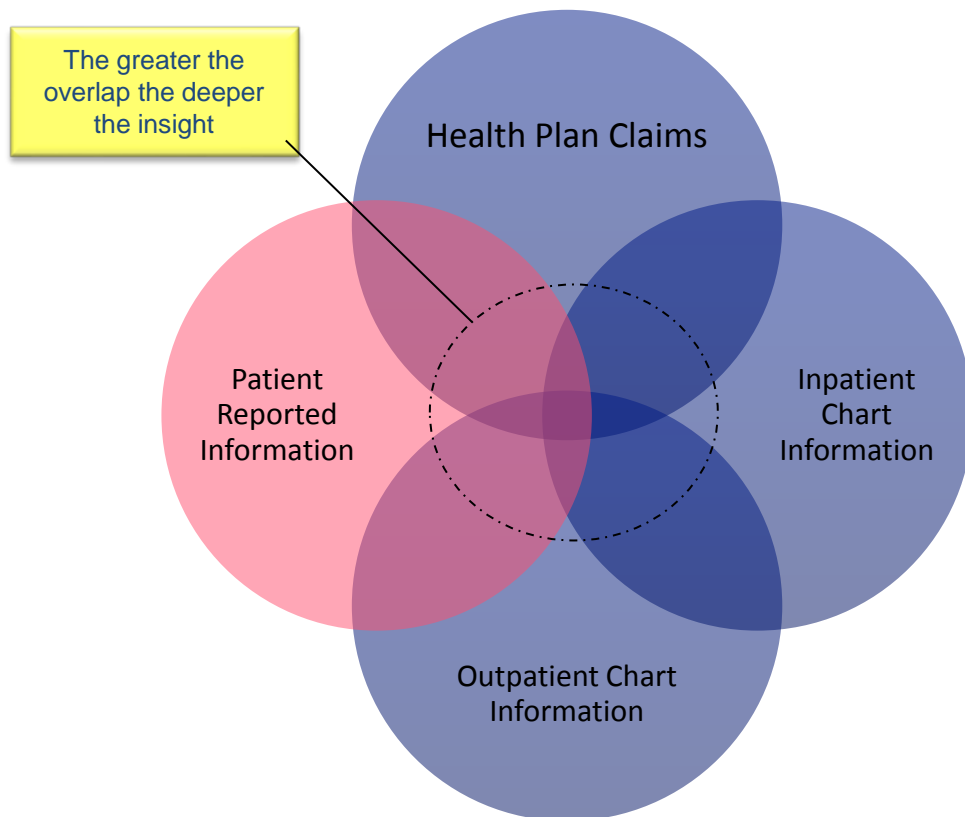Of my available options, which treatments should I use?

It depends...

Phenotype Matters

- A: Male, 25 yo, Cauc, no hx dz, no meds
- B: Male, 52 yo, African Am, hx CVD&OA, NSAID+BB
- C: Female, 67, Asian, post-MI&DM, ASA+OAD+ACEI
- D: Female, 54, Hisp, Hx Ca+PUD+RA, MTx+PPI
- E: ...etc

Drug A

Benefit — High / Avg. / Low — Med

Phenotypes: A B C D E F G H I J

Risk — Low / Avg. / High — Low

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Big Data is Less Relevant than Deep Data
The Evolution of Real World Data

The greater the overlap the deeper the insight

Health Plan Claims

Patient Reported Information

Inpatient Chart Information

Outpatient Chart Information

Each Data Source Contributes Unique Information

Health Plan Claims provides a broad view, insight into cost of care & information such as actual fill (Rx) history

Outpatient Chart Information provides rich clinical information and such endpoints as prescribed medications, lab and test results, OTC advice and reported use, family history

Inpatient Chart Information provides rich clinical information on procedures, conditions treated, medication use, lab and test results
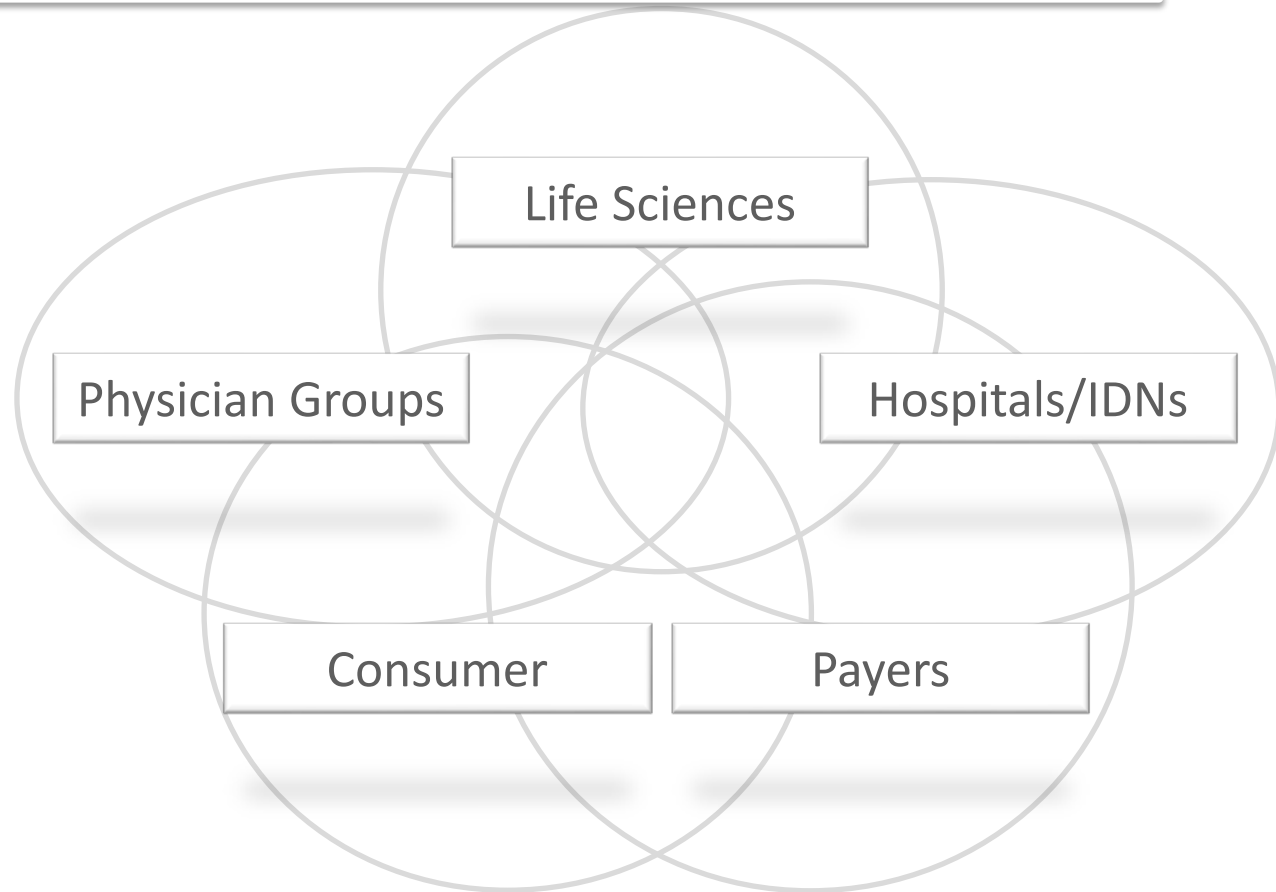
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Defragmenting the View

Each Stakeholders holds their data close for both defensive and offensive reasons
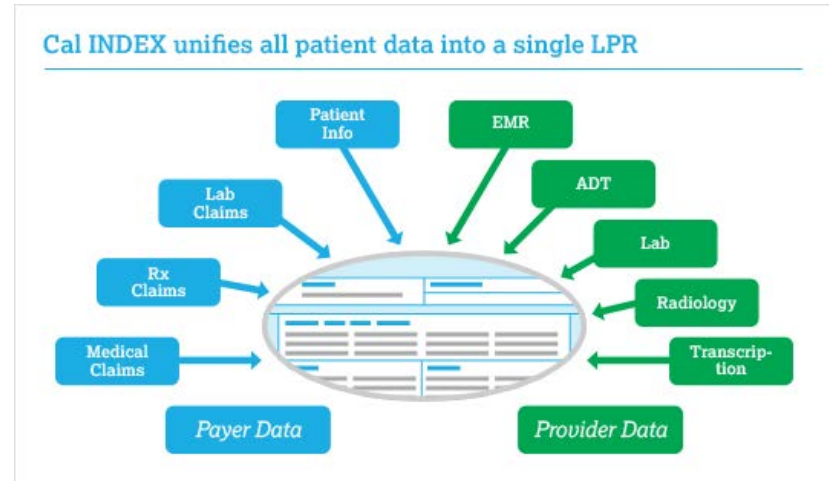
Getting the Stakeholders Onboard

We have a long history of living within a highly fragmented system

Competing Priorities

◆

Institutional Agendas

◆

History of Conflict

◆

Lack of Trust

Life Sciences

Physician Groups

Hospitals/IDNs

Consumer

Payers

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California Integrated Data Exchange – Cal INDEX

Cal INDEX unifies all patient data into a single LPR

The California Integrated Data Exchange is an independent, not-for-profit organization developing a statewide, next-generation health information exchange (HIE)

This comprehensive collection of electronic patient records will include clinical data from healthcare providers and health insurers

Cal INDEX will allow physicians, nurses and hospitals throughout the state to share patients' health information and will provide them with the tools to help them give their patients the safest, highest-quality care possible

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Core Principles of Defragmentation

Protect patient privacy and ensure data security

Minimize data mis-adventuring

Protect the business interests of the data sources

Accelerate our progress through the RWD to RWE learning curve

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Learning to Use "Big Data"
Where are we on the learning curve?

Integrated Data   EHR Data   Claims Data   Clinical Trial Data

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