

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

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Disclosures:

none relevant to today's discussion

- Research funding to the Alliance for Clinical Trials in Oncology Foundation
 - AbbVie
 - Agenus
 - Astellas
 - AstraZeneca
 - Baxalta
 - Bayer HealthCare
 - Breast Cancer Research Foundation
 - Bristol-Myers Squibb
 - Celgene
 - Complion
 - Czarnowski
 - Derse, Inc.
 - Eisai
 - Exelixis
 - Genentech
 - GHI
 - Gilead Sciences
 - GSK Total
 - Incyte Corporation
 - Janssen
 - Jazz Pharma
 - Leap Therapeutics
 - Leidos
 - Lexicon Pharma
 - Lilly
 - Maltrex
 - Merck
 - Millennium
 - Novartis
 - Pfizer
 - Pharmacyclics
 - Robert Wood Johnson Foundation
 - Roche/Genentech
 - Sagerock Advisors
 - Sanofi
 - STO
 - Syntalogic
 - Taiho Oncology
 - Takeda
 - Tesaro
 - Teva

NCI

**National Clinical
Trials Network**



ECOGACRIN
cancer research group
Reshaping the future of patient care

**CHILDREN'S
ONCOLOGY
GROUP**



NRG
ONCOLOGY

Advancing Research. Improving Lives.™

Canadian Cancer
Trials Group



Groupe canadien
des essais sur le cancer

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



NATIONAL CANCER INSTITUTE
NCTN/NCORP Data Archive

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

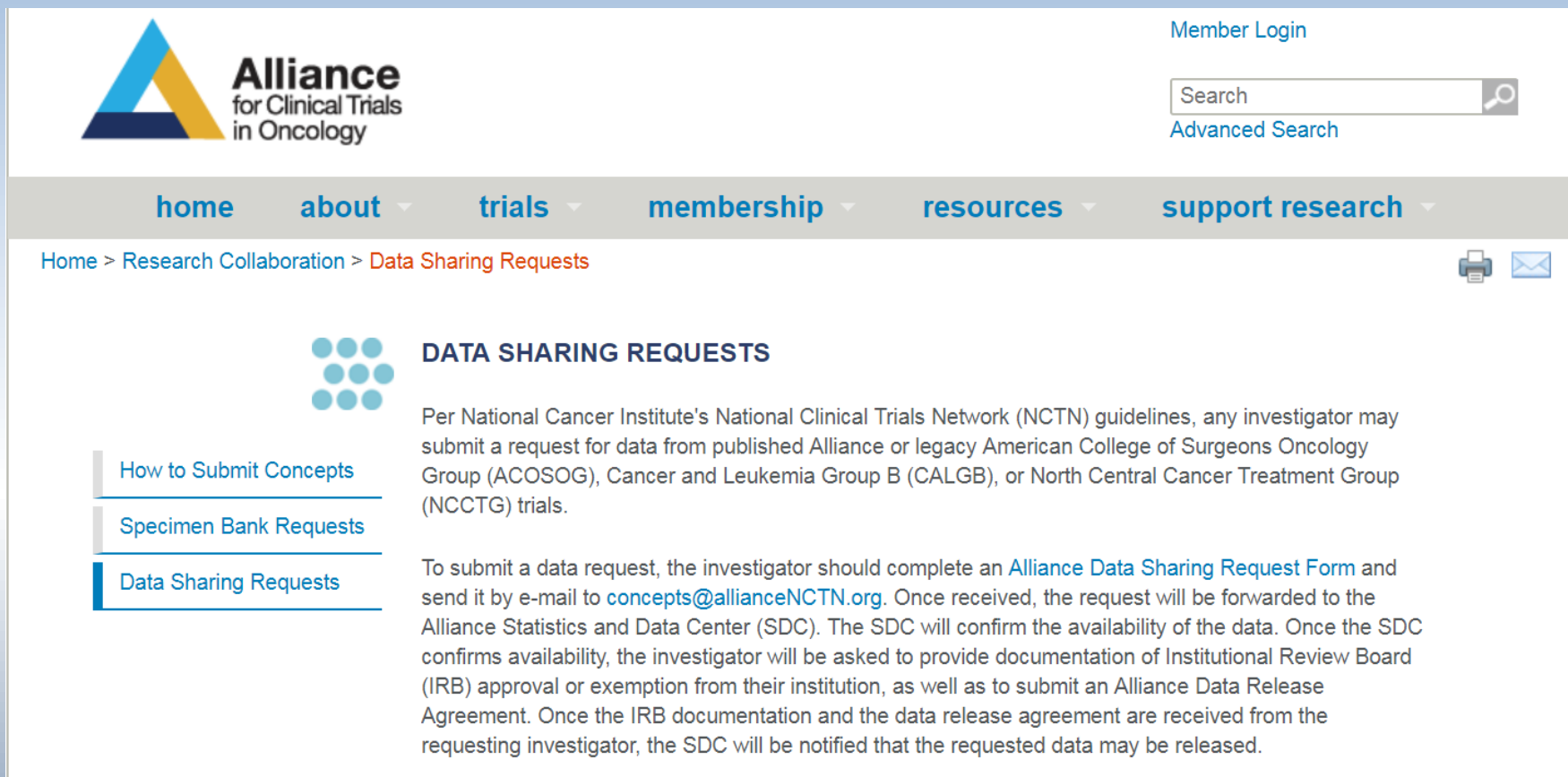


40 unique trials
23,337 patients, 355,570 specimens
15 requests completed



5 IRB-approved data transfers
4 unique trials

Alliance contributions 2015-2019



The screenshot shows the Alliance for Clinical Trials in Oncology website. The header includes the Alliance logo, a search bar, and a Member Login link. The navigation menu has links for home, about, trials, membership, resources, and support research. The main content area is titled 'DATA SHARING REQUESTS' and includes a sidebar with links for 'How to Submit Concepts', 'Specimen Bank Requests', and 'Data Sharing Requests'. The main text explains the process for submitting data sharing requests, mentioning NCTN guidelines and the need for IRB approval.

Alliance
for Clinical Trials
in Oncology

Member Login

Search
Advanced Search

home about trials membership resources support research

Home > Research Collaboration > Data Sharing Requests

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

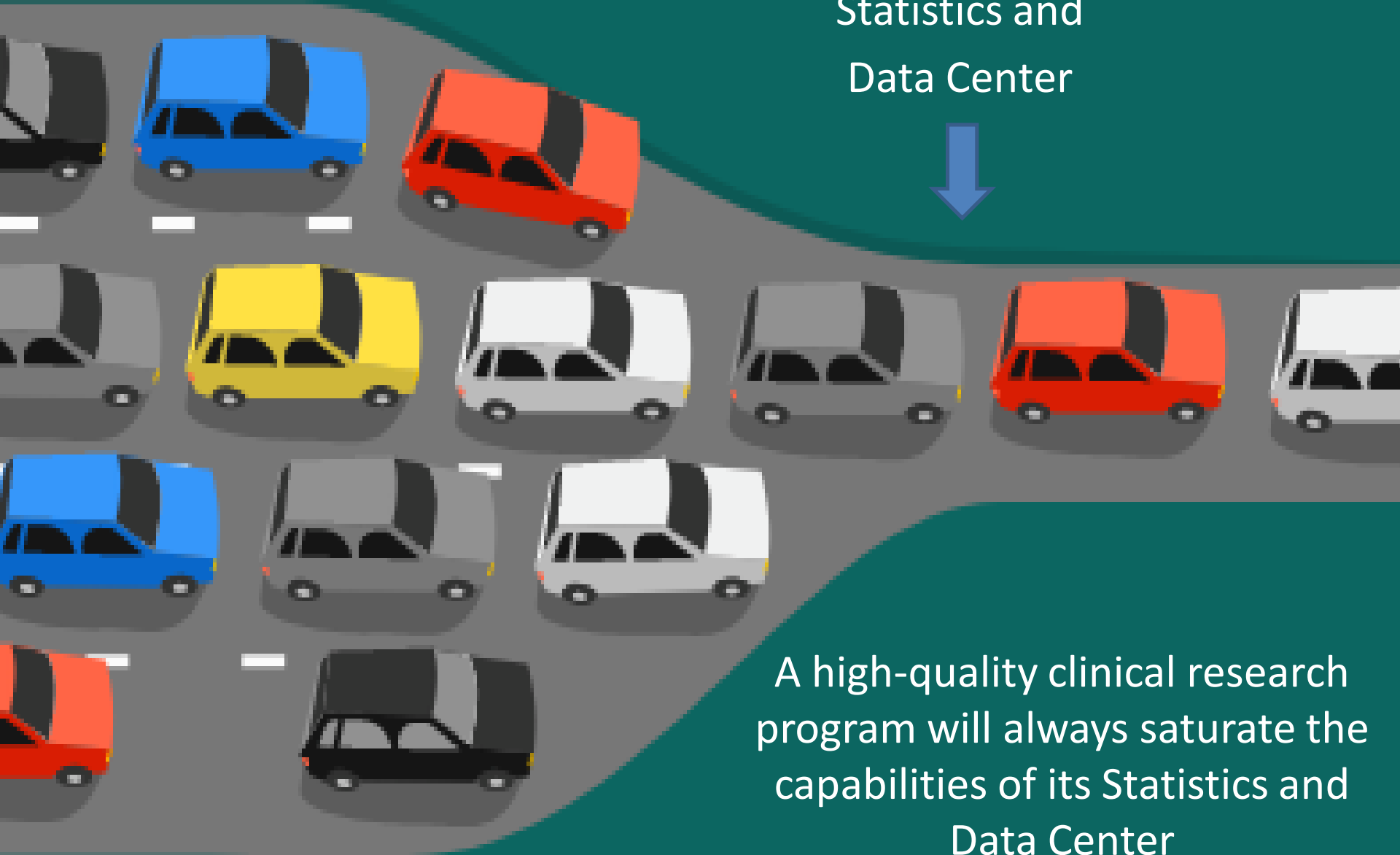
15 completed

Researcher Demands

Statistics and
Data Center



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

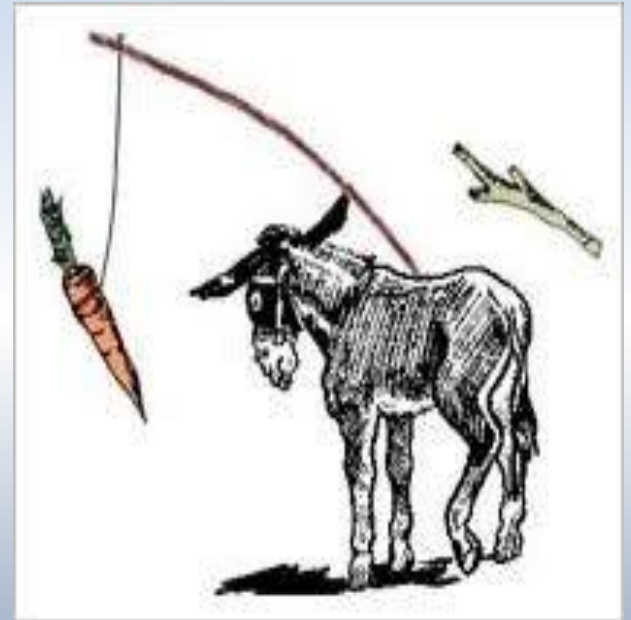
DSMB and funding
agency reports

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
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