

Next-generation capabilities and strategies to operationalize a learning healthcare system

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Leverage Strengths of Existing Constituents

- Private (For-Profit) Innovators
- Public Resources (Data and Knowledge)
(GPS, CMS, healthcare.gov, data.gov, SynPUF, ClinVar, 1M genomes)
- Open-source Community
(software and individual data contributors)

Leverage (do not re-invent) existing work: Examples

- 1) **ICHOM** – key clinical outcome versus process measures. Less than 7% of current quality guidelines are outcomes-based. Most are administrative process measures.
- 2) **PROMISE** – patient reported outcomes
- 3) **Drug Abacus** – Value-based analysis of oncology drugs

ISDOs: What Endpoints Should Be Measured?



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WE ARE GROUNDED IN A THEORETICAL FRAMEWORK

Our approach is built on a solid framework developed at Harvard Business School by Professors Michael E. Porter and Elizabeth O. Teisberg. In 2006, Porter and Teisberg wrote the well-known book, *Redefining Health Care*, which outlines the argument for using health outcomes data to redefine the nature of competition in health care.



WE ARE ROOTED IN STRATEGY

One of our founding organizations, The Boston Consulting Group, was the first to introduce competitive strategy to the business world. Their team offers more than 50 years of experience, a professional culture, and a rigorous approach to addressing challenges.



WE ARE RESEARCH-BASED THOUGHT LEADERS

Our tie to the Karolinska Institutet in Stockholm, Sweden provides us with a strong foundation in medicine and research. This world-renowned university and academic medical center is leading the way in health care discoveries. Every year, a committee from the Karolinska Institutet appoints the laureates for the Nobel Prize in Physiology or Medicine.



Example: Patient Reported Outcomes



The image shows the top section of the PROMIS website. On the left, the logo 'PROMIS' is displayed in large white letters on a blue background, with a registered trademark symbol and a graphic of a sunburst and a path. Below the logo is the tagline 'Dynamic Tools to Measure Health Outcomes from the Patient Perspective'. To the right of the logo are two photographs: one of a man in a hospital bed being visited by a woman, and another of a woman talking to a young girl. Below these elements is a navigation bar with several menu items: 'Home', 'About PROMIS®', 'Measures', 'Science', 'Software', 'What's New', 'Related Resources', 'PROMIS® For You', and a search box with a 'Search' button.

PROMIS Overview
PROMIS Mission
FAQs
Active PROMIS Studies
PROMIS Centers
PROMIS Research Sites
Video Presentations
Instructional Videos
PROMIS History
Sample Questions

[Home](#) >> [About](#) >> [PROMIS® Overview](#)

PROMIS® Overview

PROMIS® stands for Patient Reported Outcomes Measurement Information System, which is a system of highly reliable, precise measures of patient-reported health status for physical, mental, and social well-being. PROMIS® tools measure what patients are able to do and how they feel by asking questions. PROMIS measures can be used as primary or secondary endpoints in clinical studies of the effectiveness of treatment, and PROMIS® tools can be used across a wide variety of chronic diseases and conditions and in the general population.

The data collected in PROMIS® provide clinicians and researchers with important patient-reported information about the effect of therapy that cannot be found in traditional clinical measures. When used with traditional clinical measures of health, PROMIS® tools allow clinicians to better understand how various treatments might affect what patients are able to do and the symptoms they [experience](#). Not only can the reports be used to design treatment plans, but also can be used by patients and physicians to improve communication and manage chronic disease.

The uniqueness of PROMIS® lies in four key areas:

1. Comparability—measures have been standardized so there are common [domains](#) and metrics across conditions, allowing for comparisons across domains and diseases.
2. Reliability and Validity—all metrics for each domain have been rigorously reviewed and tested
3. Flexibility—PROMIS can be administered in a variety of ways, in different forms
4. Inclusiveness—PROMIS encompasses all people, regardless of literacy, language, physical function or life course.

Specific Recommendations

- 1) Database for knowledge representation (not patient data)
- 2) Content management system for policies and security (re-usability)
GIRA, WordPress, open source or donated by private sector
- 3) Tools and Standards for data liquidity from EMRs (current Interoperability requirements are a snapshot paradigm not suited for continuous learning of longitudinal data – missing outcomes over time). 3rd parties are emerging which have greatly improved capabilities (but business cases are limited and need to be further developed or supported by philanthropy or government)
- 4) Vetting of clinical algorithms of outcomes by key stakeholders (e.g., NQF, NCQA, Specialty Societies, ICHOM)
- 5) Academic Participants (credibility and reputational stakeholders)

Specific Recommendations (cont'd)

6) Security Standards (neutral and open-source agreements) – e.g., Series Seed Documents

7) Scalability (platforms that allow for rapid hypothesis-testing).
Likely a private sector contribution (R&D - \$100 M plus)

8) Education of Regulatory agencies (e.g., FDA) – but don't wait

9) Education of Specialty Societies (new observational paradigms and methods) and Regulatory agencies (e.g., FDA) – but don't wait

10) User Experience Innovation – information that is practical at the bedside (see example) for the doctor and the patient

Expand Infrastructure to Clinical Domain

Public database for knowledge representation (without patient data). Encouraging starts are still a newsfeed / textbook paradigm:

- **ClinicalTrials.gov**
- **Guidelines.gov**

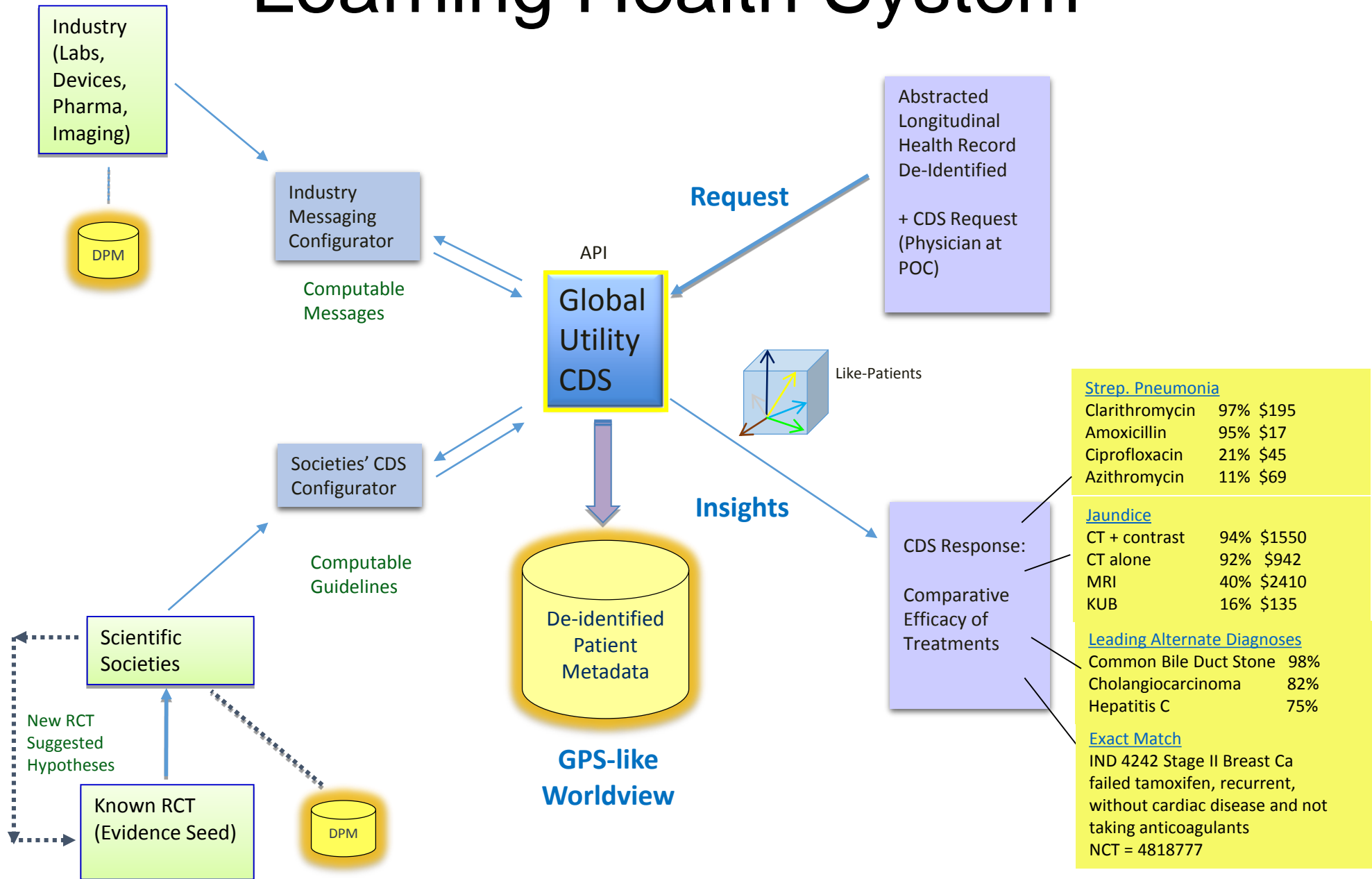
NCBI – DNA sequences of all species, tumors, gene variants (open upload)



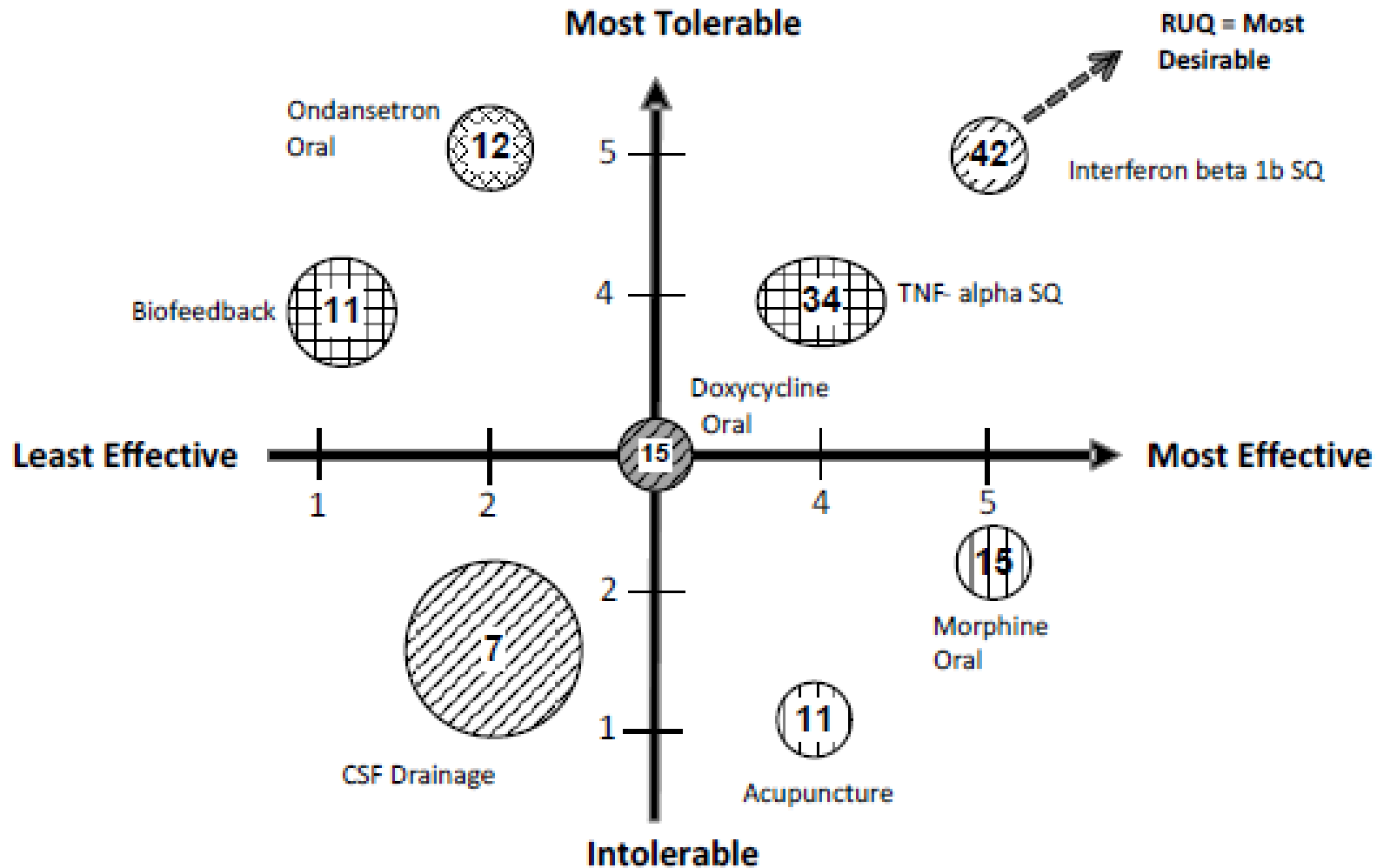
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There is no equivalent to NCBI (actual data + algorithms and programs such as BLAST) readily available for clinical use in a central repository of knowledge with machine readable grammar (download and run)

Learning Health System



Effectiveness vs. Tolerability



Intuitive
Physician
User Experience
and Patient
Understanding

Summary

- 1) What *should* be measured as clinically meaningful outcomes for each disease
 - 2) What mathematics and methodologies *should* be used for prospective and observational continuous learning (e.g., PERR for confounding)
 - 3) Development of Software, Test Cases and QA of software (private)
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- 4) Source Patient Data for selected Use cases of Comparative Efficacy (POP)
 - 5) Develop Permissions Management infrastructure, Trust Networks, and open-source documents that are re-usable to avoid inertia and costs
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- 6) Publish in reputable journals with endorsement of key stakeholders and Medical Specialty Societies
 - 7) Education of average practitioner to use results of the LHS in day-to-day care in an intuitive and user-obvious experience to enable broad adoption