

# Modeling the Dissemination and Uptake of Clinical Trials Results

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# HANC's Role and Mission

- HANC works with the six HIV/AIDS clinical trials networks funded by the Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID) with the ***intent of creating a more integrated, collaborative and flexible research structure.***
- HANC's mission is to support the science and operations of the networks by ***increasing efficiency and resource-sharing*** through coordination of critical activities across networks and with other research and advocacy partners.

# NIAID HIV/AIDS Clinical Trials Networks



# HANC Website Feature: Locator map of all NIAID HIV/AIDS Clinical Trial Network Research Sites



[www.hanc.info/resources](http://www.hanc.info/resources)



# Overall Evaluation Goals

- Develop an integrated evaluation system to support the success of DAIDS and its programs.
- Provide empirically based evidence about process and outcomes to guide decision making and program improvement.
- Ensure the highest scientific priorities are addressed.
- Promote collaboration and shared learning.
- Increase efficiency and research integration.
- Develop a culture of ongoing evaluation.

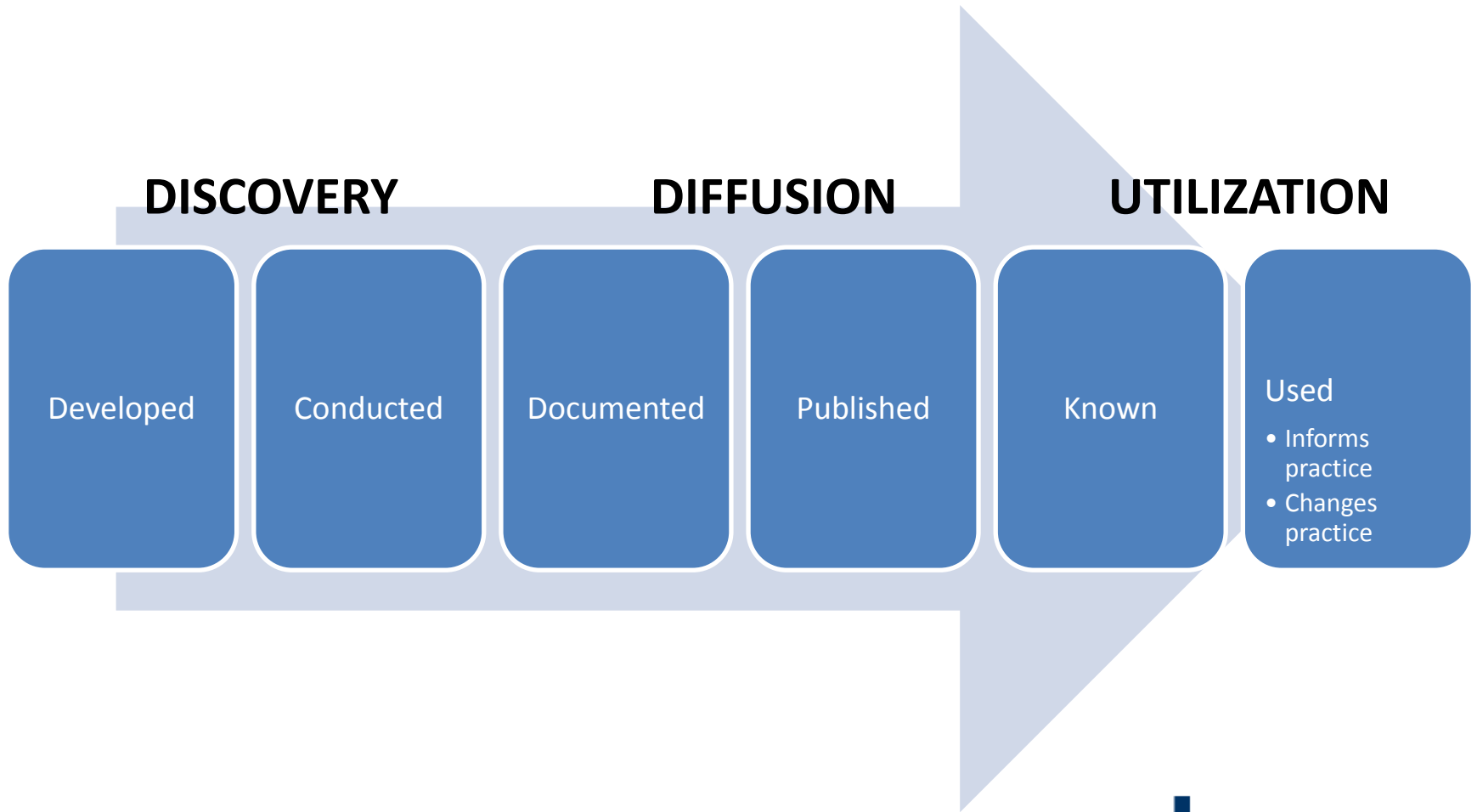
# Assessing the Impact of Scientific Research

- Most models of translational research frame the progression of knowledge through **multiple phases**:
  - In the initial phase, new clinical research knowledge is ***generated*** through systematic study, published and widely disseminated, and subsequently incorporated in the synthesized literature that specifically includes meta-analyses, systematic reviews, and guidelines.
  - In the second major phase, this emerging, synthesized knowledge is broadly disseminated and ***utilized*** in the context of practice-based research, ultimately leading to improved health outcomes.

# Assessing the Impact of Scientific Research

- More specifically, clinical research advances through **several periods:**
  - a) Development and refinement of clinical research ideas and hypotheses through peer group interactions.
  - b) Early planning, protocol development, and submission for scientific and regulatory approvals.
  - c) Study implementation and performance.
  - d) Data analysis and interpretation, presentation, and publications of results.
  - e) Translation of research results into clinical or community practice.

# Modeling the Translational Timeline





# Background

- This phased approach, however, is insufficiently precise for evaluation, and instead some argue the need for **measurable markers** along the translational pathway from research to practice [1].
- As an indicator of research utility, inclusion of **published research in the synthesized literature base** can be considered an intermediate outcome, preceding a change in clinical practice [2].
- Previous work has emphasized the use of citation analyses as a means for **studying patterns of flow** of published material within a field [3].

# Study Purpose and Objectives

- **Purpose:** Using a process marker approach, examine the feasibility of integrating time interval and citation data to model the progression, dissemination, and uptake of primary research findings.
- **Focus:** Describe the length of time (duration) needed to reach several segments of the translational research process.
- **Primary Question:** What can we learn about research dissemination from examining the entire timeline of a subset of highly recognized studies?

# Study Purpose and Objectives

## Sub Questions:

- What are the timing patterns for diffusion and utilization?
  - From publication, what do citation patterns tell us about how the research output is becoming “known”?
  - How have the studies been incorporated in the synthesized literature including meta-analyses, systematic reviews, and guidelines?

# Sample of Publications

- We selected **22 publications** from the NIAID HIV/AIDS Clinical Trials Networks from an initial set of 419 publications, published between the years of 2006-2008 [4].
- These 22 publications were the initial results of **primary studies (main, interventional)** and were considered highly valued work within the research enterprise.
- All 22 publications were within **the top 10%** of highly cited papers.

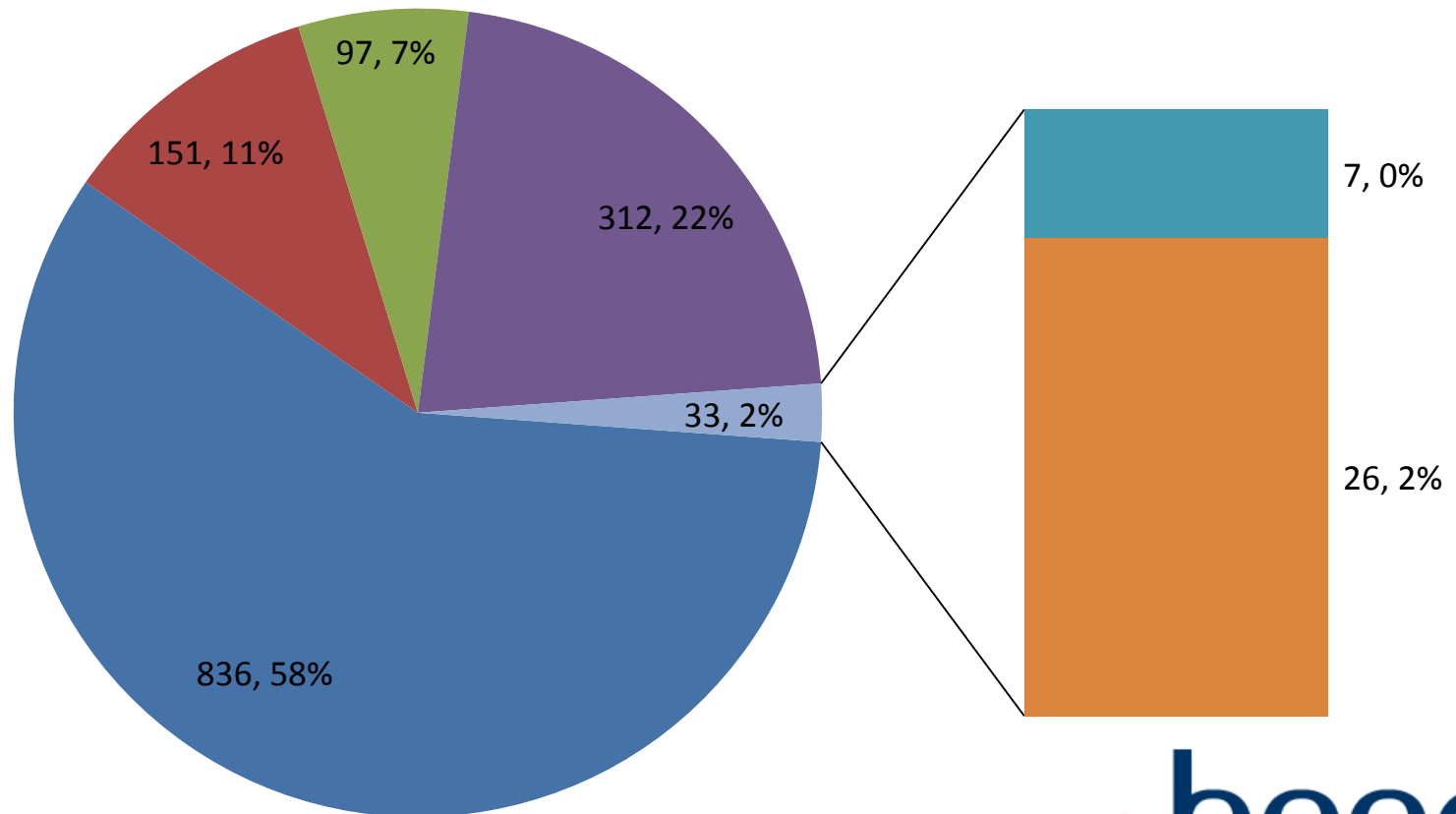
# Methodology

- For the 22 network primary study publications, we evaluated **time to publication** from study initiation and subsequent **time to citation and dissemination** in secondary outputs.
- Using the dates as markers and analyzing the intervals between markers, we were able to **model individual timelines** for each clinical protocol and the subsequent published results.
- We examined these patterns individually and collectively within specific intervals, as well as across the entire timeline.

# Citations for 22 Papers

## Distribution of all 1429 Citations: 2006-2010

■ Article   ■ All Other   ■ Proceeding Paper   ■ Review   ■ Meta-Analysis   ■ Guideline



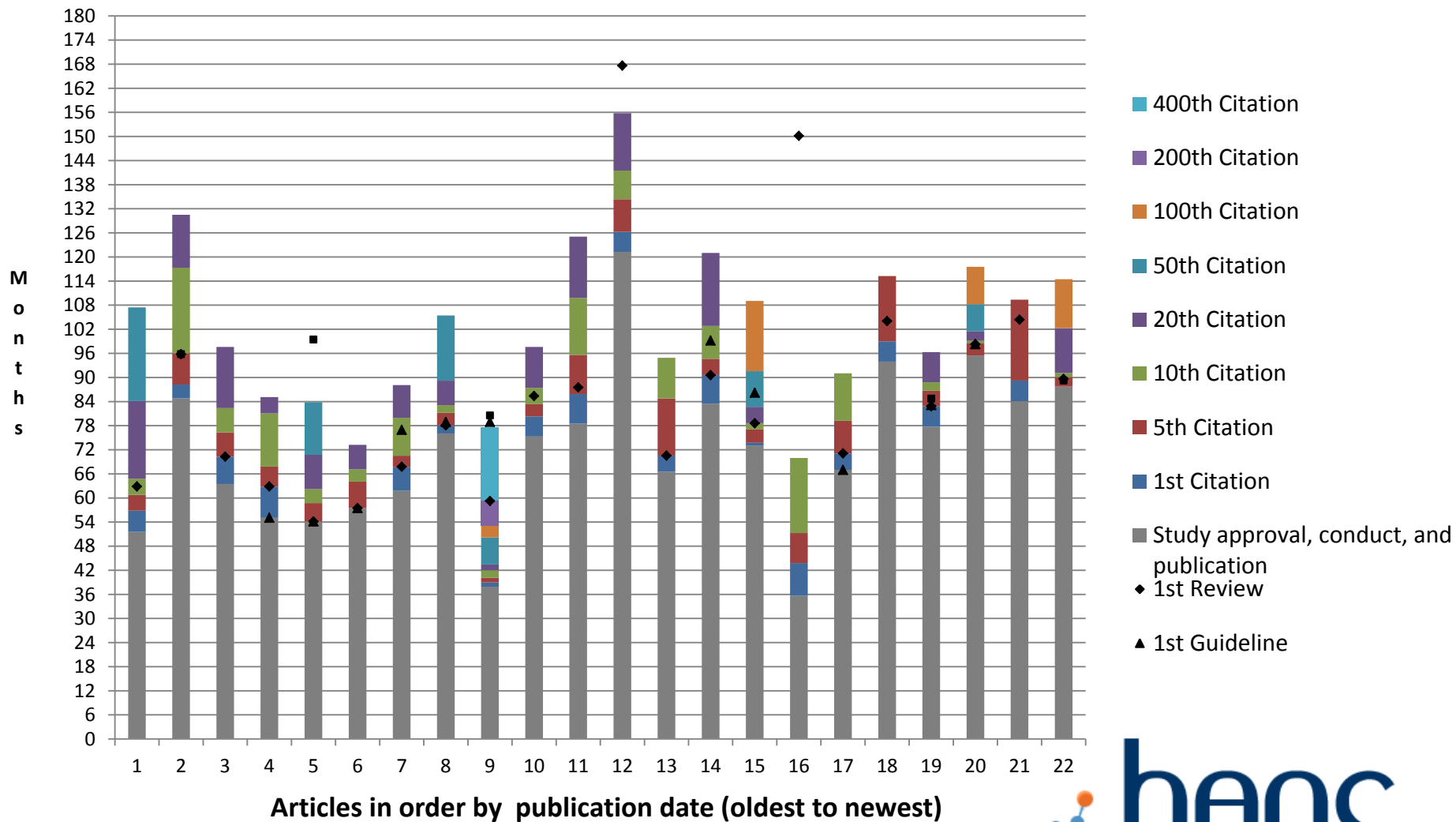
# Results

## Time (in Months) to Event – Descriptive Characteristics of Sample of 22 Papers

	N	Mean	SD	Med	Min	Max
Study approval, conduct, publication	22	71.90	19.75	74.14	35.65	121.25
1st citation from publication	22	4.05	2.75	5.00	.00	8.10
5th citation from publication	22	6.58	4.82	4.80	1.20	20.10
10th citation from publication	20	7.19	6.06	5.10	.70	21.30
20th citation from publication	17	9.71	5.46	8.50	1.50	19.30
50th citation from publication	7	10.71	7.55	8.90	.10	23.30
100th citation from publication	4	10.50	6.04	10.75	3.00	17.50
200th citation from publication	1	6.20	.	6.20	6.20	6.20
400th citation from publication	1	18.10	.	18.10	18.10	18.10
Time from publication to 1 <sup>st</sup> Review	22	13.96	24.56	6.95	.00	114.48
Total time until 1 <sup>st</sup> Review	22	85.87	28.03	80.71	54.14	167.64
Time from publication to 1 <sup>st</sup> Guideline	11	8.74	12.40	2.90	.00	41.03
Total time until 1 <sup>st</sup> Guideline	11	75.94	15.95	78.95	54.14	99.18
Time from publication to 1 <sup>st</sup> Meta-analysis	5	21.48	20.81	11.00	1.50	45.30
Total time until 1 <sup>st</sup> Meta-analysis	5	89.95	7.75	89.23	80.55	99.44

# Results

## Primary Studies Dissemination Landscape





# Results

- On average, the 22 primary studies took about **6 years** to complete the review, conduct, and results publication process.
- From the point of publication, most of the 22 papers were included in **secondary outputs** within 2 years.
- About two-thirds of papers had reached the **20<sup>th</sup> citation milestone** within 3 years.
- Half of the papers were cited in a **published clinical guideline**; on average they were cited within 1 year.

# Results

- Compared to earlier studies of clinical research, these findings suggest that **select HIV/AIDS trial results are disseminated and utilized relatively rapidly.**
- The **average influence** of the publishing journal's articles over the first 5 years after publication was strongly related to the pace of uptake in the peer review literature.
- However, the **status of the journal**, based on citation metrics, in which the primary studies papers were published had no influence on when it was included in synthesized research.

# Discussion

- Unique to this examination is the integration of citation milestones as indicators or markers of the progression of study findings in the peer reviewed literature.
- Although our sample was small, this approach may be useful in **future bibliometric analyses** with larger numbers of protocols and their primary outputs.
- We can use bibliometrics data to track citation trends on the individual and group article level, and where appropriate, create **time-oriented benchmarks**.
- We can integrate the timing data to **quantitatively gauge** how this HIV/AIDS clinical trials program is informing research and practice.

# Discussion

- We posit that not only can citation data be used to assess the dispersion of published work, but the **rate of speed** at which it moves.
- We suggest that by delineating *when* a publication reaches a particular milestone, the interval from the previous milestone can reveal much about the pace of uptake.
- Instead of the focus being placed exclusively on the **volume** of citations as a means of indicating utilization of research outputs, this illustration focuses on the rate of uptake as a more dynamic indication of dissemination and utilization.

# Acknowledgements

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- The HANC evaluation projects are conducted in collaboration with Concept Systems, Inc. and the National Institute of Allergy and Infectious Diseases.

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