

# A Framework for Evaluating Large Scale Acquired Immune Deficiency Syndrome (AIDS) Clinical Research Networks

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American Evaluation Association, Baltimore, MD  
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# Biomedical Research: Evaluation Context

- Increased biomedical research funding 1947-2006
- Shift to “big science”
- Two recent, major reports
- Government wide accountability movement

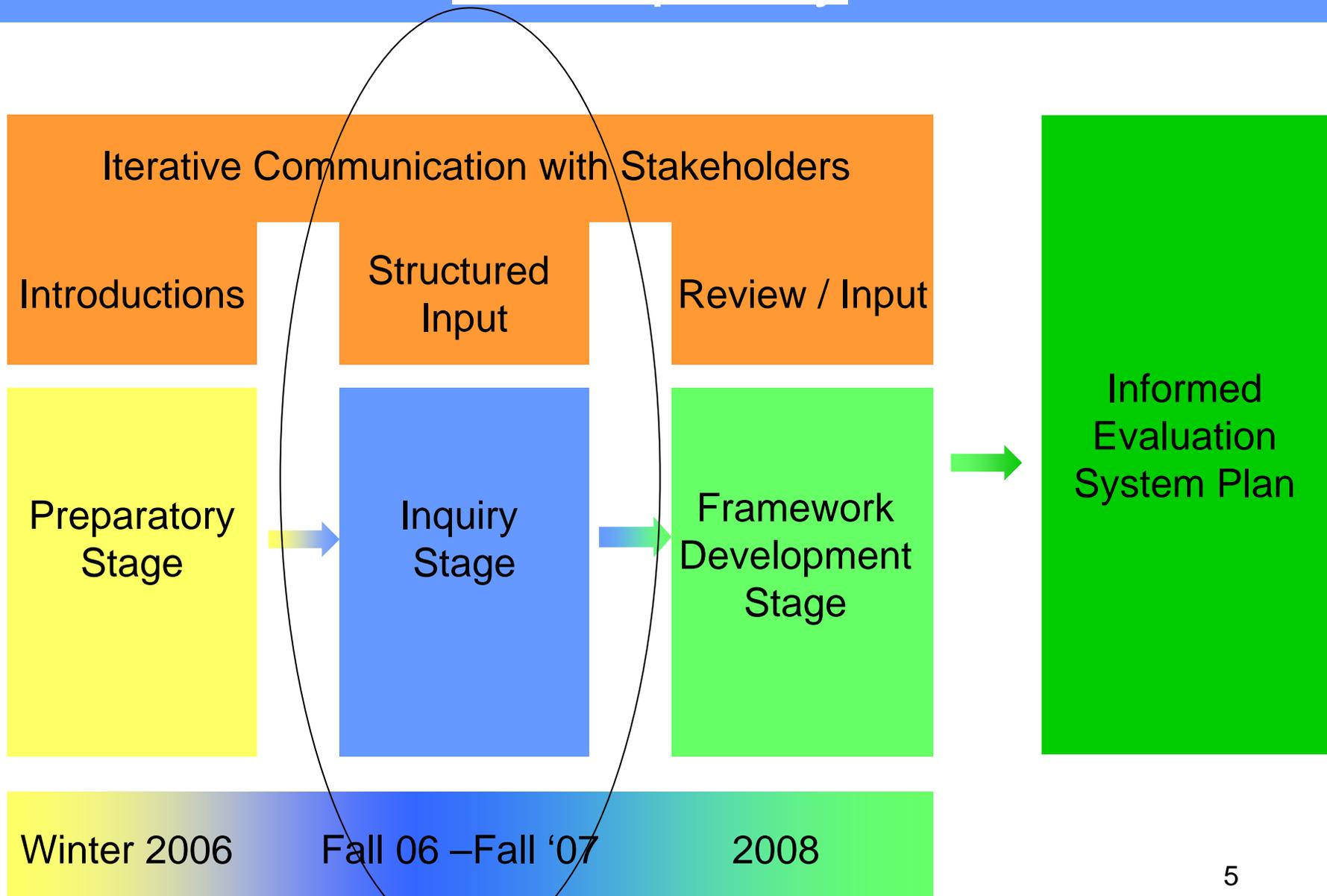
# Project Context

- 40 million people living with AIDS
- NIAID Division of AIDS funds world's largest HIV/AIDS clinical trials network
  - ~\$300M, international effort
  - Restructured in 2006
  - Increased coordination across 6 networks

# Project Goals

- Plan collaboratively for a comprehensive, integrated evaluation system to:
  - Support success
  - Provide empirically based evidence
  - Ensure scientific priorities are addressed
  - Promote collaboration and shared learning
  - Increase efficiency and research integration
  - Develop a culture of evaluation

# Phase I: Participatory Process



# Inquiry Process



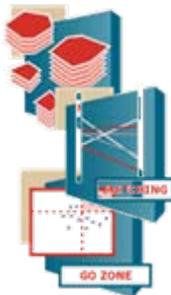
**Planning:** Planners and Core Group developed *focus prompt* - “Coordinated clinical research networks will be successful if...” and identified *participants* (December-February 2006)



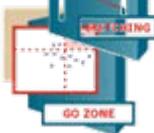
**Idea Generation:** Participants *brainstormed* ideas, CSI conducted document analysis (March 2006)



**Idea Synthesis:** Planners synthesize large set of ideas to manageably sized set (less than 100 ideas) (April 2006)



**Structure Ideas:** a subset of participants sort and rate; larger group rates the results of the idea development (Sept 06-March 07)



**Analysis:** CSI runs analysis, create *maps, pattern matches* and “go zones,” based on the map (April 2007)



**Interpretation and Use:** (Summer 2007) and Subsequent Framework Development (e.g. Evaluation Measurement Task Force work) (Fall 2007)

# Focus Prompt

***“Coordinated clinical research networks will be successful if...”***

# Generated Ideas Based On....

*“Coordinated clinical research networks will be successful if...”*

- Documents
- Interviews (32)
- Focus Groups (5)
- Web-based Brainstorming (~185)

# Participation Summary

- 102 people sorted (32%); 90 useable for analysis
- 323 people rated (43%); 308 useable for analysis
- Diverse participation :
  - 6 different areas of science
  - 10 different roles (network core; clinical trials unit/site; lab; govt; community; pharma/biotech; pharmacy;NGO; Advisory Group; Other)
  - 6 continents

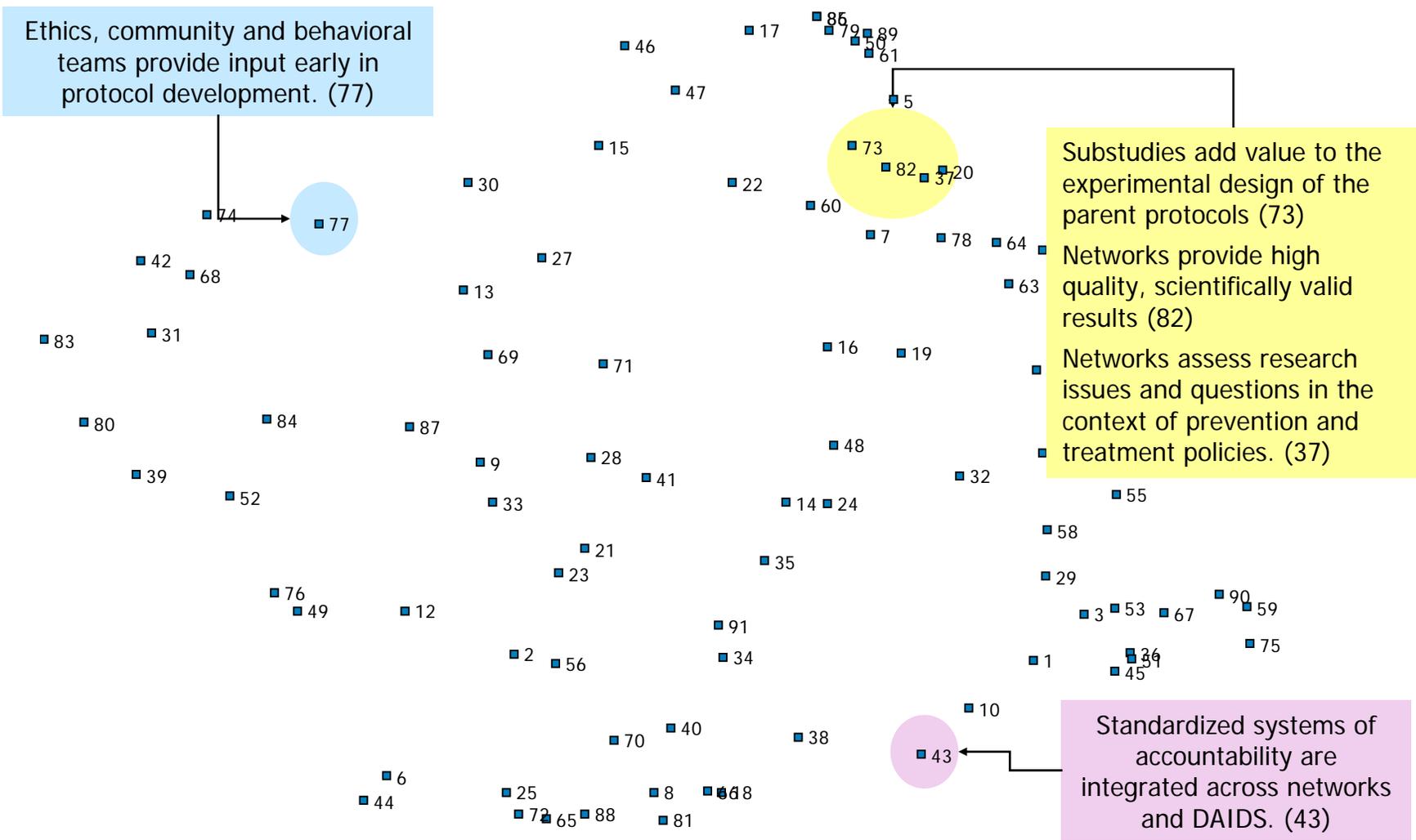
# Conceptual Sorting Input Analysis

- Aggregation of Individual Sort Data
- Similarity Matrix
- Multidimensional Scaling
- Cluster Analysis

# This initial map shows all the elements in relation to one another.

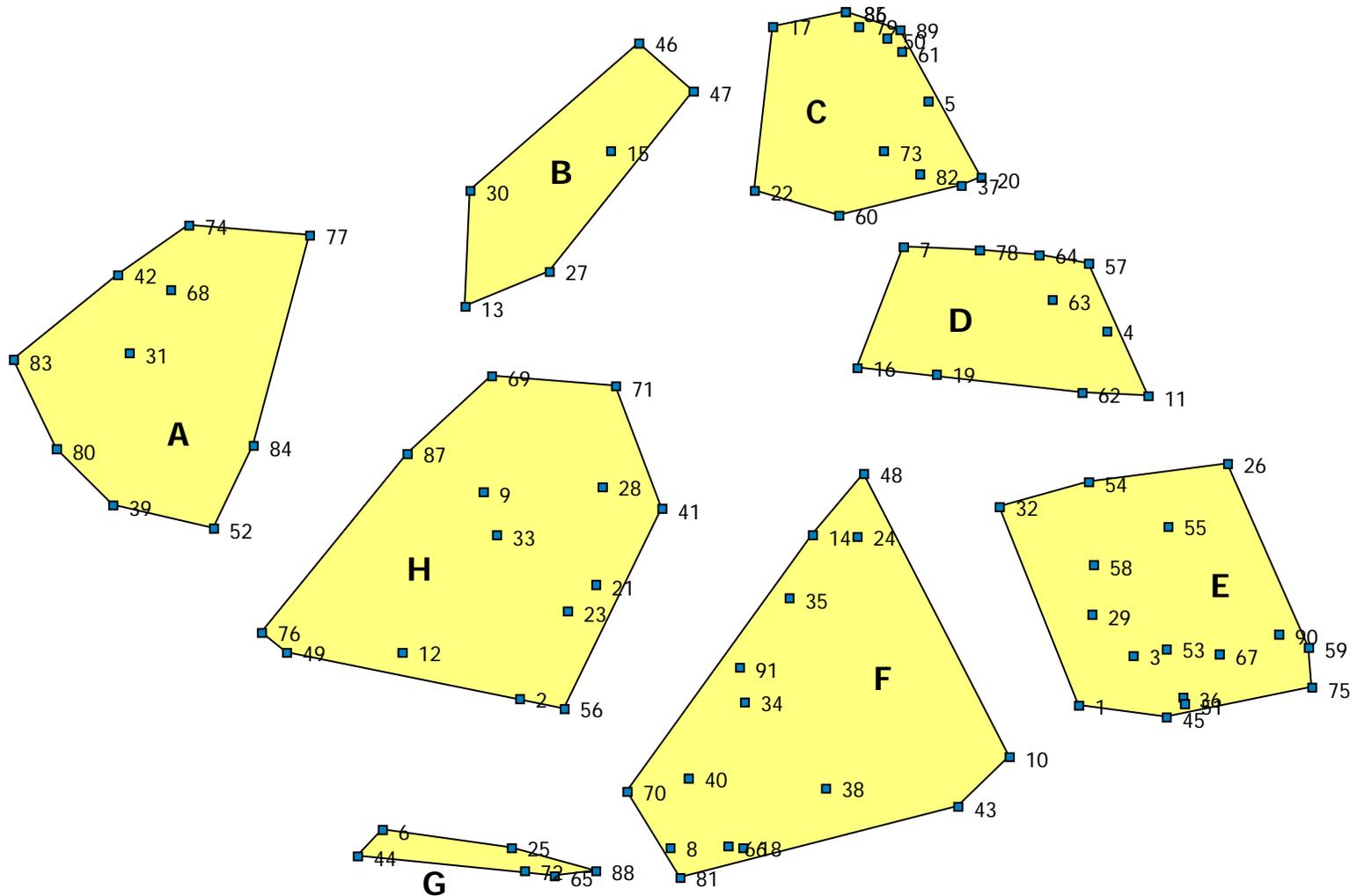


# Conceptually different ideas are further apart; similar ideas are closer together



“Coordinated clinical research networks will be successful if...”

# The detailed ideas are organized into groups



...so that many concepts can be considered in a shared structure

# Community Involvement

appropriate and relevant community representation is included at all levels; institute, network, and site. (31)

consideration is given to the differences in conditions in resource poor nations. (39)

the dignity and human rights of participants are respected. (42)

sites have the scientific and technical skills needed to pursue the research agenda. (52)

the community is included in every stage of a protocol (68)

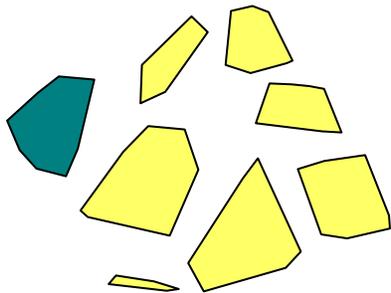
research is conducted acknowledging the culture, norms and values of the community they are working with. (74)

ethics, community and behavioral teams provide input early in protocol development. (77)

research sites provide hours to make participation accessible to subjects. (80)

community support, training and education are provided. (83)

clinical trial sites successfully meet recruitment and retention goals (84)



# Communication, Collaboration, Harmonization

standardize key laboratory procedures across the networks. (1)

leadership and trial sites are consulted to identify areas that will benefit from harmonization and closer collaboration (such as laboratory SOPs, data management, training, etc.), but are supported to address the needs that are unique to the network. (3)

there are standardized tool kits for use in behavioral studies. (26)

there is worldwide collaboration. (29)

public-private partnerships with industry collaborators are used. (32)

networks harmonize key training, laboratory, network evaluation, data management, and other key functions across networks. (36)

effective cross network training is utilized. (45)

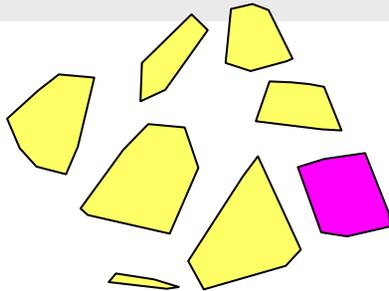
networks develop and support mutually beneficial coordination among the networks and DAIDS and other relevant NIH networks, federal agencies and NGO research organizations. (51)

networks develop a harmonized data management system. (53)

networks are cost effective in getting studies accomplished. (54)

the vision and goals are shared. (55)

there is communication within each network. (58)



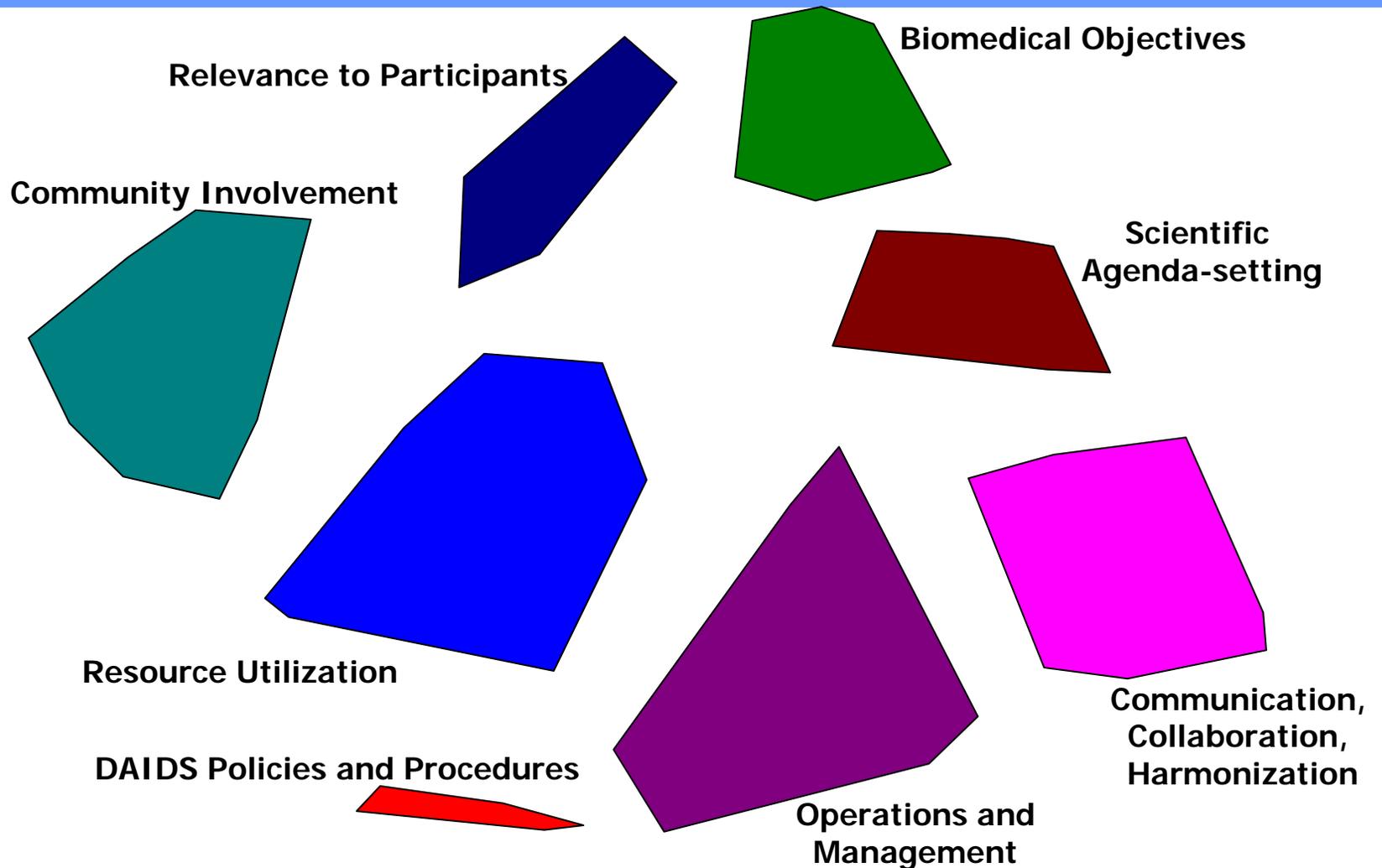
annual and biannual meetings of the networks overlap to allow for sharing of scientific data and future planning of the scientific agenda of each group. (59)

information, resources and materials are shared across networks. (67)

there is regular and frequent communication among clinical research networks. (75)

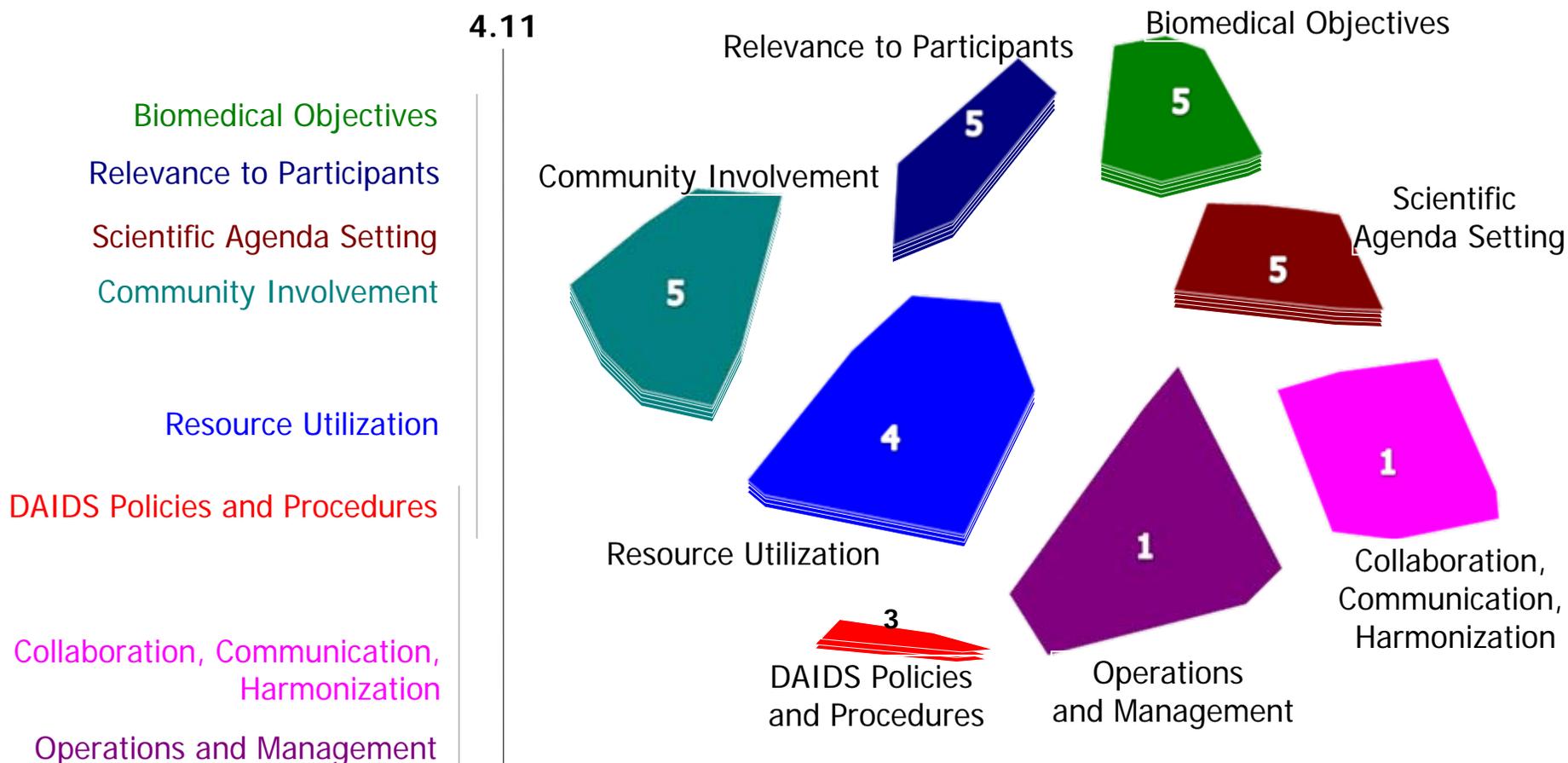
there is collaboration within and among the networks. (90)

# The Emergent Structure



...contains all the details and provides a conceptual framework.

# Importance Ratings of All Participants

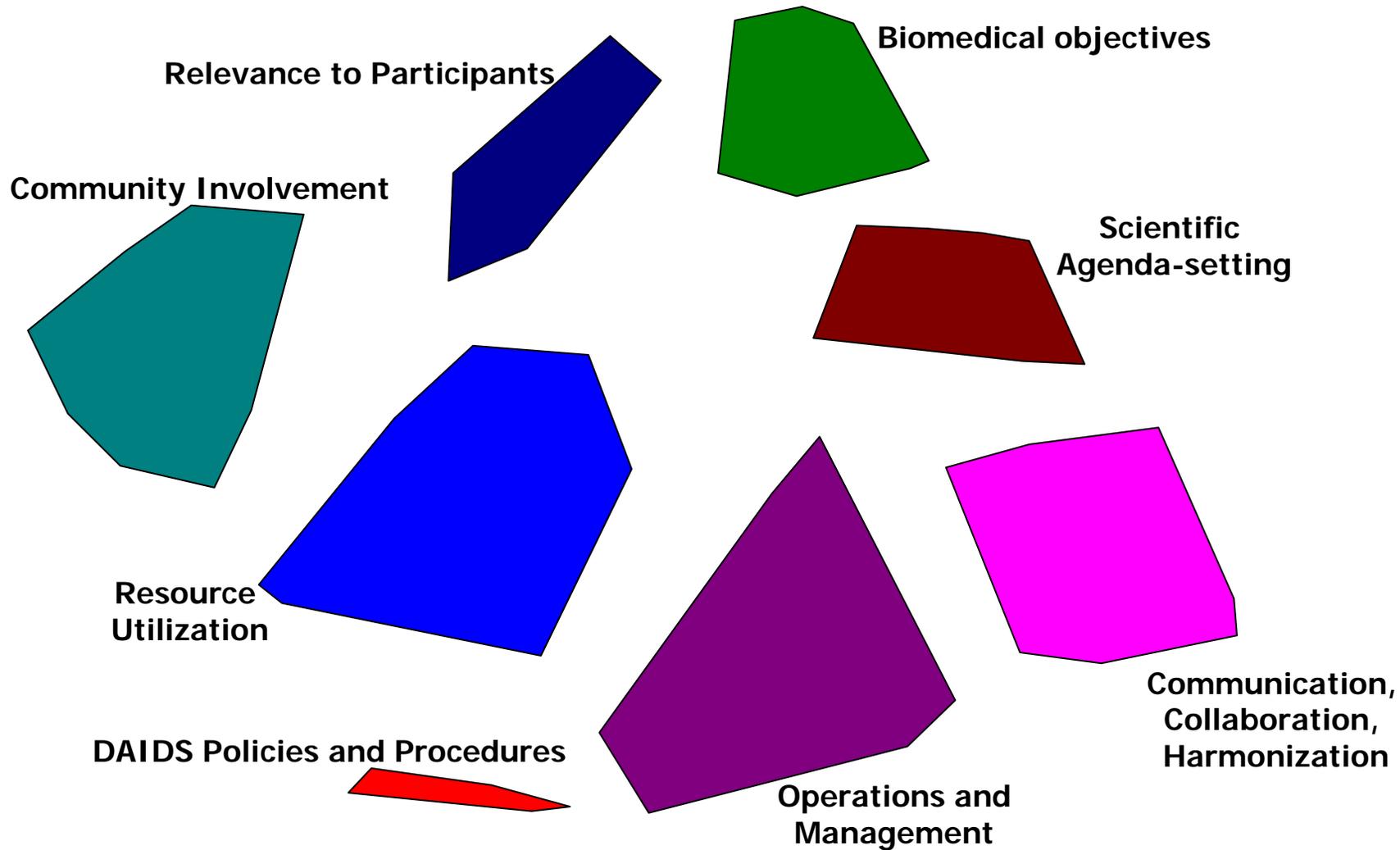


\*significantly different from \* at .05 level

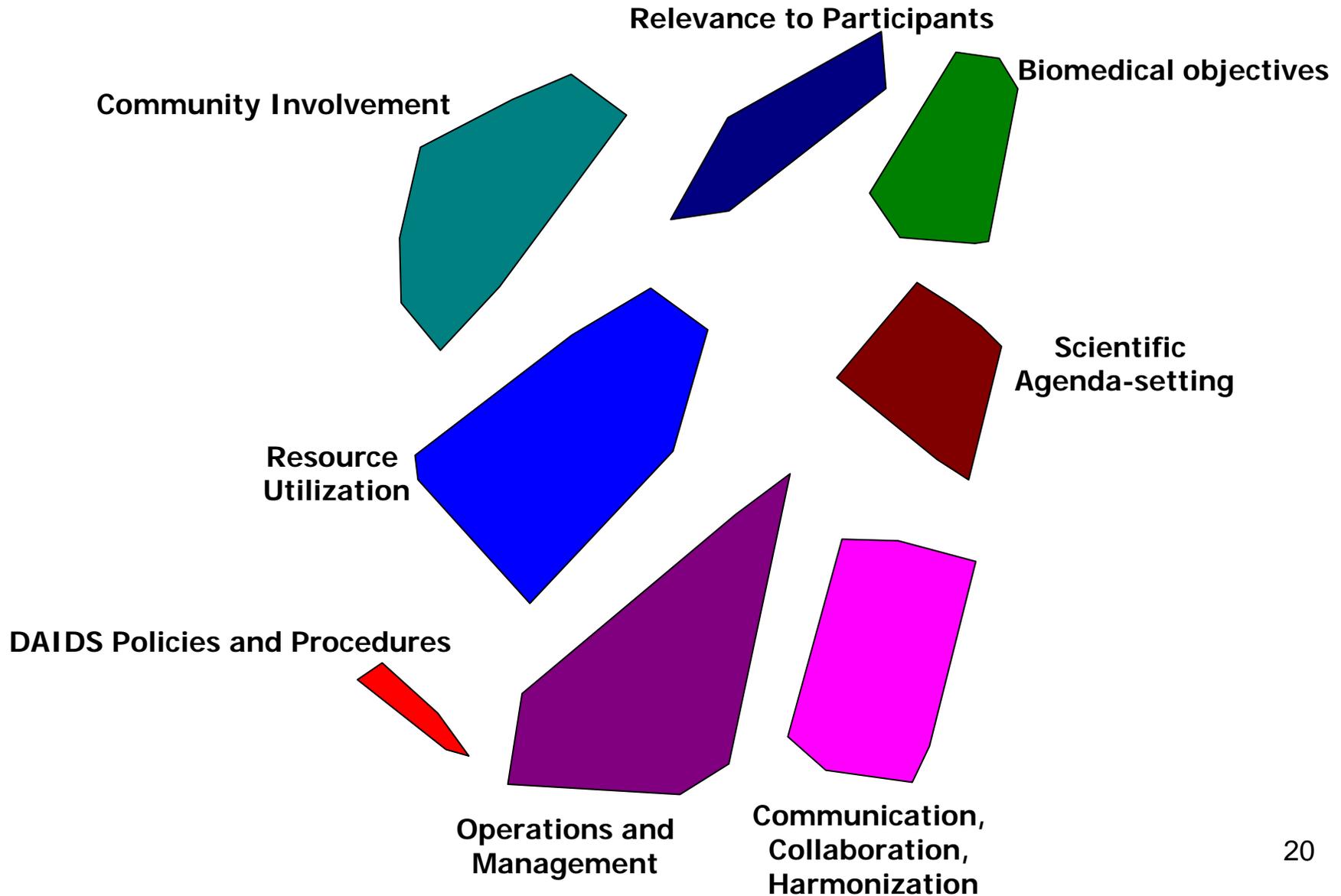
# Subgroup Analyses

- Compare subgroups' perceptions of importance according to responses to participant questions:
  - Primary area of science
  - Role
  - Years of involvement
  - Continent
- Comparisons may be on the conceptual (cluster) level or on the item level within each cluster

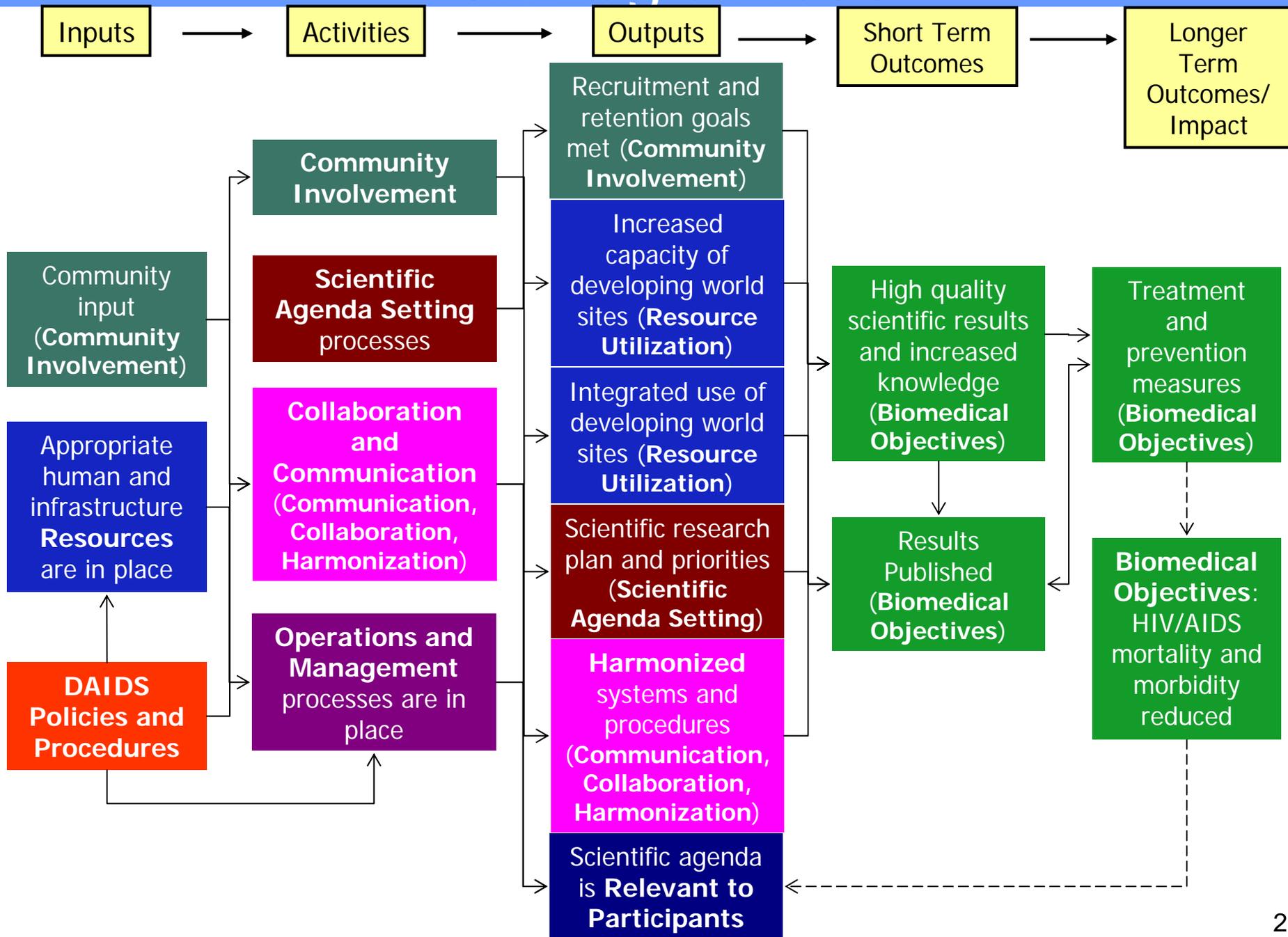
# The Emergent Structure



# The Emergent Structure (rotated)



# Draft Logic Model



# Next: Using the Evaluation Framework.....

- Convene Evaluation Measurement Task Force (EMTF)
- Organize existing tools, methods
- Develop measures
- Identify data sources
- Discuss measurement approaches

# Thank you.

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## ***DAIDS Project Office:***

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# Community Involvement

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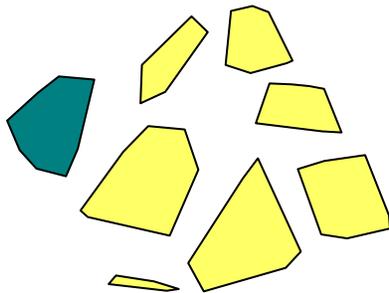
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# Relevance to Participants

research is appropriately integrated with clinical and community service delivery (13)

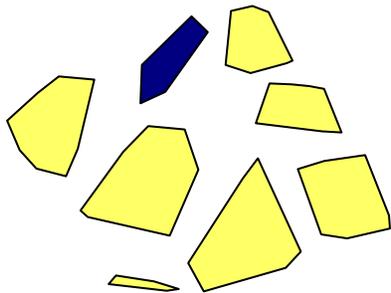
the questions to be addressed are relevant to the country/populations in which the study is done. (15)

networks consider the gender, ethnicity, socioeconomic status, and other demographic characteristics of the target population during planning. (27)

populations at greatest risk for HIV/AIDS are adequately represented in clinical research. (30)

high impact research results get translated into practice. (46)

treatments for HIV-infected people in special populations are evaluated. (47)



# Biomedical Objectives

networks produce results that inform the way in which HIV infection is treated and prevented. (5)

the development of antiretroviral (ARV) resistance is minimized. (17)

networks focus on answering the top scientific questions related to the treatment and prevention of HIV and its complications. (20)

criteria for the advancement of the most efficacious and least toxic products are developed. (22)

networks assess research issues and questions in the context of prevention and treatment policies. (37)

evaluate vaccines for the prevention of HIV sexual transmission among populations at risk. (50)

scientific results are published and disseminated widely. (60)

the understanding of HIV-1 pathogenesis is furthered. (61)

substudies add value to the experimental design of the parent protocols. (73)

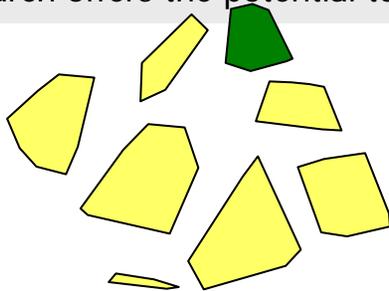
a safe and at least partially effective microbicide is identified. (79)

networks produce high-quality, scientifically valid results. (82)

mortality (death rate) from HIV/AIDS is reduced or eliminated. (85)

morbidity (rate of occurrence) of HIV/AIDS is reduced or eliminated. (86)

research offers the potential to find practical strategies for HIV prevention that can be applied quickly. (89)



# Scientific Agenda Setting

networks obtain scientific input and involve a large group of clinical investigators in the research agenda. (4)

networks develop protocols with attainable goals. (7)

there is collaboration with experts outside the networks. (11)

there is communication and cooperation between stakeholders in the planning of science. (16)

there is acknowledgement of and support for the scientific contributions of international research partners. (19)

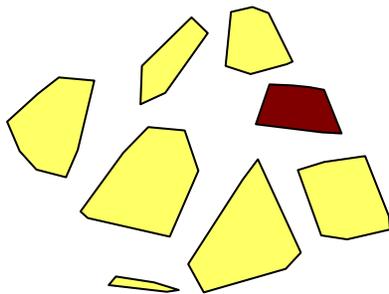
networks integrate biomedical and technological advances with behavioral intervention strategies. (57)

networks focus on complementary pieces of the research agenda. (62)

networks reassess and reprioritize their scientific priorities as the field evolves. (63)

networks focus on high priority trials that will not be done in the private sector. (64)

the proposed scientific priorities and research plan is feasible. (78)



# Communication, Collaboration, Harmonization

standardize key laboratory procedures across the networks. (1)

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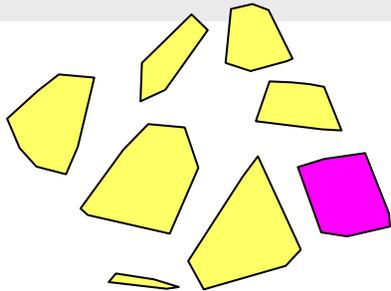
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# Operations and Management

DAIDS has methods for managing complex endeavors. (8)

the standard operating procedures across each of the networks are consistent. (10)

there is a performance-oriented network culture. (14)

DAIDS medical officers/ program officers provide a consistent level of input/oversight to all networks. (18)

there is a streamlined protocol development and implementation process. (24)

there are uniform standards for site development. (34)

each component of the network (committees, SDMC, labs, ops centers, sites) has the authority to perform its duties and responsibilities without the interference of the others. (35)

a central IRB system is established. (38)

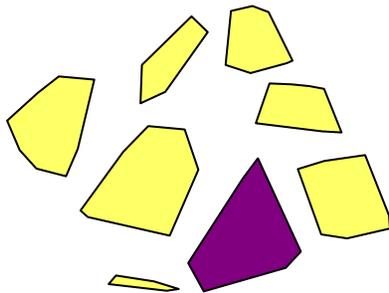
efficient and reasonable regulatory processing can be established. (40)

standardized systems of accountability are integrated across networks and DAIDS. (43)

protocols are closed out, analyzed and published in a timely manner. (48)

clear direction is given on which DAIDS priorities are within the scope of the networks versus which DAIDS priorities should be achieved via other grant mechanisms. (66)

DAIDS staff who work with the studies have a voice in decisions to approve proposals/ protocols. (70)



DAIDS provides clear, consistent messages about goals, objectives and expectations. (81)

there is a defined process for networks to use in reviewing future site expansion. (91)

# DAIDS Policies and Procedures

DAIDS develops a clear policy that facilitates generic drug use. (6)

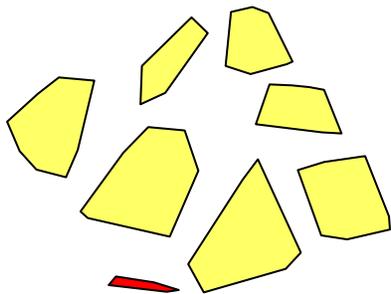
NIAID's budgeting process for the networks and the sites is transparent. (25)

NIAID considers multiple factors in funding networks and sites. (44)

DAIDS develops a clear policy about the purchase of study products (e.g. ARVs, vaccines, prophylactics). (65)

DAIDS policies reflect what is required for good science, protection of human subjects, and safety. (72)

DAIDS streamlines their monitoring/ auditing procedures. (88)



# Resource Utilization

there is consistent and equitable resource allocation within networks. (2)

networks provide developing world sites with the clinical, regulatory, pharmacy, and laboratory support needed to ensure quality. (9)

there is accountability at all levels. (12)

there is integrated use of domestic and international sites. (21)

there is expertise in infrastructure development. (23)

CTUs can implement protocols from different priority areas. (28)

investigators commit adequate time to network activities. (33)

nonproductive activities are curtailed early. (41)

there is management of specimen flow (including from site to site-affiliate-lab to repository to end-point lab). (49)

the administrative burden on sites is minimized. (56)

principal investigators demonstrate scientific leadership and innovation. (69)

investigators are diverse, representing minority, international, female and/or young investigators. (71)

the Core Laboratory is composed of Specialty Laboratories selected to provide requisite breadth of laboratory expertise to support the comprehensive agenda of the networks. (76)

investigators have adequate qualifications and experience. (87)

