



Scott Shaunessy
CSDR Co-founder and Chair
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Focus on great researcher experience

Simple, easy to use website and Request process



Most complete and trusted analytics platform:



SAS 9.4:

- SAS Studio
- SAS Enterprise Guide
- SAS Graph
- SAS Stat
- SAS Universal Viewer

Open Source



- | | |
|----------------------|-------------------------|
| • JAGS-4.2.0 | • Adobe Reader |
| • GTK+ | • Plink 1.07 |
| • WinBUGS | • Python 3.6.3 |
| • OpenBUGS | • Java 1.8 |
| • Excel viewer | • R version 3.4.3 |
| • Word viewer | • R Studio version .4.3 |
| • Apache Open Office | • 71 R Packages |

Licensed Commercial Software



Phoenix WinNonlin

- 2019 +++

Challenges and Solutions since 2013

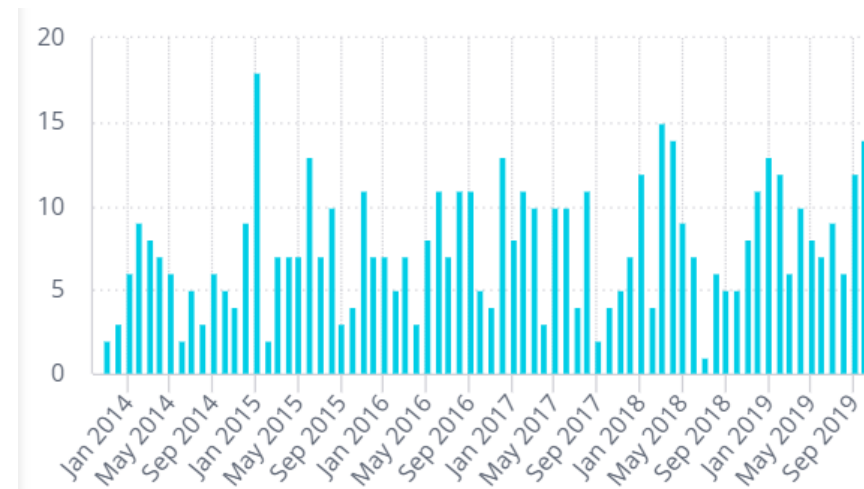
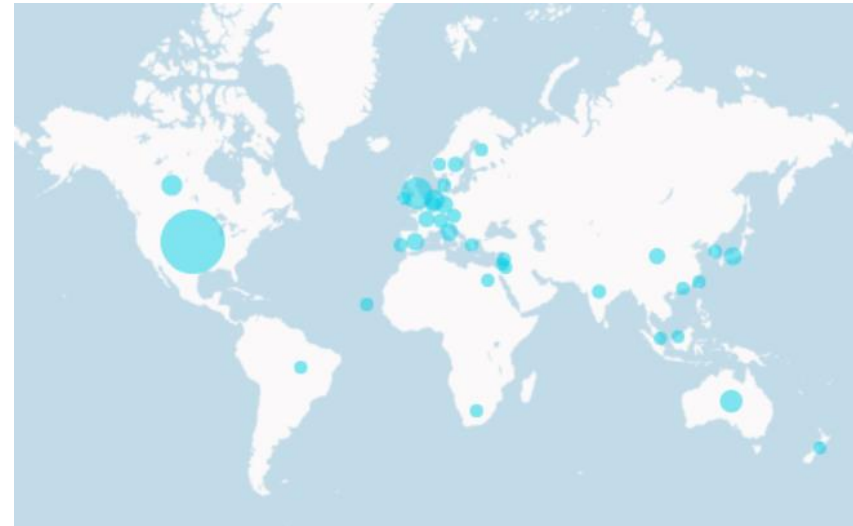
- Independent Review Panel (IRP)
 - Original IRP was selected by the members and not seen as truly independent. We approached Wellcome Trust in 2015 to select IRP and be secretariat. Result has been very successful. Rotating group of 5 IRP members including Jeffery Koplan MD (Emory University) as IRP Chair. Wellcome can also pull in therapeutic area experts as needed.
- Transparency
 - Our members want to be completely transparent about Metrics so we developed a metrics page which is updated quarterly (Metrics in later slide)
- Speed to research
 - Always an effort to reduce time from request to data access. There are several factors that can cause delays in process but biggest hold up is the signing of the Data Sharing Agreement.
 - All 15 companies have cooperated to develop a single DSA that is very favorable for the institution but still get redlines.
 - New- “Cycle Time” Metrics being released this week on ClinicalStudyDataRequest.com

Challenges and Solutions since 2013

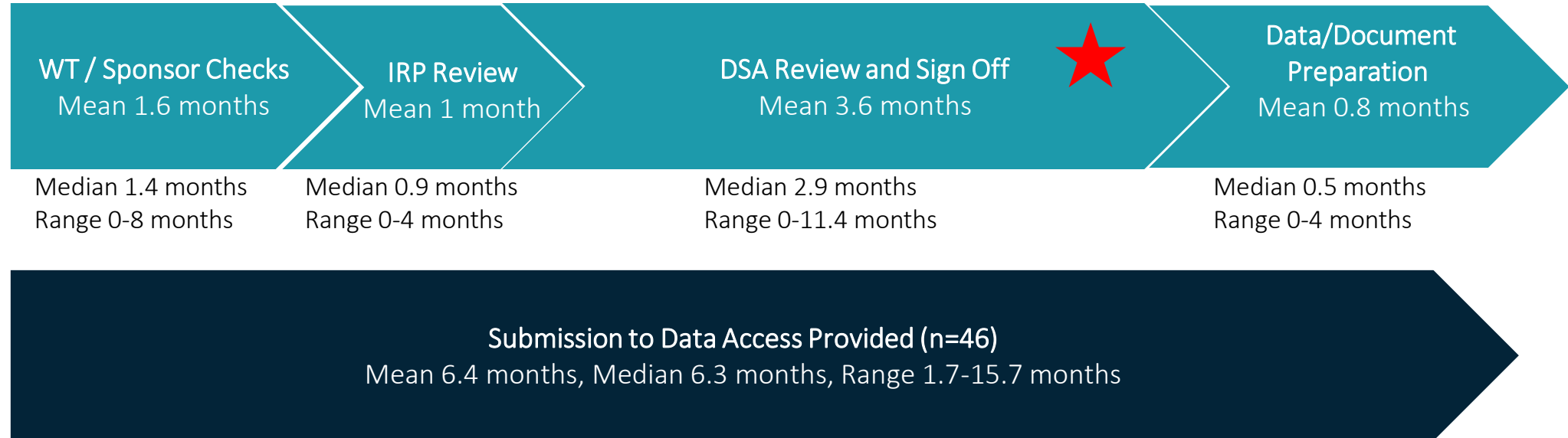
- Sharing data between other multi sponsor and single sponsor platforms
 - Many researchers are challenged with the issue of data being housed in various disparate sources. Multiple data sharing platforms, individual company systems, academic data platforms...
 - Sometimes, to do their research, they must actually conduct multiple parallel research projects and then try to combine results. A challenging task!
 - Data sharing platforms and companies need to come together to help solve this problem.
 - The result will be better research, better outcomes and the advancement of human health.

Results- since January 1, 2014

- Over 3,100 studies listed from 20+ data providers representing 100+ disease areas
- 543 research proposals submitted from 34 different countries
 - Steady stream of proposals each month
- 266 Data access projects initiated
- Over 60 published articles (about 35 more in process)



Cycle Times for Research Proposals submitted in 2018 (n=97)



Primary factors that affect the timelines:

- Institution's DSA review process
- Response to questions from IRP Secretariat
- Sponsor review meeting schedules
- Ongoing enquiry for studies not listed on CSDR

WT = Wellcome Trust Secretariat
DSA = Data Sharing Agreement
IRP = Independent Review Panel



DSA Review and Sign-off period can be greatly reduced if the [standard DSA](#) is accepted