Real World Experience With RWD in Community Practices

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Fit for Care vs Fit for Research: The Realities of Community Research

- As GB Shaw might have said.. *Healthcare and biopharma are two industries separated by a common set of data*
- The requirements of pharmaceutical researchers and regulators can at times seem like arcane, nonsensical whims ..
- But often the community researcher is naive, understaffed, lacking in informatics and regulatory expertise, and lacking an economic incentive
- Healthcare data is not ‘dirty’ or ‘poor quality’ - it is fit for care data*. It is not fit for research as it stands - this requires work.
- Adverse Events as example…

*This is not to say that there aren’t problems with completeness, accuracy, and bias

Fit for Care vs Fit for Research: The Realities of Community Research Settings

- The EHR is a measure of the healthcare process*, the regulatory submission is a statistical measure of difference
  - EHR: Focus on clinical concepts, scheduling, reimbursement…
  - Reg research: Focus on standards, reproducibility, statistical measures
- Transformation of data ‘fit for care’ into data ‘fit for research’ requires…
  - Informatics and coding expertise
  - Data Science expertise
  - Time and Effort
- The typical community researcher has none of these

*It is not a bucket of data

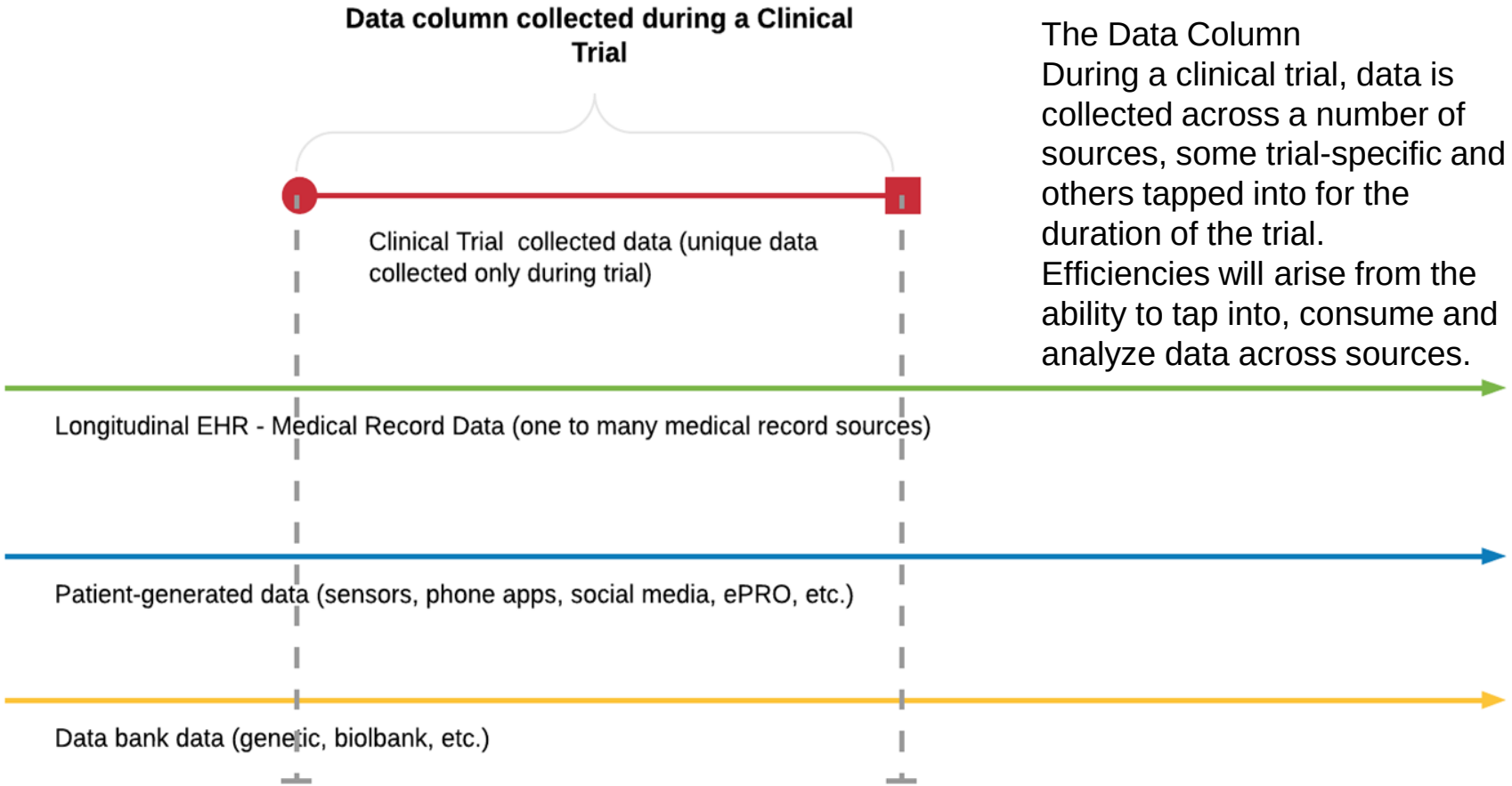
We should accept that healthcare data requires a large amount of curation to be transformed into ‘regulatory-grade’ data.

In the past, humans (CRAs) provided the work required to transform the data. Removing the humans does not fix the transformation problem.

Using healthcare data for regulated research will always require transformation - and therefore work

Three Data Pillars for Modern Clinical Research

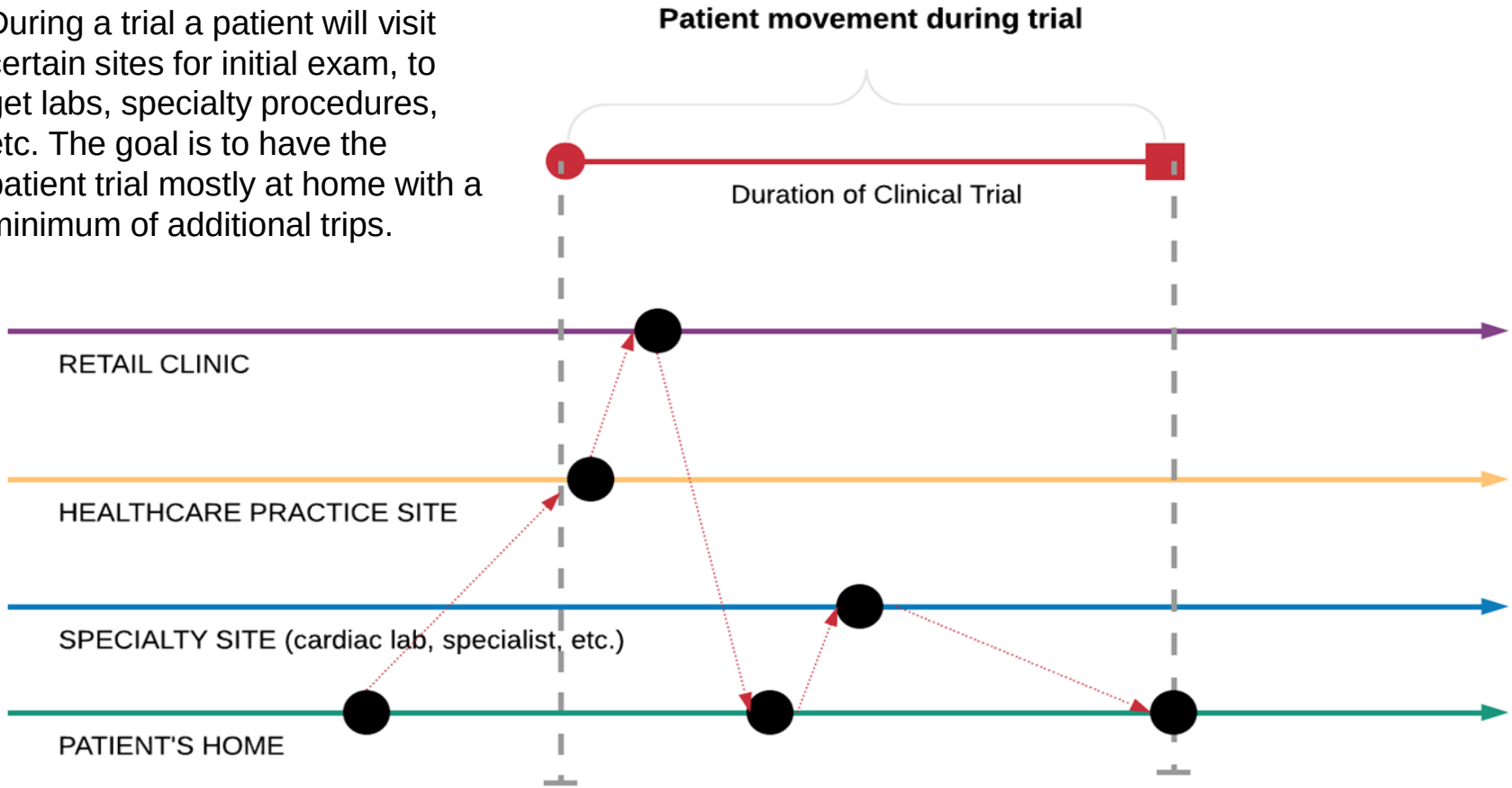
- To complicate our problem - as we're trying to figure out the EHR, the fact is, we have three data streams or pillars that are qualitatively different from one another...
- Clinical Trial Data
  - We usually take this for granted, but it is very clearly a very specific type of data
- EHR Data
  - As discussed, data fit for another purpose that needs to be woven into and become similar in specificity, provenance and rigor to the rest of the CT data
- Patient-Generated Data
  - The newest category, ecompassing everything from surveys to ePRO to genomics



The Data Column
During a clinical trial, data is collected across a number of sources, some trial-specific and others tapped into for the duration of the trial.
Efficiencies will arise from the ability to tap into, consume and analyze data across sources.

Patient Movement

During a trial a patient will visit certain sites for initial exam, to get labs, specialty procedures, etc. The goal is to have the patient trial mostly at home with a minimum of additional trips.



eSource, as we typically define it, is a specific case of a more general problem. We have been staring so long at the EHR that we have lost our perspective.

We will not be successful at forcing data streams fit for other purposes (and driven economically for other reasons) to conform to the most strict standards to the point where the EHR and CT data become synonymous (venture funding to the contrary)

We need to accept the reality that the people using the EHR will not be capable of producing the resources needed to transform that data for clinical trials any time soon.

One approach: Provide the infrastructure to community providers to allow them to ‘plug in’ to clinical research. Infrastructure means data, applications, a ‘clinical control layer’ that provides regulatory guidance.

Remove the need for special expertise, remove the administrative overhead, provide an incentive for community participation.

Accept the fact that the work of data transformation, of the EHR, of patient-generated data, will need to take place - locate that work away from the community provider - at the infrastructure level.

In other words, to fix eSource, fix the underlying issues.

Two suggestions…

The ghost of the tech metaphor...

We've (mostly) disabused ourselves of the paper metaphor, but we now need to get rid of the 'tech' metaphor..

...we think, design and regulate with an 'EHR' in mind, a piece of technology, rather than just the data, the relationships, and how it is used.

Eventually we need to separate data completely from it's form factor and stop defining one in terms of the other. This confuses us to no end when we try to talk about 'source'.

Last suggestion…

Think of data as the electricity of our times..it's not the machine, it's what powers the machine.

"In 1881, Edison built electricity generating stations at Pearl Street in Manhattan and Holborn in London. Yet by 1900, less than 5% of mechanical drive power in American factories was coming from electric motors. The age of steam lingered."*

They had to rearrange the factory floor to get productivity from electricity. We need to rearrange our clinical trials, and our thinking, to take advantage of data by meeting the data where it lives, then figuring out how to create processes and do work at the right point to make it fit for research.

*Why didn't electricity immediately change manufacturing? By Tim Harford. BBC World Service, 50 Things That Made the Modern Economy 21 August 2017

Thank You