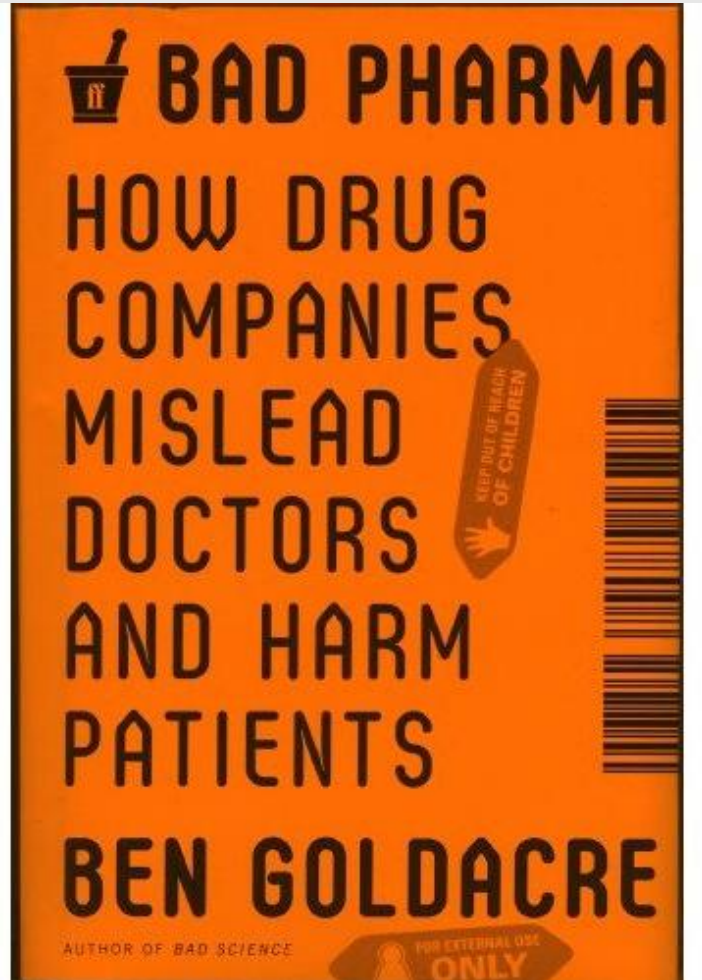


Partners in Interoperability: What FHIR Means to Biopharma

October 18-19, 2016
Johns Hopkins University
Mt. Washington Conference Center
Baltimore, MD

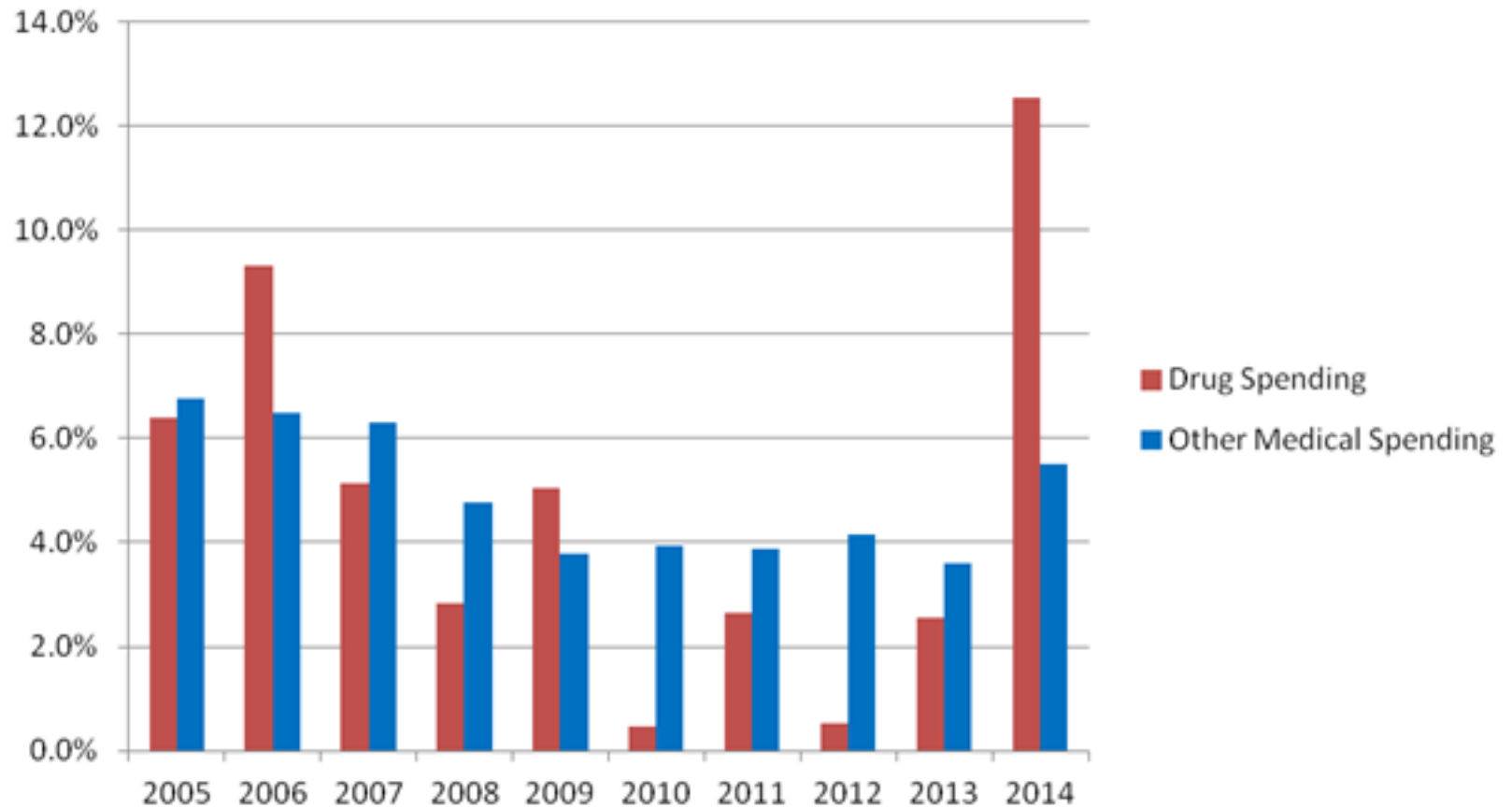


Public Perceptions of Pharma



Pharma Under Fire

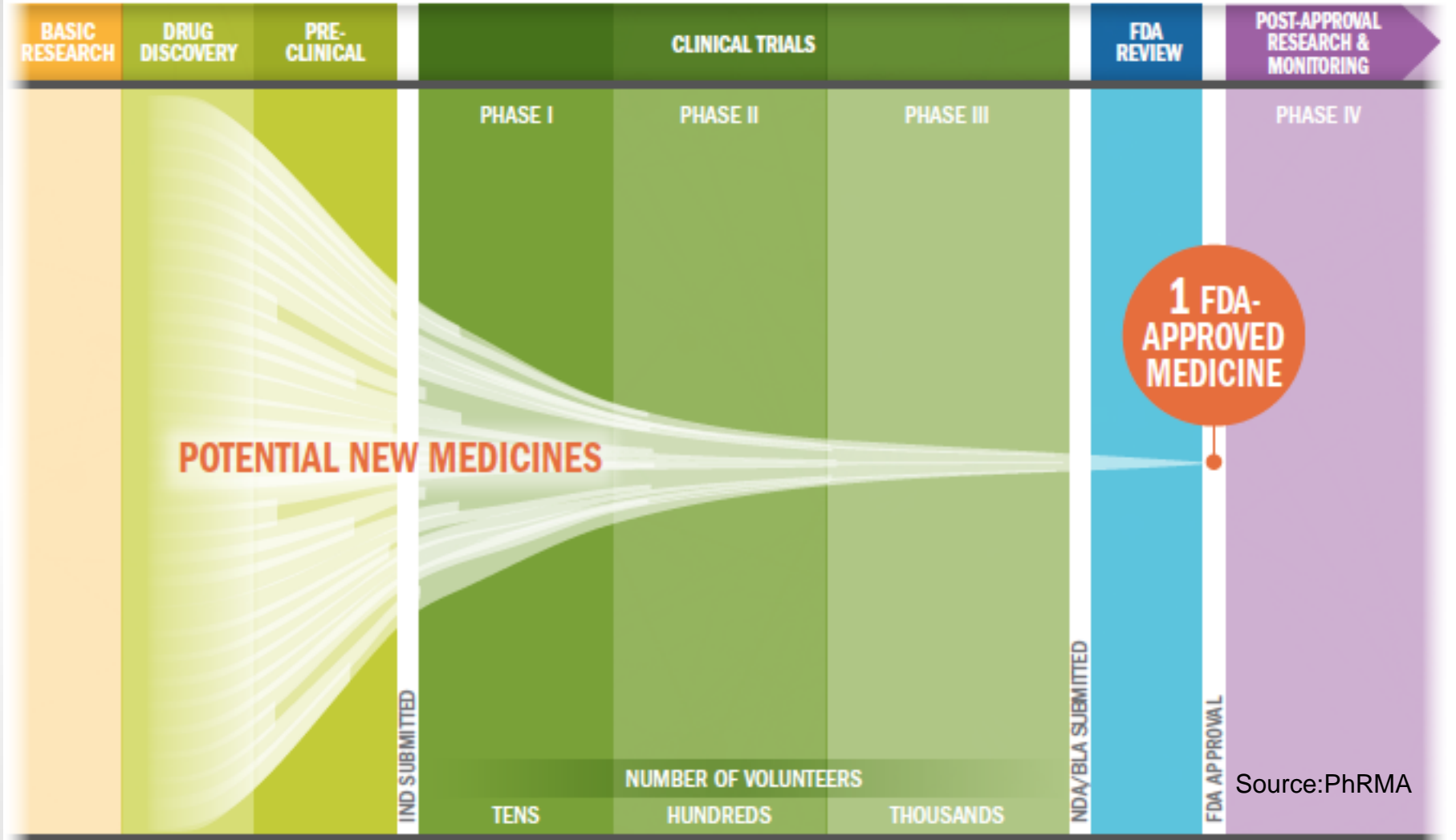
Growth in Healthcare Spending



Partners in
Interoperability™



THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS



Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

~10% Chance

>10 years; ~\$2.6B



Partners in Interoperability™

Changing Perceptions

- Historically, Pharma has viewed healthcare as a market and customer
- Recently Pharma is being viewed as a key part of the healthcare ecosystem – increasing focus on patient centricity
- Past silo mentality has resisted using healthcare data or sharing research data
 - Data quality insufficient for research
 - Key data buried in unstructured notes

What FHIR Means for BioPharma

- Make healthcare data more consistent and more available for research, safety, epidemiology, HEOR...
- Opportunities to improve efficiency of clinical trials, shorten timelines, reduce costs
- Open new pathways to improve interactions with clinicians, payers and patients
 - SMART-on-FHIR as an example

FHIR Uses in Clinical Research

- Evaluate feasibility of protocol eligibility; find subjects
- Pull EHR data to pre-populate EDC CRFs
- Apply DCF changes to update EHR (sync with EDC)
- Collect patient-originated data (eCOA, ePRO, symptoms) for EHR or EDC
- Capture genetic information to support precision medicine
- Capture real world evidence from multiple EHR systems for signal detection, pragmatic trials ...
- Improved method of eConsent
- FDA Reviewer drilldown to view EHR source records
- Improve Risk Evaluation and Mitigation Strategies
- Potentially provide a window into protocol execution

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Viet Nguyen Leidos, Inc.

