



NIH Collaboratory
Health Care Systems Research Collaboratory

Data Quality Assessment Recommendations

Steering Committee Meeting, August 19-20, 2014
Bethesda, MD

Meredith Nahm Zozus, PhD
Assoc. Director, Clinical Research Informatics
Duke Translational Medicine Institute

Rethinking Clinical Trials



Data Quality Assessment Recommendations v1.0

Initiated by

1. Inventory of data sources and data quality assessment plans proposed in first round UH2 applications,
2. UH3 review criteria requiring data validation



Guiding Principles

- Need to demonstrate that data on which conclusions are based are capable of supporting them
- Should not assume use of a common data model for individual research projects
- Recommendations should be practical and reasonably achievable



Iterative Development

- Started with literature review
- Four versions reviewed by the PDSDQ core
- Last version/s reviewed by leadership of the EHR and Biostatistics Cores
- Presented to a PCORI data quality working group
- Reviewed by HCS Collaboratory for publication release
- Released in July 2014

Located in Knowledge Repository

Browser address bar: <https://www.nihcollaboratory.org/Pages/Knowledge-Repository.aspx>

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Health Care Systems Research Collaboratory

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Knowledge Repository

A collection of Collaboratory documents and resources.

Stakeholder Interviews

Type	Name	Description
	Betsy-Wilder	Betsy Wilder, Director of Office of Strategic Coordination of the NIH Director - NIH Common Fund, discusses the Health Care Systems Research Collaboratory at the October 2012 Steering Committee meeting.
	Catherine-Meyers	Catherine Meyers of the NIH's Office of Clinical Regulatory Affairs discusses the Health Care Systems Research Collaboratory at the October 2012 Steering Committee meeting.
	Ed-Hammond	W. Ed Hammond of Duke University discusses the Health Care Systems Research Collaboratory at the October 2012 Steering Committee meeting.
	Gary-Rosenthal	Gary Rosenthal discusses his Demonstration Project at the October 2012 Steering Committee meeting.
	Jeremy-Sugarman	Jeremy Sugarman of the Johns Hopkins Berman Institute for Bioethics discusses the Health Care Systems Research Collaboratory at the October 2012 Steering Committee meeting.

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Collaboratory Products

Title	Name	Description
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Archived Grand Rounds

Title	Name	Presenter	Date	Collaboratory Affiliation
TRANSFoRm: European Perspectives on Implementing the Learning Healthcare System	Grand-Rounds-08-01-14	Corrigan, Derek; Curcin, Vasa; Delaney, Brendan	8/1/2014	Kings College London; Royal College of Surgeons
TRANSFoRm: European Perspectives on Implementing the Learning Healthcare System	GR Slides 08-01-14	Corrigan, Derek; Curcin, Vasa; Delaney, Brendan	8/1/2014	Kings College London; Royal College of Surgeons
Health System Leaders Working Toward High-Value Care Through Integration of Care and Research	Grand-Rounds-07-25-14	Larson, Eric	7/25/2014	Group Health Research Institute
Health System Leaders Working Toward High-Value Care Through Integration of Care and Research	GR Slides 07-25-14	Larson, Eric	7/25/2014	Group Health Cooperative; Group Health Research Institute
The Ethics and Regulatory Landscape: Is a Massive Public Campaign Needed?	Grand-Rounds-07-18-14	Terry, Sharon; Califf, Robert	7/18/2014	Genetic Alliance; Duke University; Duke University Medical Center

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Recommendations

- 1 - Key data quality dimensions to be measured
- 2 - Description of formal of assessments
- 3 - Reporting data quality assessment with research results



Recommendation 1

Accuracy, completeness, and consistency be formally assessed for data elements used in subject identification, outcome measures, and important covariates.

Why? These are most impactful on the ability of data to support research conclusions.



Recommendation 2

Specifics for measuring accuracy, completeness and consistency

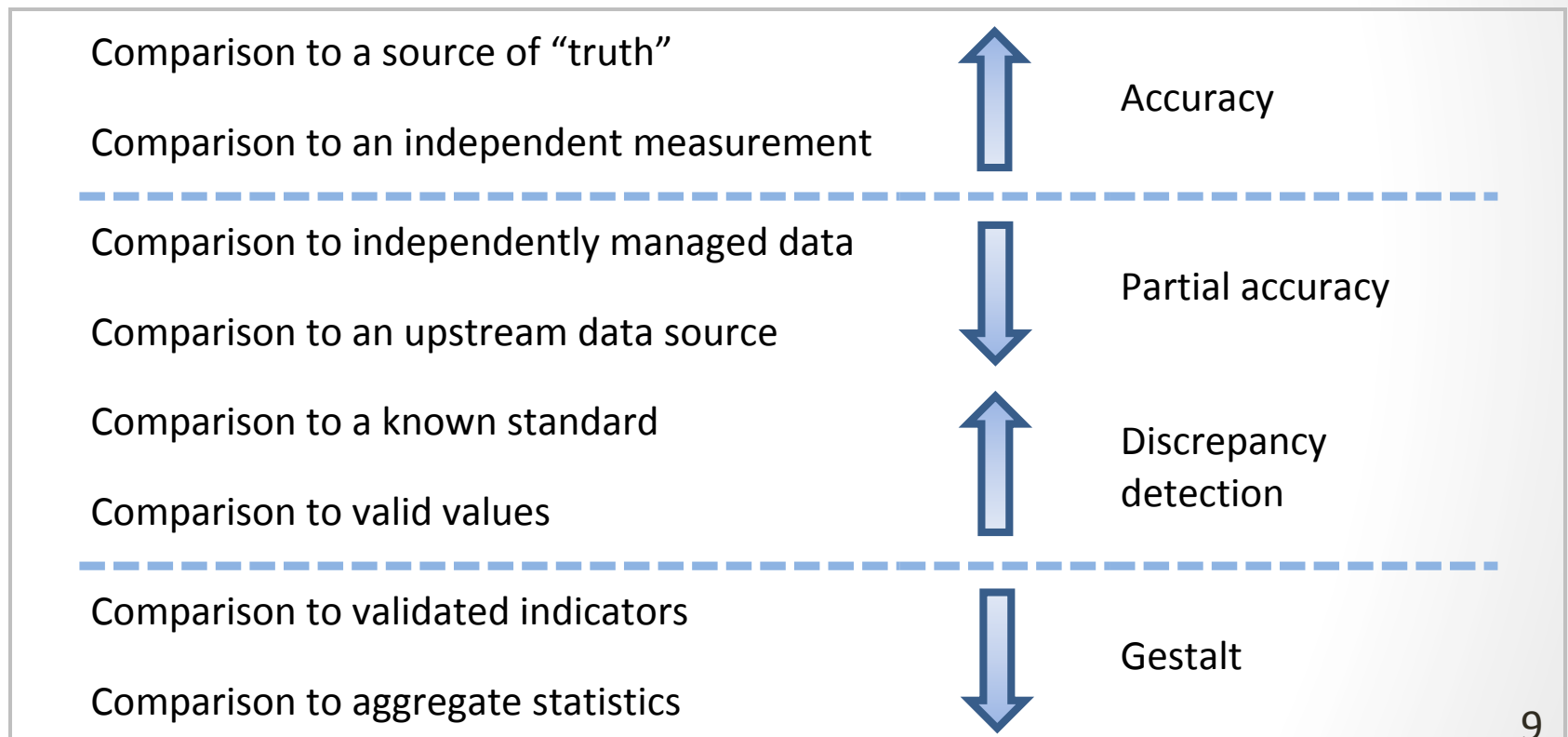
Completeness assessment recommendation:

- four-part completeness assessment.
- Same column and data value completeness measures can be employed for monitoring completeness during the study.
- The completeness assessment applies to both prospectively collected and secondary use data.
- Additional requirements suggested by the Good Clinical Data Management Practices (GCDMP) document, such as on-screen prompts for missing data where appropriate, apply to data collected prospectively for a study.

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Recommendation 2 cont.

The highest practical accuracy assessment in the hierarchy should be used



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Recommendation 2 cont.

Consistency assessment recommendation: Identification of:

- a) areas where differences in clinical documentation, data collection, or data handling may exist between individuals, units, facilities, sites, or assessors, or over time and
 - b) measures to assess consistency and monitor it throughout the project.
- A systematic approach to identifying candidate consistency assessments should be used. Such an approach will likely be based on review of available data sources, accompanied by an approach for systematically identifying and evaluating the likelihood and impact of possible inconsistencies.
 - This recommendation applies to both prospectively collected data and secondary use data.

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Recommendation 2 cont.

Impact assessment recommendation: Use of completeness, accuracy, and consistency assessment results by the project statistician to test sensitivity of the analyses to anticipated or identified data quality problems, including a plan for reassessing based on results of data quality monitoring throughout the project.



Recommendation 3

Data quality assessments should be reported with research results.



Acknowledgements

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