Quantum Leap: Realizing the Long-Held, Mostly Undelivered Promise of EDC

Case Study – The Benefits of Leveraging Real-time (Direct) Data Entry

MAY 22, 2013

For information contact:
Dean Gittleman, Sr. Director of Operations
Target Health Inc, 212-681-2100
Dean.gittleman@targethealth.com

Target Health Inc

A Touch of Philosophy

Every truth passes through three stages before it is recognized:

In the first it is ridiculed
In the second it is opposed
In the third it is regarded as self-evident

(Arthur Schopenhauer)

Questions???

What is keeping you *today* from fully adopting 21st century tools and processes?

$200,000 - $250,000

Direct Savings in one 18-site study, in nine months, as a result of reduced on-site monitoring

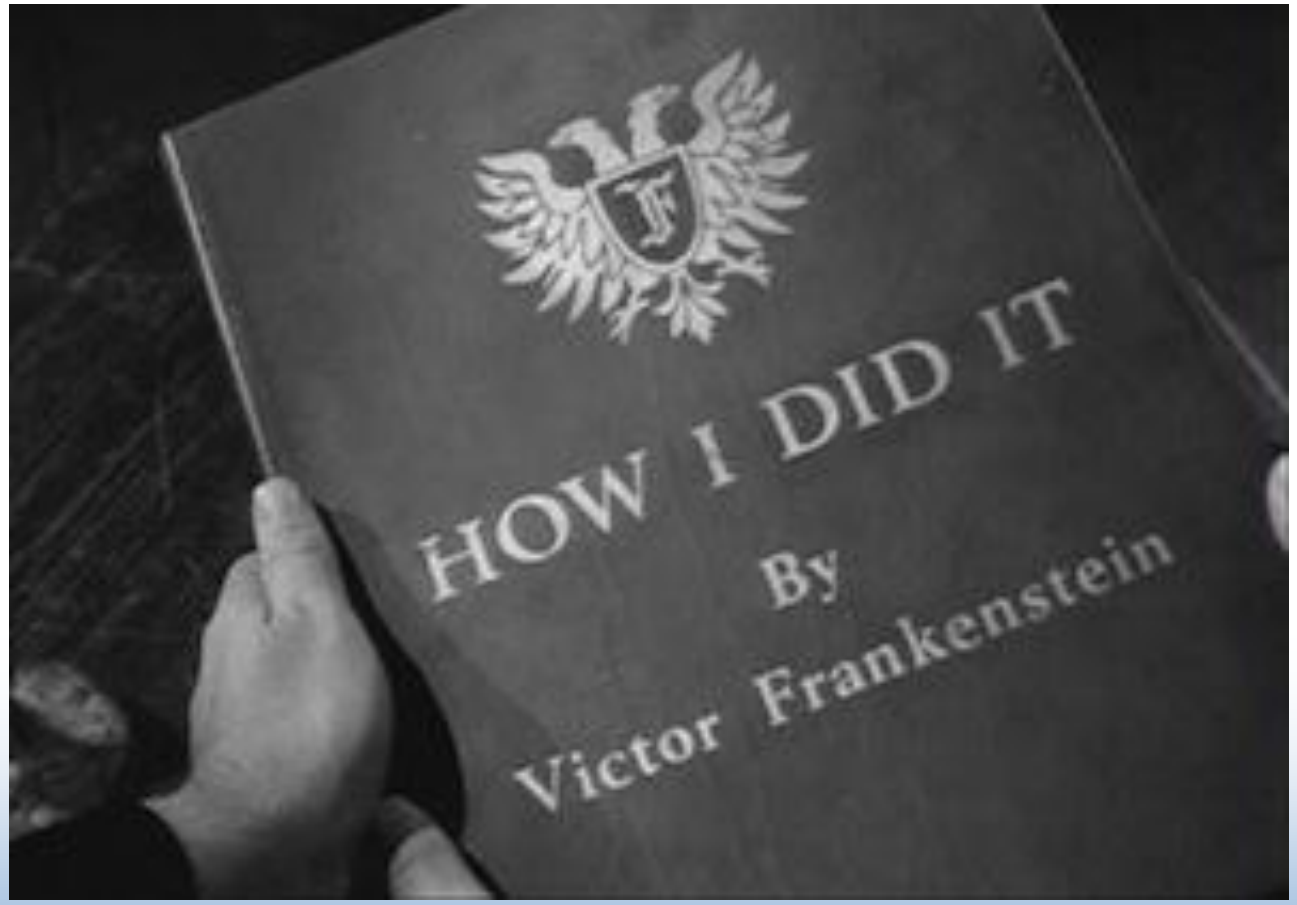
This figure does *not* take into account:

- Savings accrued to sites
- Improved site/sponsor relationships
- *Value* of making faster, mid-course corrections
- Improved quality of data (w/associated cost savings)

Themes for Today's Talk

- "Young Frankenstein"
- "All You Need is Love"
- "There's No Place Like Home"

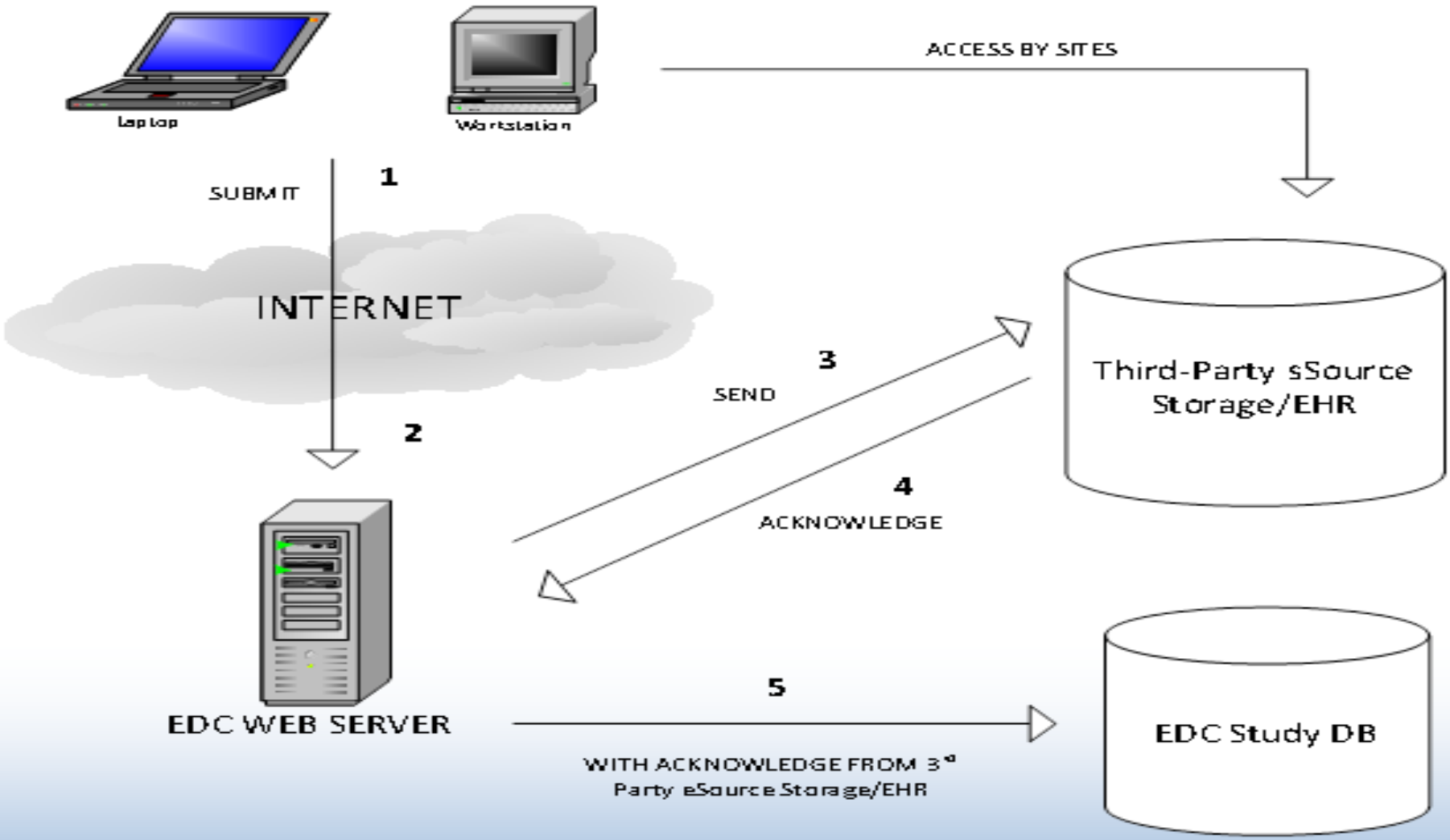
“Young Frankenstein”



How We Did It

- Committed to 21st Century Approach
- Focused on Quality (mind-set)
- eSource-enabled EDC system (tool)
- Risk-based Monitoring plans (process)
- Central/Remote Monitoring (process)
- "QbD" Meetings (process)

-------- Site --------


Laptop
Workstation
ACCESS BY SITES
SUBMIT
1
INTERNET
2
3
SEND
4
ACKNOWLEDGE
Third-Party sSource Storage/EHR
EDC WEB SERVER
5
WITH ACKNOWLEDGE FROM 3rd Party eSource Storage/EHR
EDC Study DB

Credibility From Ongoing Programs

Met with FDA at Type C meeting under a US IND

11 Studies initiated under 6 INDs

- 2 INDs with Big Pharma
- 2 INDs with mid-size pharma
- 2 INDs with small pharma

NDA planned Q4 2013

Quality Defined

Quality in clinical trials = the absence of errors that matter

What are “Errors that Matter”?

Errors that have a meaningful impact on

- Patient safety or
- Interpretation of trial results

What We Achieved (1)

- Dramatic reduction in on-site Monitoring visits and associated costs
- 90(+)% of data entered *during subject visits*
- Queries back to sites within hours
- Comfort level that sites were properly managing subject safety

What We Achieved (2)

- Numerous, rapid, mid-course corrections
  - Protocol changes
  - Additional sites
  - EDC form or edit-check changes
  - Site and monitor re-training
- Comfort level that sites understood and were following protocol
- Comfort level that study enrollment was consistent with sponsor expectations

Benefits of eCTR-enabled DDE

Predicated on:

1. Getting the data into the database early, i.e., in real-time
2. Reviewing the data early and often, coupled with
3. a willingness to act on the data

“All You Need is Love”

“All You Need is Love”

There's nothing you can do that can't be done.

…

It's easy.

There's nothing you can make that can't be made.

Very Sage

Why Innovating Is About Doing, Not Talking

From <http://www.linkedin.com/today/post/article/20130321172703-5935179-why-innovating-is-about-doing-not-talking>

"An idea not coupled with action will never get any bigger than the brain cell it occupied." - Arnold H. Glasgow

From <http://www.linkedin.com/home?trk=hb_tab_home>

Real-time data capture NOT coupled with "real-time" monitoring will yield little value.
"Real-time" monitoring NOT coupled with associated action plans (and willingness to take action) will also yield little value. – D. Gittleman

Very Sage

Misquoted from the review of the book, *The Power of Positive Deviance*

"…it is easier to act your way into a new way of thinking, than to think your way into a new way of acting…"

From <http://www.anecdote.com.au/archives/2010/07/book_review_the.html>

“There’s No Place Like Home”

“There’s No Place Like Home”

The ability to adopt 21st century clinical development processes is *not* a function of outside forces and obstacles

-- rather, it depends on internal *mind-set and willingness* to move past comfort zone.

You have had the capability all along.

Thank You

Dean Gittleman, Sr. Director of Operations
Target Health Inc.
261 Madison Avenue, 24th Floor, New York, NY 10016
dgittleman@targethealth.com
www.targethealth.com

TARGET HEALTH INC., founded in 1993, is a private, New York City-based, full-service eCRO, engaged in all aspects of Drug and Device Development, including Regulatory Affairs Strategic Planning, Clinical Research, Data Management, Biostatistics, Medical Writing and the paperless clinical trial.