Finding Value in Sharing Clinical Trial Data: Overcoming Usability and Sustainability Challenges

Monica M. Bertagnolli, MD
Dana-Farber/Brigham & Women’s Cancer Center
Alliance for Clinical Trials in Oncology
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Data sharing as a fundamental goal

Characteristics of a successful trial:

- Answers important questions
- Achieves timely accrual of appropriately representative patients
- Addresses disparities
- Generates high quality data
- Creates resources for future use
  - data
  - biospecimens
Alliance Participation in the NCI’s National Clinical Trials Network:
65 Years of Multi-institutional Clinical Trials Data

1955: Protocol #1 for patients with acute leukemia
   – 4 institutions, carbon copies

2007: ACCENT Group established
   – Adjuvant therapy of colon cancer

2010: 68 trials enrolling
   – 7 semi truck loads of paper

2011: Adoption of NCTN-wide electronic data management system

2015: NCTN-NCORP Data Archive
Platforms for Alliance Data

NCTN/NCORP studies published on or after January 1, 2015

“legacy” trials: studies completed before availability of NCTN/NCORP Data Archive

Biospecimens linked to clinical trials data

Germline genomic analyses linked to clinical trials data

All other requests
Alliance contributions 2015-2019

38 publication datasets
33 unique trials

22 publication datasets
20 unique trials

40 unique trials
23,337 patients, 355,570 specimens
15 requests completed

5 IRB-approved data transfers
4 unique trials
DATA SHARING REQUESTS

Per National Cancer Institute's National Clinical Trials Network (NCTN) guidelines, any investigator may submit a request for data from published Alliance or legacy American College of Surgeons Oncology Group (ACOSOG), Cancer and Leukemia Group B (CALGB), or North Central Cancer Treatment Group (NCCTG) trials.

To submit a data request, the investigator should complete an Alliance Data Sharing Request Form and send it by e-mail to concepts@allianceNCTN.org. Once received, the request will be forwarded to the Alliance Statistics and Data Center (SDC). The SDC will confirm the availability of the data. Once the SDC confirms availability, the investigator will be asked to provide documentation of Institutional Review Board (IRB) approval or exemption from their institution, as well as to submit an Alliance Data Release Agreement. Once the IRB documentation and the data release agreement are received from the requesting investigator, the SDC will be notified that the requested data may be released.

143 data sets shared
100 external collaborators
43 Alliance members

January to October, 2019
28 data requests received
15 completed
A high-quality clinical research program will always saturate the capabilities of its Statistics and Data Center.
Data quality monitoring

Results analysis and manuscript preparation

New study design

DSMB and funding agency reports

Data use requests
Motivation

- Publications list the source of the data
- Co-authorship when significant contributions to the new knowledge is generated by the shared activity
- Funding agencies make data sharing a condition of awards and provide resources to support this activity
- Core values: Responsibility to clinical trials participants to share data in ways that bring the most benefit to society
What makes Alliance data sharing possible?

• **Planning** for data use
  – Contracts and agreements
  – Consent

• **Data Standards**
  – Standard data formats
  – Electronic data capture

• **Resources** specifically for data sharing
  – Alliance Data Sharing Working Group
  – Additional available platforms
Alliance Data Sharing Champions

Selina Chow, MD
Chair, Alliance Data Sharing Working Group
University of Chicago

Sumithra Mandrekar, PhD
Alliance Group Statistician
Mayo Clinic Rochester

Mark Watson, MD
Alliance Biorepository Director
Washington University School of Medicine