Challenges and Case Studies with Big Data in Clinical Trials

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Agenda

- Case Studies & Lessons Learned
- Incentive to Innovate
- Suggested Models

Case Study: Mobile Medical Application

Osteoarthritis

- Randomized, Open Label Study Assessing the Effect of a Novel Smartphone Application on Mobility after Treatment with (Device Name) Compared with Standard Follow-up in Patients with Osteoarthritis of the Knee
- Device Class: Class 2

- Subjects Screened: 300
- Subjects Enrolled: 211
- Expected- 20 sites; Actual- 17 sites
- Expected- 200 subjects; Actual- 211 subjects

Challenges

- Unfamiliarity of the technology by study staff at some sites was challenging. The Sponsor decided to issue a few sites test Smart Phones with the MMA so the study staff could familiarize themselves with its use and better assist their study subjects.
- Technology-related problems with the MMA, Activity Band, and Smart Phones caused frustration for study subjects, as well as study coordinators and physicians.
- Software version controls for the MMA, servers that supported the application, Smart Phone versions, and Activity Band software versions presented many challenges and, in some cases, resulted in the loss of data. Ensuring each subject was operating on the correct version of each software was a challenge.
- Maintaining enough devices in order to replace a high rate of malfunctioned, damaged, and in some cases, lost devices.

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- MMA text was only available in English which, by default, allowed enrollment only of individuals who could read and comprehend English.
- The MMA was available only on one Smart Phone platform (i.e., iOS or Android or Windows) rather than on multiple platforms.
- MMA data transfers from the application developer to Chiltern External Data Services presented challenges as this External Data contained the primary endpoint data, and, as a result, had to be 100% verified for accuracy.

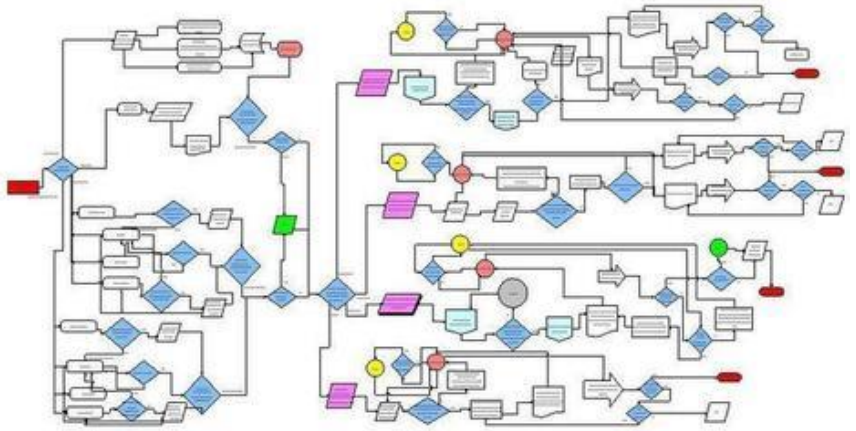
eSource/eCOA Lesson Learned Example

People	Process	Technology (Device & Web Reports)
Lack of awareness of eCOA & eCOA regulatory guidelines (specifically around linguistic validation, equivalency testing etc.)	Incomplete/Poor Vendor Validation (Experienced at Initial build, system and software upgrades)	Malfunctioning Devices i.e. hardware
Lack of experienced Vendor PMs, Study PMs and DMs	High turnaround time with data changes	Importing devices to challenging countries (i.e. India)
Inadequate training provided during Investigator meetings	Timeline (i.e. Go-live) delays	Vendor Selection & Modality of data collection
	eCOA-EDC Integration Issues	Reports are available after FSI, as part of the Vendors SDLC
	Incomplete/Poor quality documentation (i.e. Project Management Plan, Data Transfer Specs)	Reports lack the ability to detect signal vs. background, and most importantly fraud/trends
	Inconsistent processes from one Vendor to another, one study or program to another	
	Poor Helpdesk Support	

Where are the Sources of the Problems?

Technology

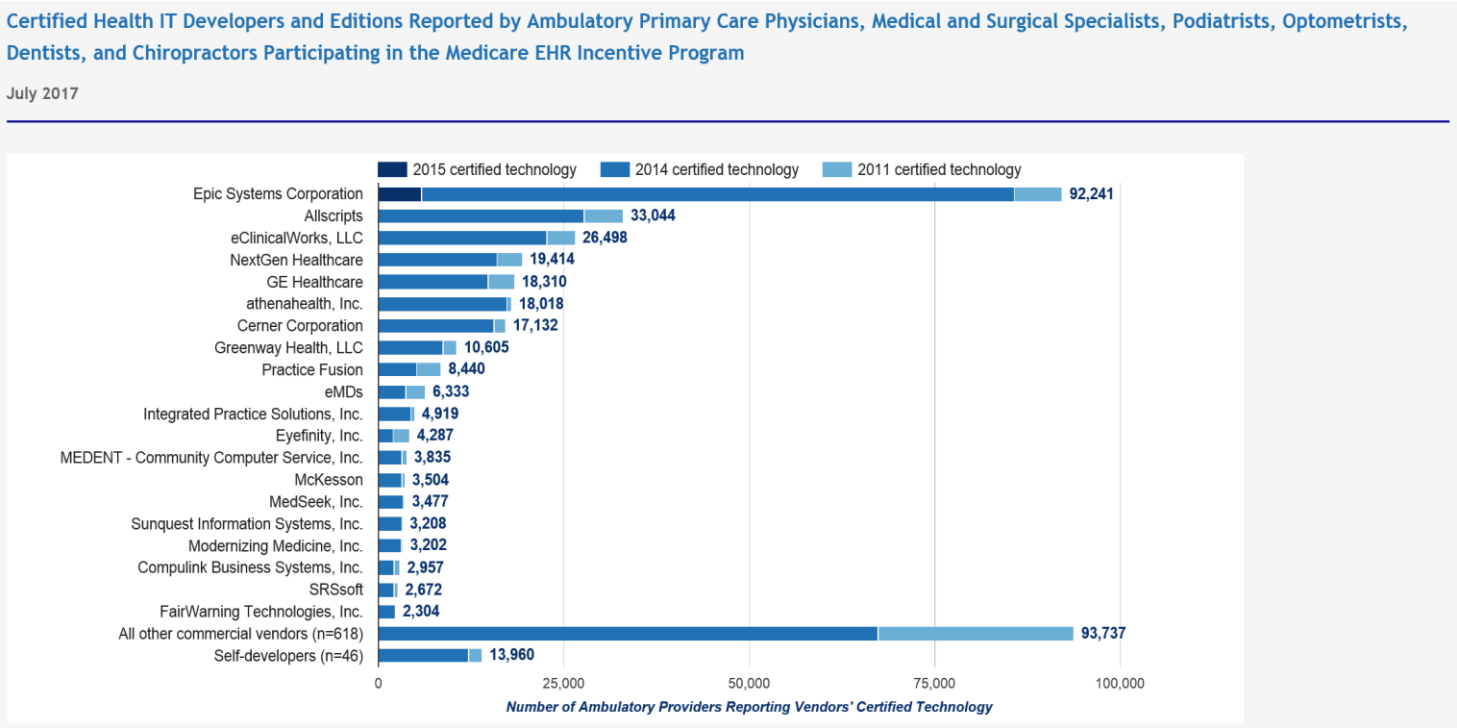
Process



People

Data Incentives

"The forces that have led to a global epidemic of overtesting, overdiagnosis, and overtreatment are easy to grasp. **Doctors get paid for doing more, not less.** We're more afraid of doing too little than of doing too much. And patients often feel the same way. They're likely to be grateful for the extra test done in the name of "being thorough"—and then for the procedure to address what's found."
- Atul Gawande



As of July 2017, **684 health IT** developers supply certified health IT to 354,395 ambulatory primary care physicians, medical and surgical specialists, podiatrists, optometrists, dentists, and chiropractors participating in the **Medicare EHR Incentive Program**

http://www.newyorker.com/magazine/2015/05/11/overkill-atul-gawande
https://dashboard.healthit.gov/index.php

Big Data in Pharma Incentives

"Historically, the pharmaceutical industry has recruited **SAS programmers** who have executed **well-defined analyses** of clinical trials in a standardized, efficient manner. This worked well, given that clinical trials have been designed to answer questions about efficacy and safety with **clean data sets** in an **industry-standard structure** with **few missing values**."

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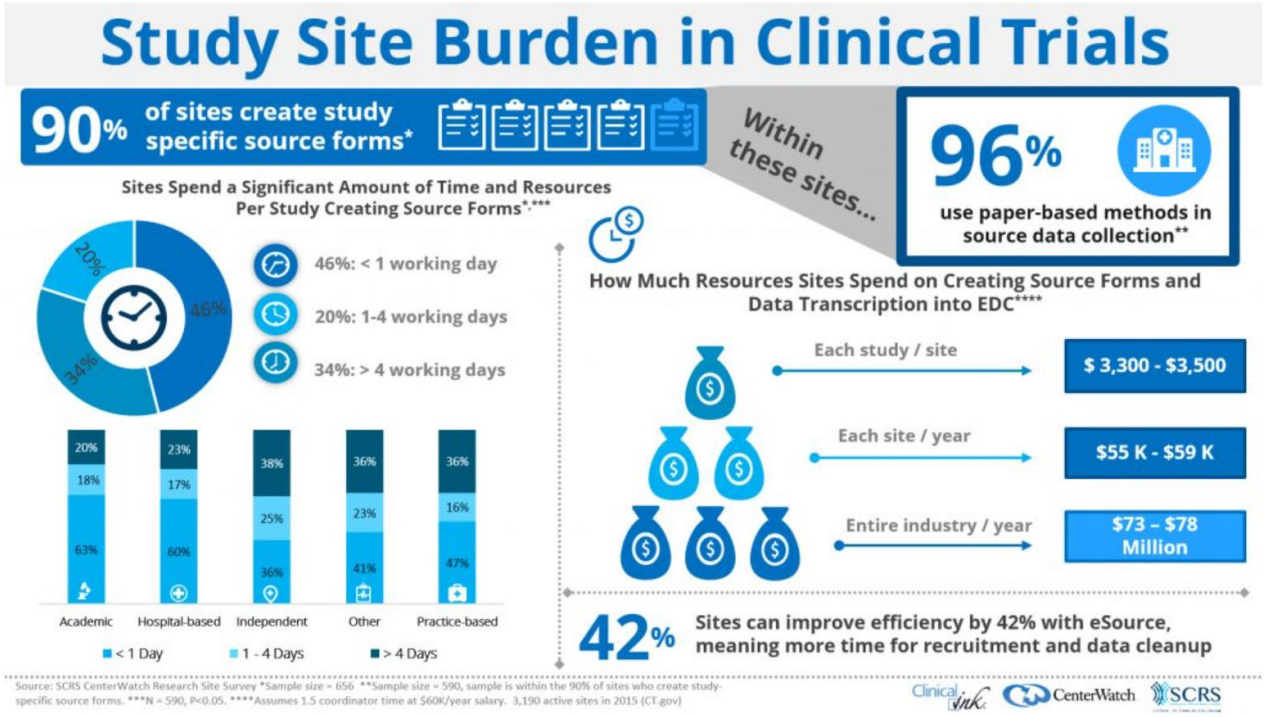
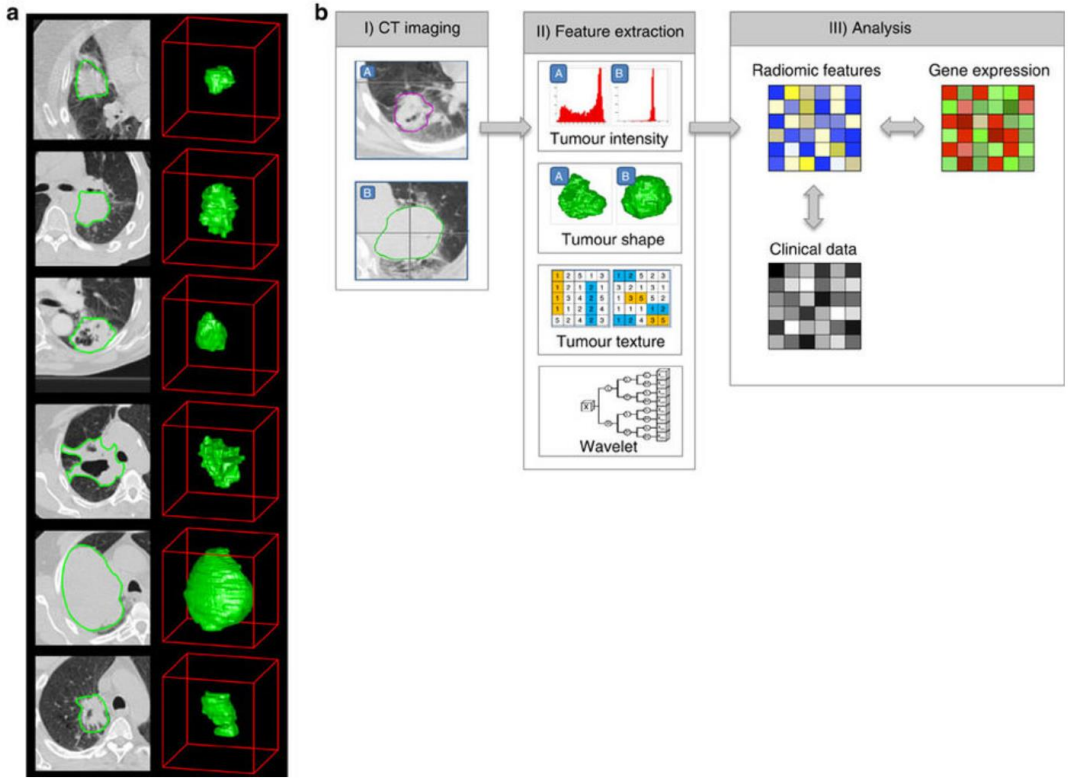


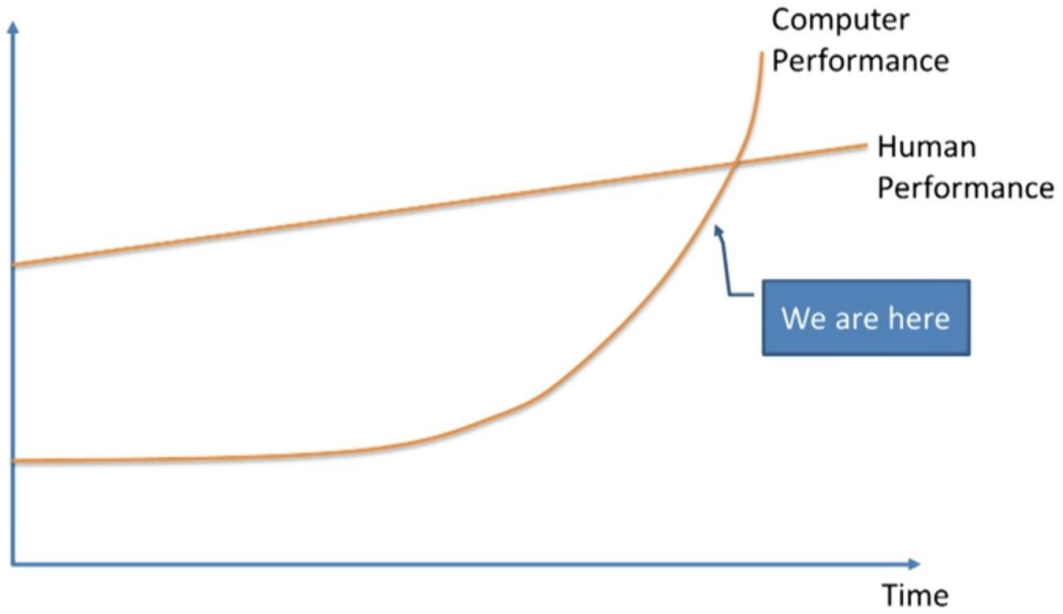
https://hbr.org/2016/11/the-promise-and-challenge-of-big-data-for-pharma
http://www.clinicalink.com/site-source-form/

Can We Adapt to a Sustainable Model

Figure 1: Extracting Radiomics Data from Images

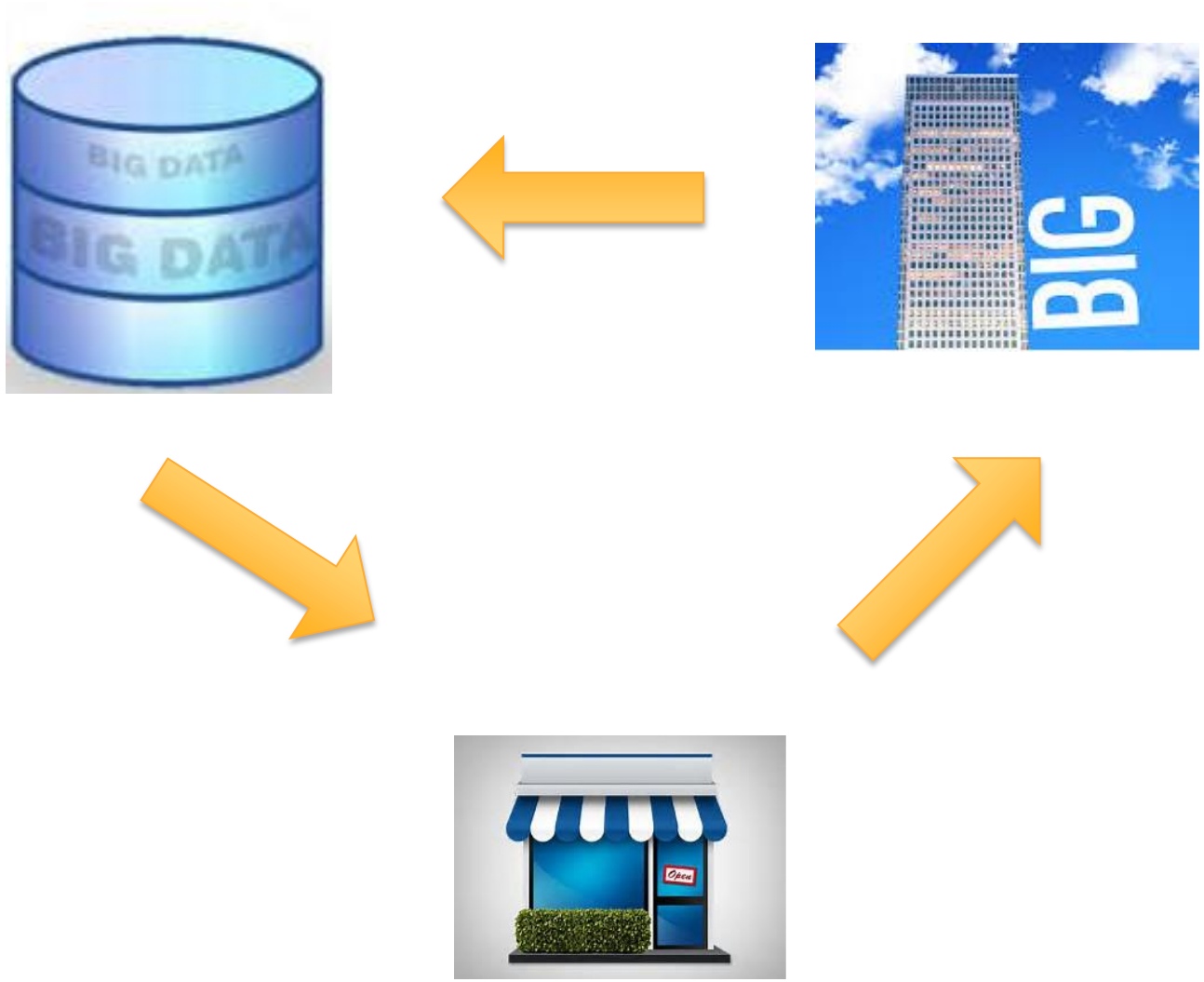
From: Decoding tumor phenotype by noninvasive imaging using a quantitative radiomics approach





http://www.nature.com/articles/ncomms5006
https://www.ted.com/talks/jeremy_howard_the_wonderful_and_terrifying_implications_of_computers_that_can_learn

Suggested Model



- Small organization focused on solving a small problem with the opportunity for a large incentive
- Align with big organization to obtain big data access
- Leverage machine learning to consolidate decisions

Thank You

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