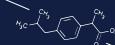


PhUSE 2017

Putting Sisypheus Out of a Job

Making healthcare-research a reality

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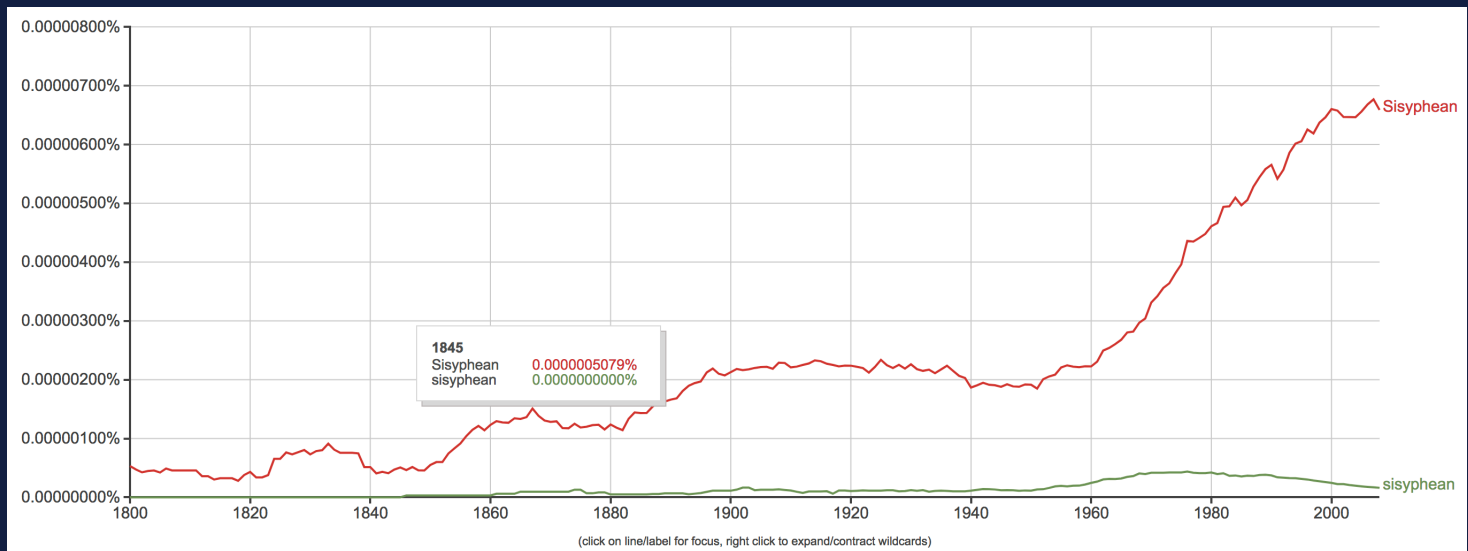
Sisyphean

/ˌsɪsɪˈfiːən/ 

adjective

adjective: **Sisyphean**

denoting a task that can never be completed.



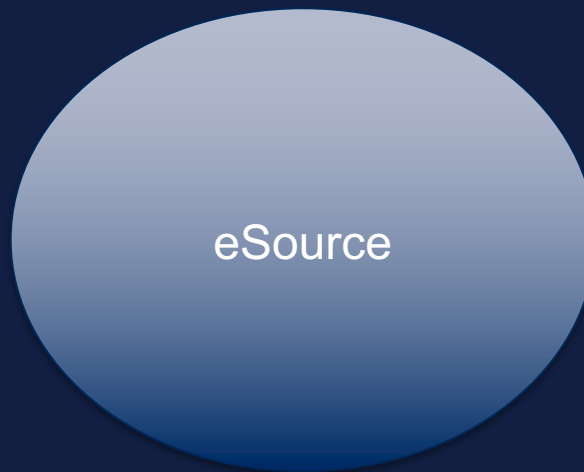
Google Books Ngram Viewer

What is driving the need for Healthcare Research?



Electronic Source Data in Clinical Investigations

FDA 2013



Eliminate unnecessary duplication of data

Reduce the possibility for transcription errors

Encourage entering source data during a subject's visit, where appropriate

Eliminate transcription of source data prior to entry into an eCRF

Facilitate remote monitoring of data

Promote real-time access for data review

Facilitate the collection of accurate and complete data

Duke Study – OB/GYN Registry (2015)

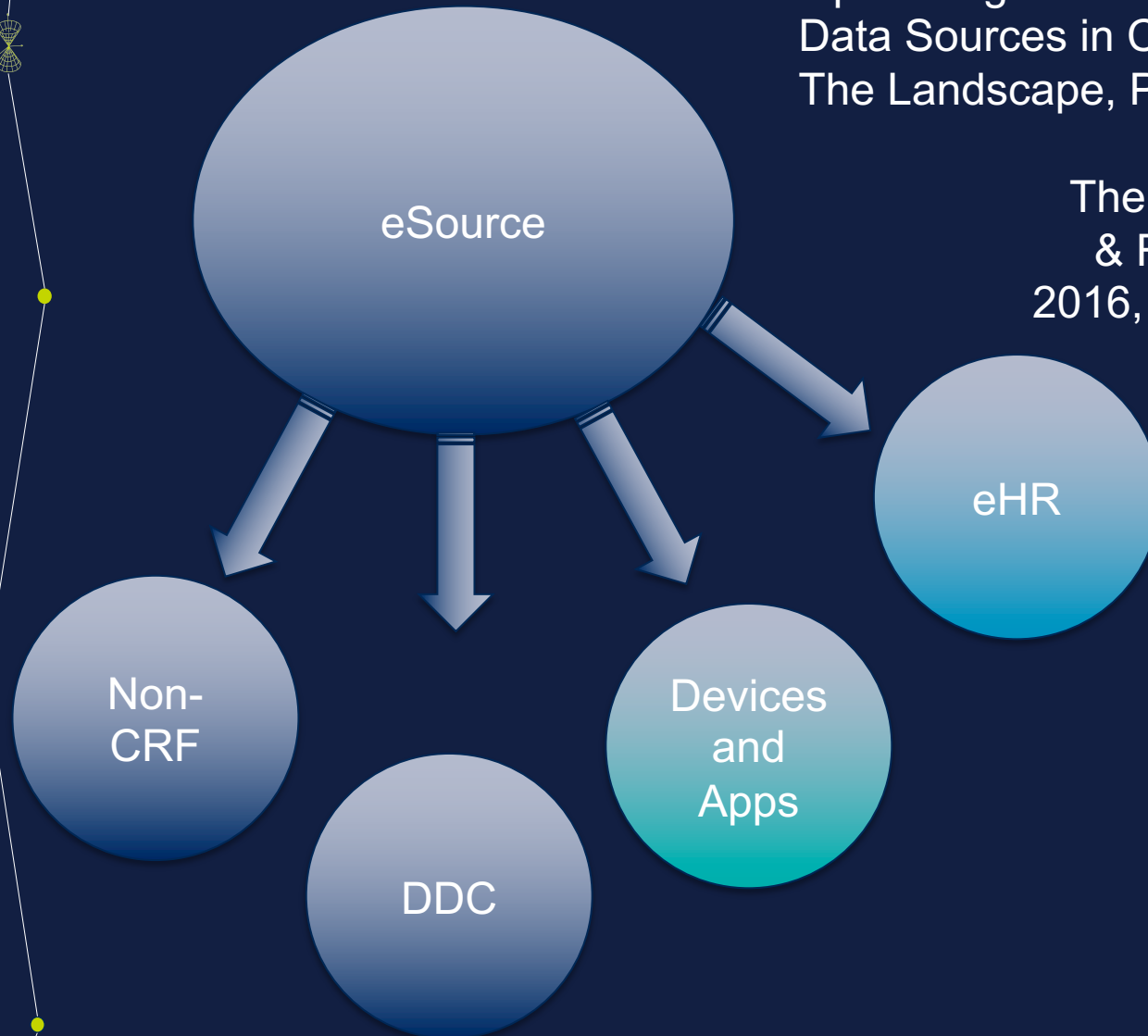
- Coverage was 10 of 400 total fields
- 37% reduction in time (eSource flow vs. traditional flow)
- 100% reduction in error rate for eSource data (from 9% → 0%)
- eSource Workflow required 1 less FTE

“A comparative effectiveness study of eSource used for data capture for a clinical research registry” – Nordo et. Al.

International Journal of Medical Informatics 103 (2017) 89–94

Optimizing the Use of Electronic Data Sources in Clinical Trials: The Landscape, Part 1

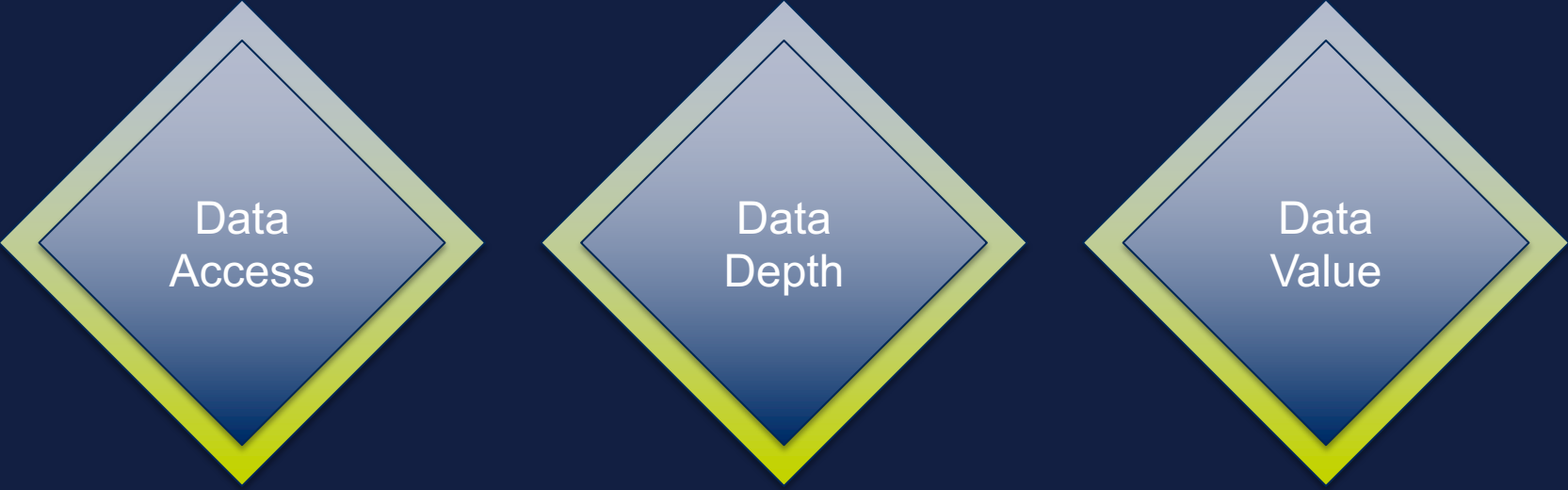
Kellar et al,
Therapeutic Innovation
& Regulatory Science
2016, Vol. 50(6) 682-696



What have been the blockers?



Commonly identified issues with EHR Data



Data
Access

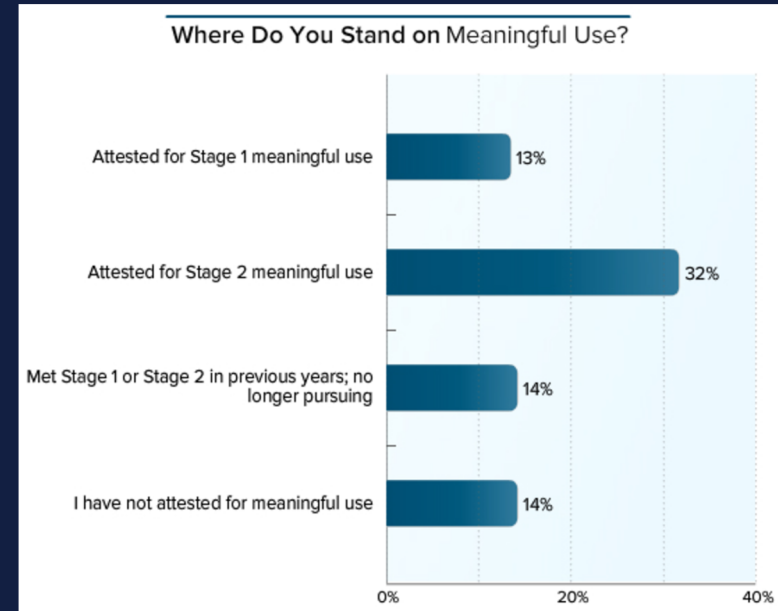
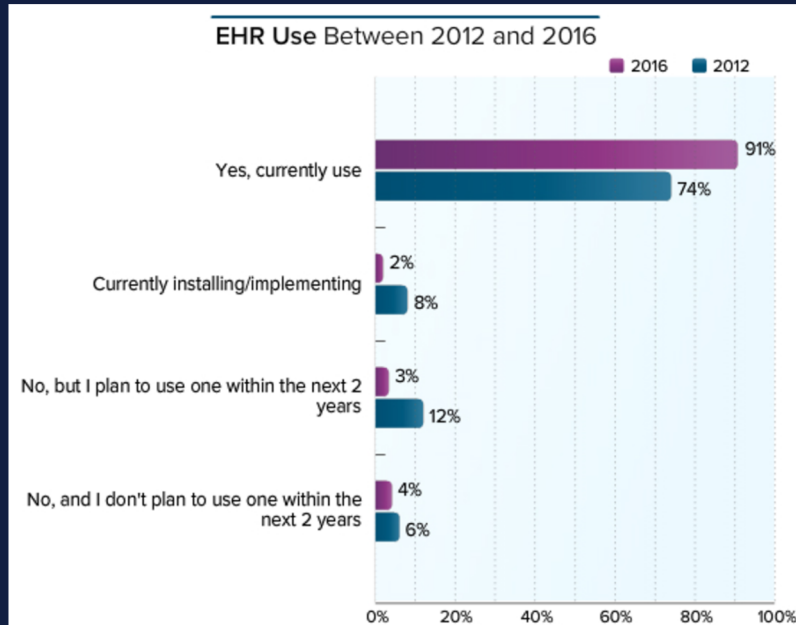
Data
Depth

Data
Value

Addressing Data Access



More healthcare centres are computerised (Medpace 2016)



Medscape EHR Report 2016: Physicians Rate Top EHRs
<http://www.medscape.com/features/slideshow/public/ehr2016>

Data export is integral

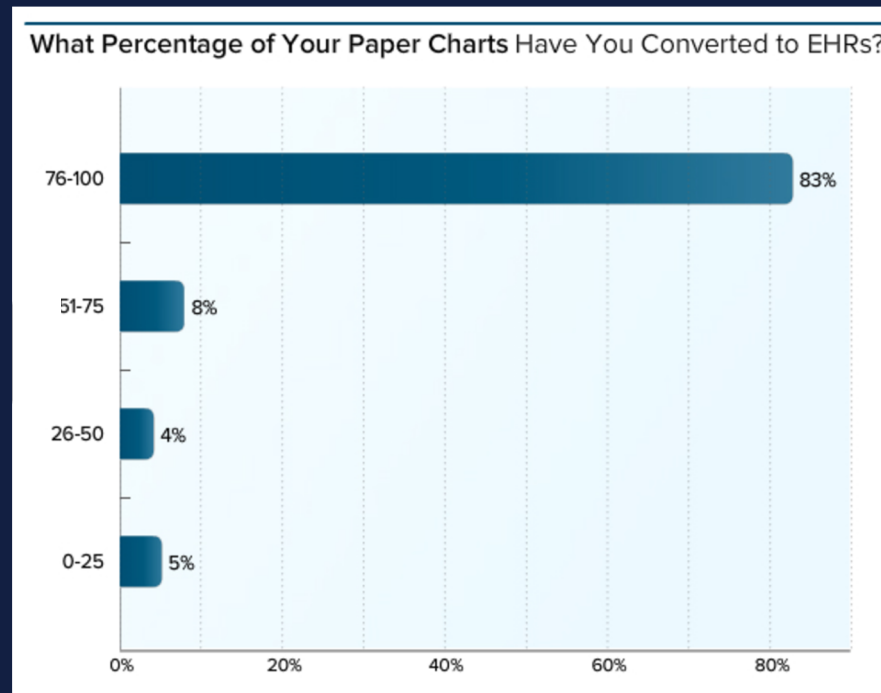
- Provide patients with an electronic copy of their health information (MU1)
 - HL7 Continuity of Care Document (CCD) as a converged standard
- Common Clinical Data Set (MU2/3)
 - Defined by the Office of the National Coordinator (ONC)
 - Includes: Demographic, Lab Results, Medications, Procedures...
 - Required to be centrally reported

https://www.healthit.gov/sites/default/files/commonclinicaldataset_ml_11-4-15.pdf

Addressing Data Depth and Value



More 'clinical' data are being captured in EHR systems (Medpace 2016)



Medscape EHR Report 2016: Physicians Rate Top EHRs
<http://www.medscape.com/features/slideshow/public/ehr2016>

Does the CCD address Data Access?



It must ... to a degree

- CCD forms the central communication modality for the prior Research Initiatives
 - Retrieve Form For Data Capture (RFD)
 - Retrieve Process for Execution (RFE)
 - Clinical Research Data Capture Profile (CRD)
- Profiles and initiatives... is it ready for (Meaningful) Use?
 - Yes, RFD is in some use
 - But is CCD more generally useable?

DM

```

<patient>
  <name use="L">
    <given>VICTORIA</given>
    <family>TEST</family>
  </name>
  <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1" codeSystemName="AdministrativeGenderCode" displayName="Female" />
  <birthTime value="19830122" />
  <maritalStatusCode code="Single" codeSystem="2.16.840.1.113883.5.2" codeSystemName="MaritalStatusCode" displayName="SINGLE" />
  <religiousAffiliationCode code="Other" codeSystem="2.16.840.1.113883.5.1076" codeSystemName="ReligiousAffiliation" />
  <raceCode code="2106-3" codeSystem="2.16.840.1.113883.6.238" codeSystemName="CDC Race and Ethnicity" displayName="WHITE" />
  <ethnicGroupCode codeSystem="2.16.840.1.113883.6.238" codeSystemName="CDC Race and Ethnicity" nullFlavor="UNK" />
  <languageCommunication>
    <languageCode code="ENG" />
    <preferenceInd value="true" />
  </languageCommunication>
</patient>

```

CM

```

<manufacturedMaterial>
  <code nullFlavor="UNK">
    <originalText>
      <reference value="#med3" />
    </originalText>
    <translation code="762004" codeSystem="2.16.840.1.113883.6.88" codeSystemName="RxNorm" displayName="Necon 1/50 (28) 1-50 Mg-McG Or Tabs" />
    <translation code="52544-245-31" codeSystem="2.16.840.1.113883.6.69" codeSystemName="NDC" displayName="Necon 1/50 (28) 1-50 Mg-McG Or Tabs" />
    <translation code="59716" codeSystem="2.16.840.1.113883.6.253" codeSystemName="Medispan Drug Descriptor ID" displayName="Necon 1/50 (28) 1-50 Mg-McG Or Tabs" />
    <translation code="25990002700310" codeSystem="2.16.840.1.113883.6.68" codeSystemName="Medi-Span Generic Product Identifier" displayName="Necon 1/50 (28) 1-50 Mg-McG Or Tabs" />
    <translation code="59716" codeSystem="2.16.840.1.113883.6.162" codeSystemName="Med-File (Medi-Span)" displayName="Necon 1/50 (28) 1-50 Mg-McG Or Tabs" />
  </code>
</manufacturedMaterial>

```

LB

```

<component>
  <observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.20.22.4.2" />
    <id root="1.2.840.114350.1.13.65.2.7.6.798268.2000" extension="92286755.1" />
    <code code="X11529-5" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="CYTOPATHOLOGY">
      <originalText>
        <reference value="#Result23Comp1Name" />
      </originalText>
    </code>
    <text>
      <reference value="#Result23Comp1" />
    </text>
    <statusCode code="completed" />
    <effectiveTime value="20130713133620" />
    <value xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:type="ED">
      <reference value="#Result23Comp1Value" />
    </value>
  </observation>
</component>

```

Initiatives for semantic interoperability

- **PhUSE KeyCRF**

- Embed Semantic Tags in ODM pointing to locations in a CCD

- **CDISC EHR to CDASH**

- Define the alignment between CDASH (and SDTM) Domains and Elements with CCD Sections
- Publish the mappings into CDISC SHARE
- Need more volunteers!

StudyDesign: Demographics (DM_1) [DM_UseCase1]

Demographics [DM_UseCase1]

1.*	Birth Date [Birth Date] //recordTarget/patientRole/patient/birthTime/@value	[BRTHDAT] [BRTHYR] Birth Year Req (2012-2014) [BRTHMO] Birth Month NReq
2.*	Sex [Sex] //recordTarget/patientRole/patient/administrativeGenderCode/@code	[SEX] [A:F] ☐ Female [A:M] ☐ Male
3.*	Ethnicity [Ethnicity] //recordTarget/patientRole/patient/ethnicGroupCode //recordTarget/patientRole/patient/sdtc:ethnicGroupCode	[ETHNIC] [A:HISPANIC OR LATINO] ☐ Hispanic or Latino [A:NOT HISPANIC OR LATINO] ☐ Not Hispanic or Latino [A:NOT REPORTED] ☐ Not reported [A:UNKNOWN] ☐ Unknown
4.*	Race [Race] //recordTarget/patientRole/patient/raceGroupCode //recordTarget/patientRole/patient/sdtc:raceGroupCode	[RACE] [A:AMERICAN INDIAN OR ALASKA NATIVE] ☐ American Indian or Alaska Native [A:ASIAN] ☐ Asian [A:BLACK OR AFRICAN AMERICAN] ☐ Black or African American [A:NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER] ☐ Native Hawaiian or Other Pacific Islander [A:WHITE] ☐ White

Key: [*] = Item is required

Better living through Resources - FHIR



The HL7 Fast Healthcare Interoperability Resource (FHIR)

- Created as part of a 'response' to the perceived failure of the HL7 v3 RIM
- Present the Patient record as a series of Resources (eg *Patient, MedicationAdministration, Procedure*)
- Allows CRUD using **simple** actions with **understood** semantics
 - Create – POST
 - Read – GET
 - Update – PUT, PATCH
 - Delete - DELETE

How will FHIR change the Data Capture Process?

- Everything is a URI
- Everything is Versioned
- Use a *Subscription* Resource
- SMART-on-FHIR
 - Patient Resource-level consent
 - Embeddable into EHR systems
- New Resources

Research Resources

- **ResearchStudy**

- A Resource representing a Study (including Arms, Study Intervention, Condition of Interest)
- <https://api-stu3.hspconsortium.org/clinresearch/open/ResearchStudy/16660>

- **ResearchSubject**

- A Resource representing a Study Participant (linking Patient to ResearchStudy)
- <https://api-stu3.hspconsortium.org/clinresearch/open/ResearchSubject/16661>

What are some of the challenges?

- **Standardisation of Adoption by Vendors (FHIR/CCD)**
 - Timelines
 - Cost
- **Approaches to Patient Privacy**
 - GDPR, HIPAA
- **International variations**
- **Operational issues**
 - Data cleaning
 - Research datapoints
 - Controlled Terminology

How we are engaging

- **HL7 Connectathon Events**
 - Baltimore, San Antonio, Madrid, San Diego
 - New Orleans (Jan 2018)
- **Transcelerate eSource Workgroup**
 - Sponsorship of San Diego Event
- **Biomedical Research and Regulatory (BR&R) group**
- **PhUSE Research on FHIR Group (1330 today, RW04)**

Who was Sisyphus?



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Sisyphus – Greek King a ‘Criminal’

- Denied Zeus to ease the plight of his subjects.
- Created a world where there was no more death through wit, intelligence and guile.