

Challenges of Assembling *Cohorts (and Collaborations)*

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Some Examples

Collaborative Study of the Genetics of Asthma

NHLBI supported 4 R01s (1997-2003)

Collaboration post-award

Coordinating Center 2 years into project

Type 1 Diabetes Genetics Consortium (2002-2010)

Candidate gene Association Resource (CARE)

NHLBI supported primary site (2006-2011)

Limited support for contributing cohorts

NHLBI Exome Sequencing Project (2008-2011)

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Type 1 Diabetes Genetics Consortium

In the beginning...

- November 1998; NIH Consensus Conference
- April 2000; Diabetes Y2K Workshop (Skagen, Denmark)
- May 2000; JDRF/NIDDK conference call
- November 2000; NIDDK Genetics of Type 1 Diabetes Conference
- T1DGC Steering Committee established (Rich as Chair)

Getting organized...

- February 2001; Conference call to establish study aims
- March 2001; Steering Committee to define resources (NIDDK)
- June 2001; Steering Committee to define the project (Copenhagen)
- August 2001; Steering Committee and T1DGC members (Seattle); plans finalized for study; *Rich to write grant*

Timeline

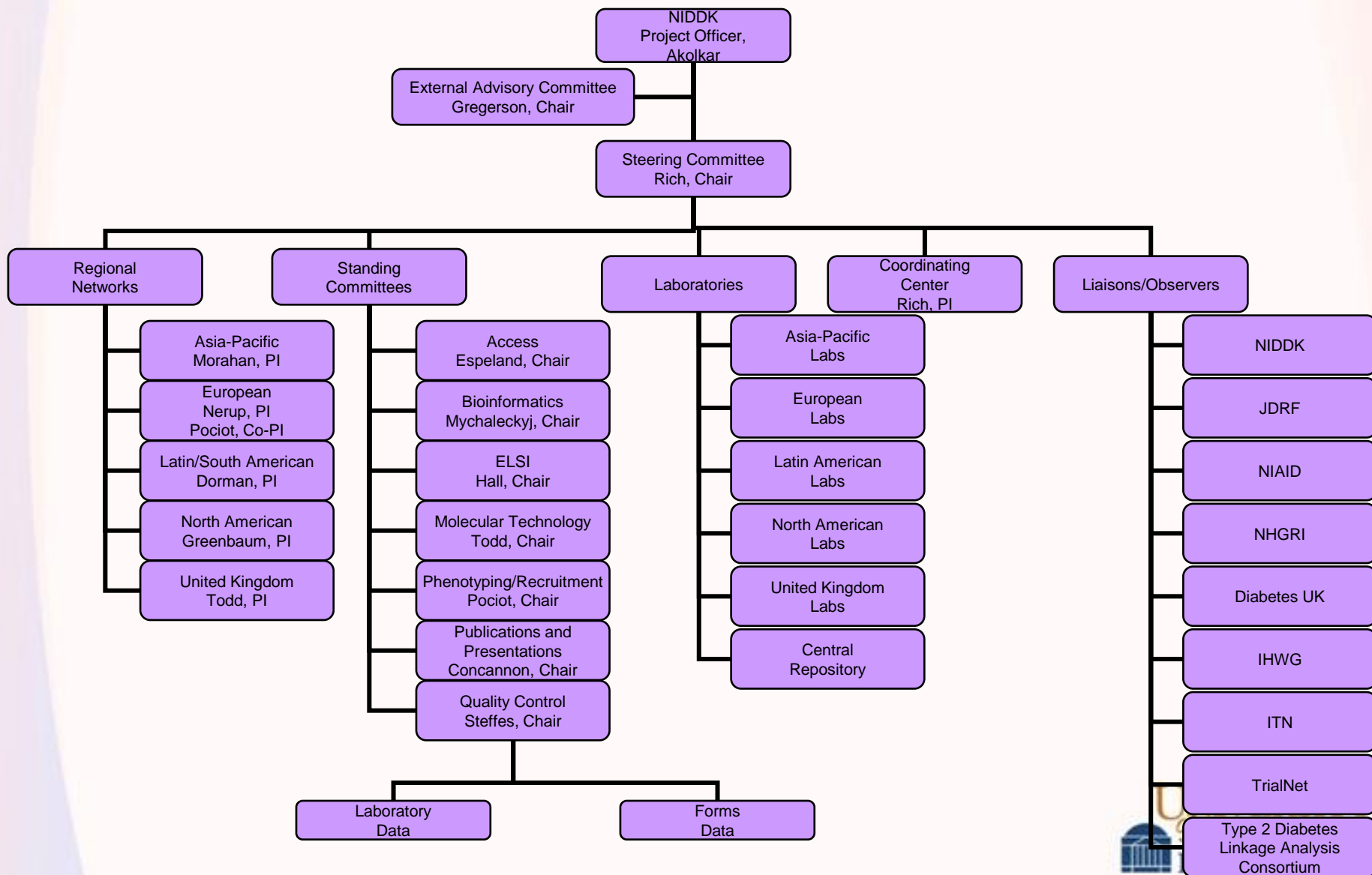
Application process

- Grant writing, submitted February 2002
- NIDDK Council May 2002
- Requested start date July 1, 2002
- Actual Start Date September 1, 2002

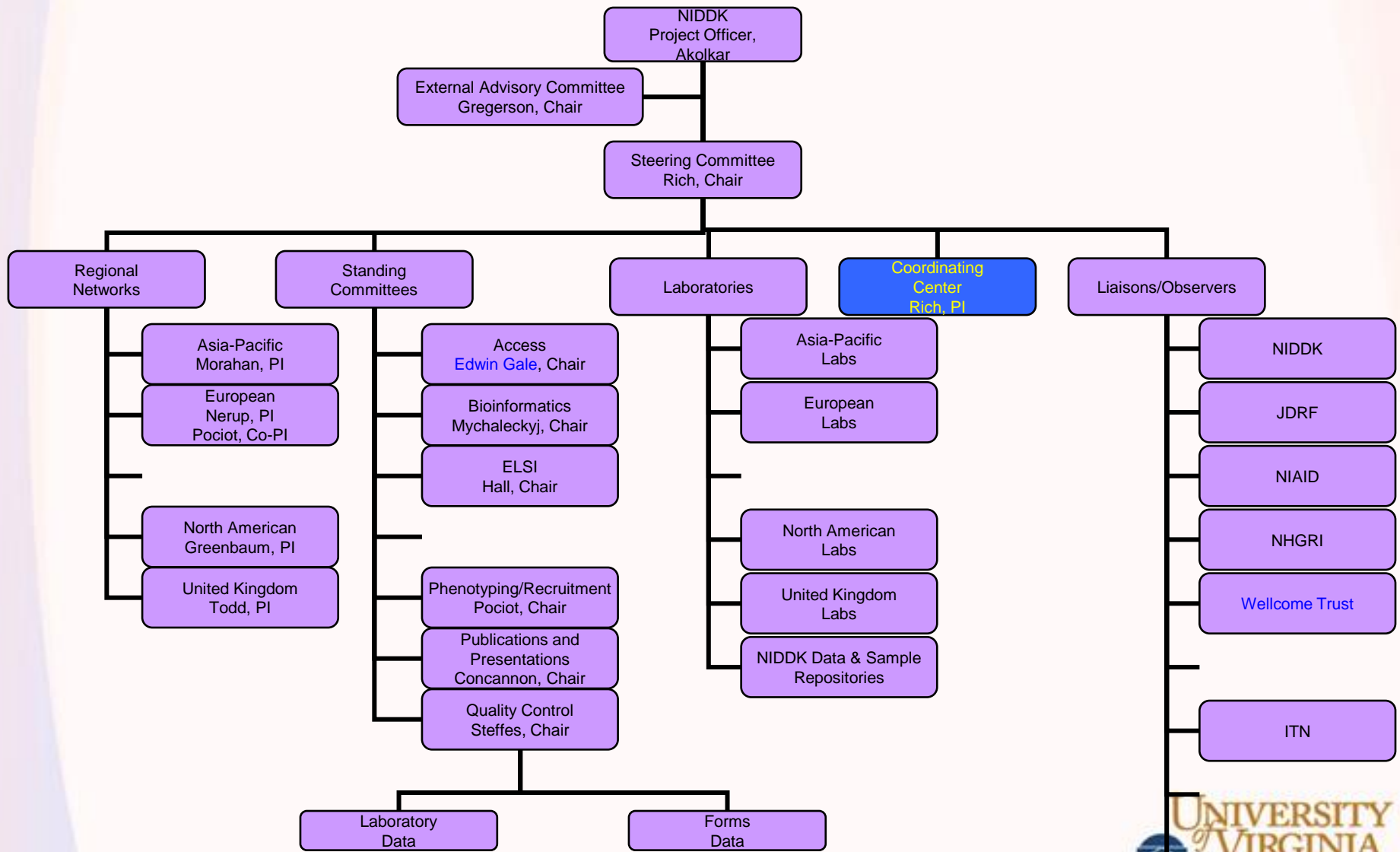
Develop a Coordinating Center

- Clinic/regional site identification and computing issues (data entry, tracking, inventory, labels)
- Form development/questionnaires
- Manuals of Operations/Procedures
- CIDR samples and genome scan (batch 1/3)

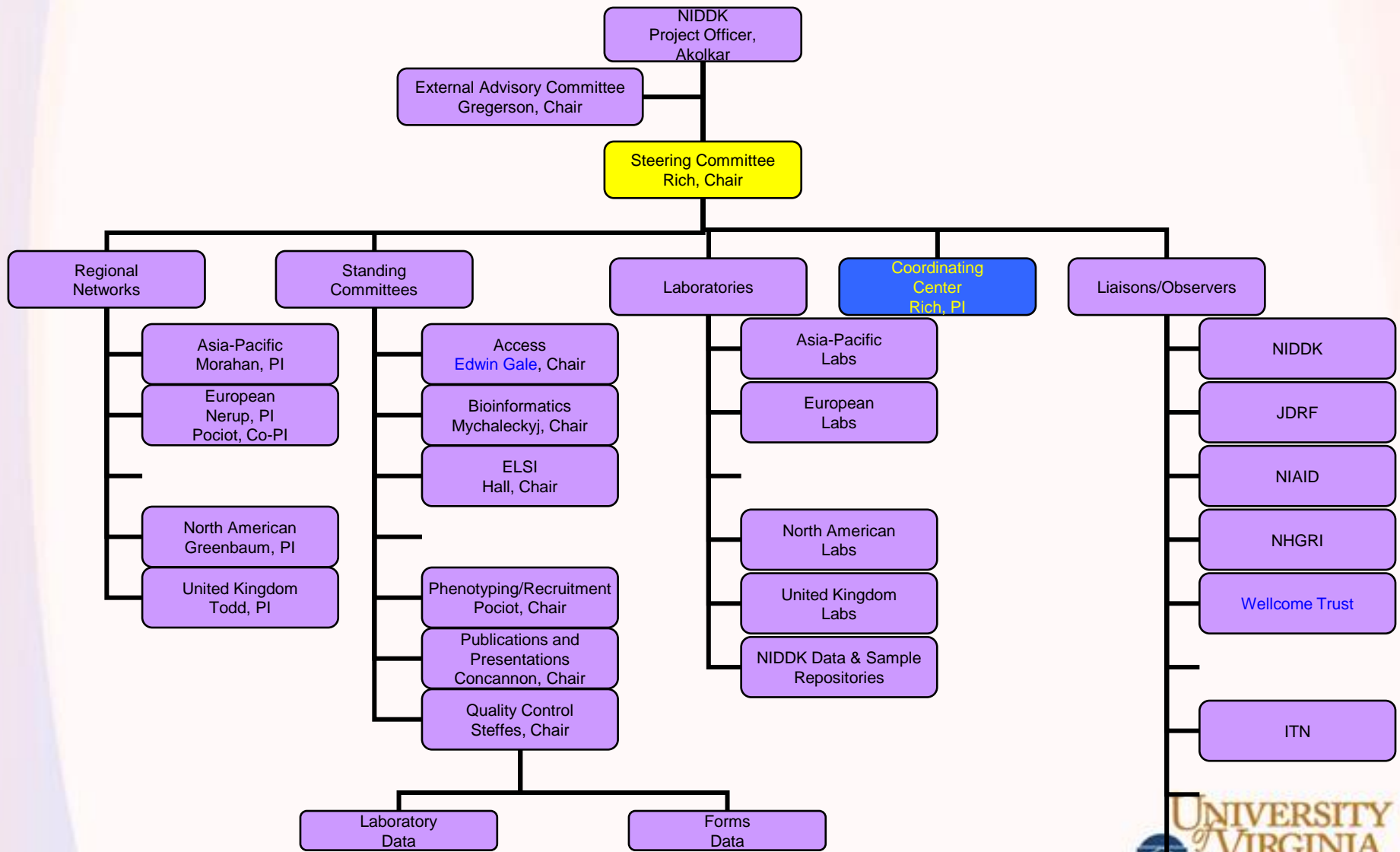
Initial T1DGC Study Organization Chart



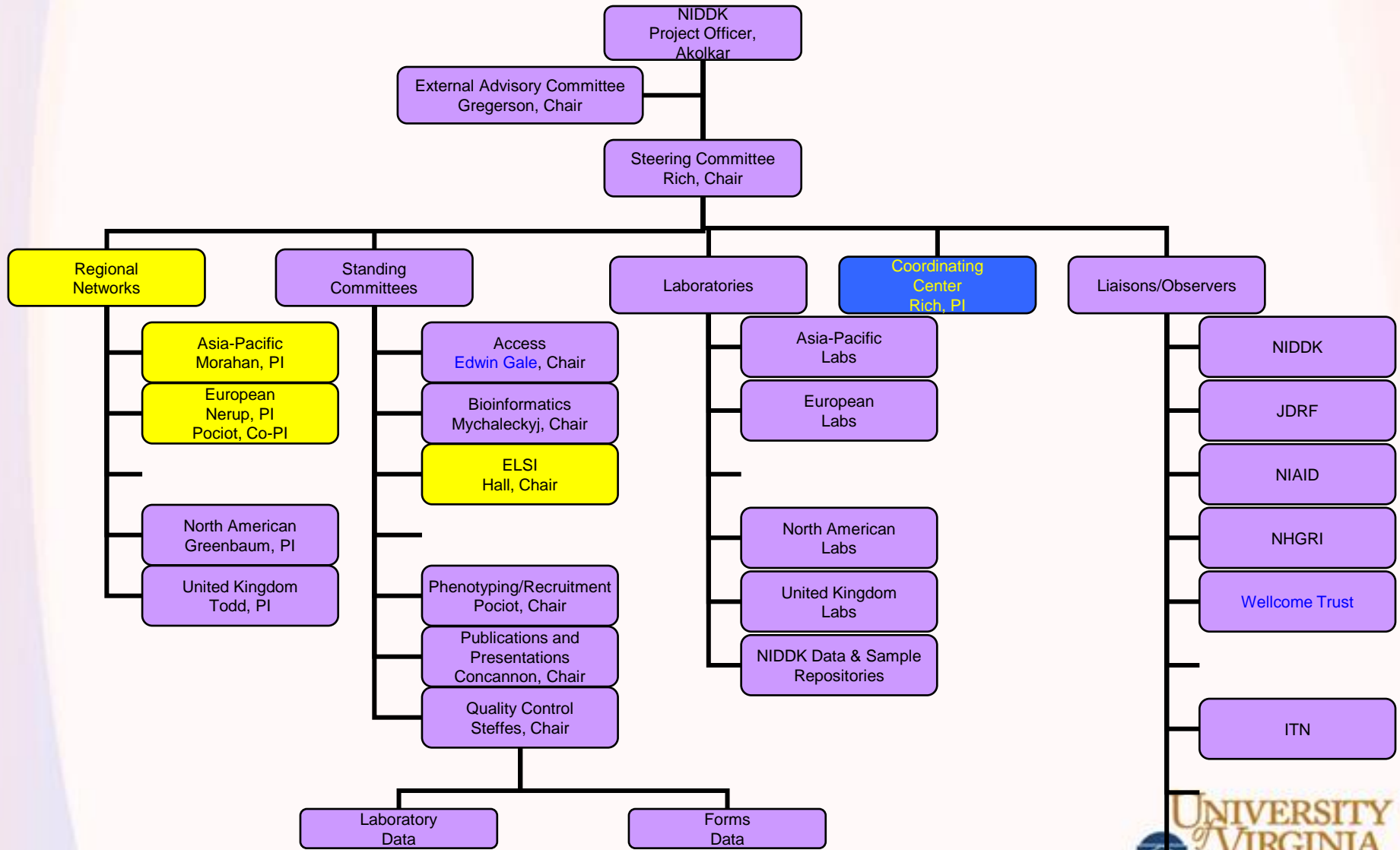
Final T1DGC Study Organization Chart



Points of Emphasis

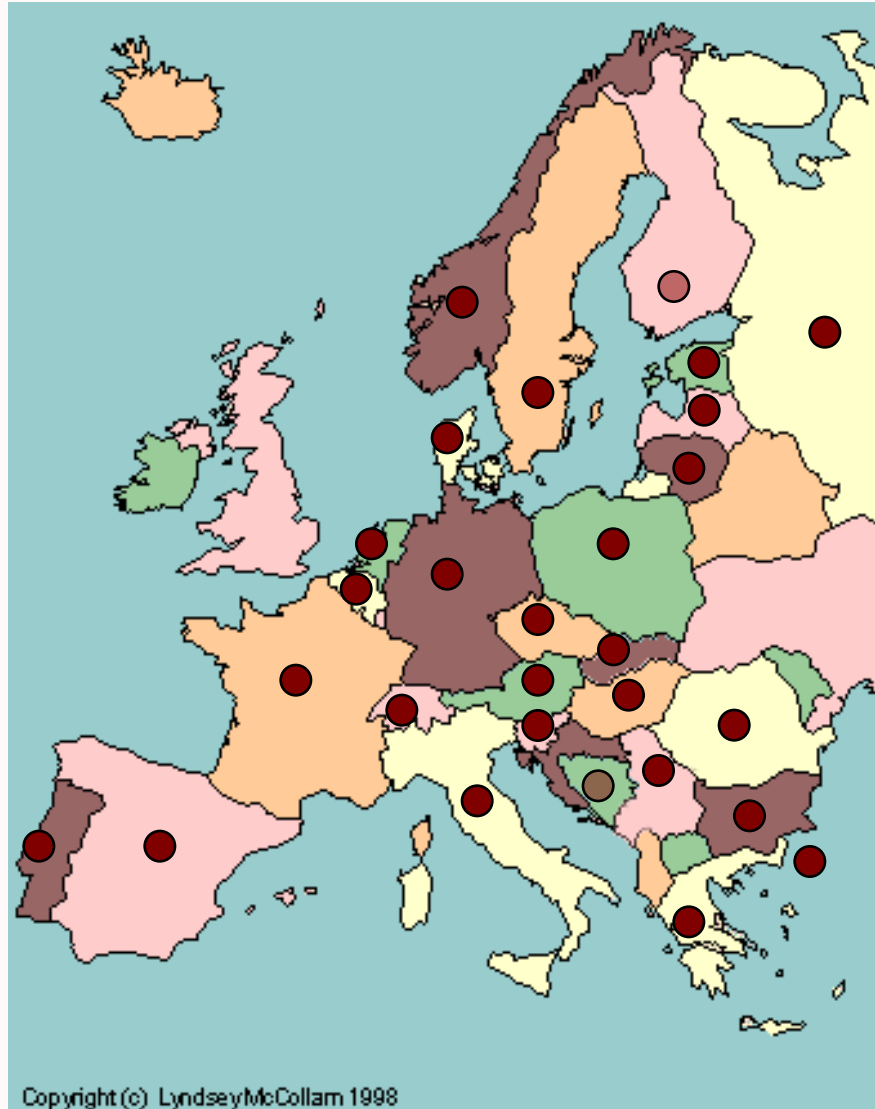


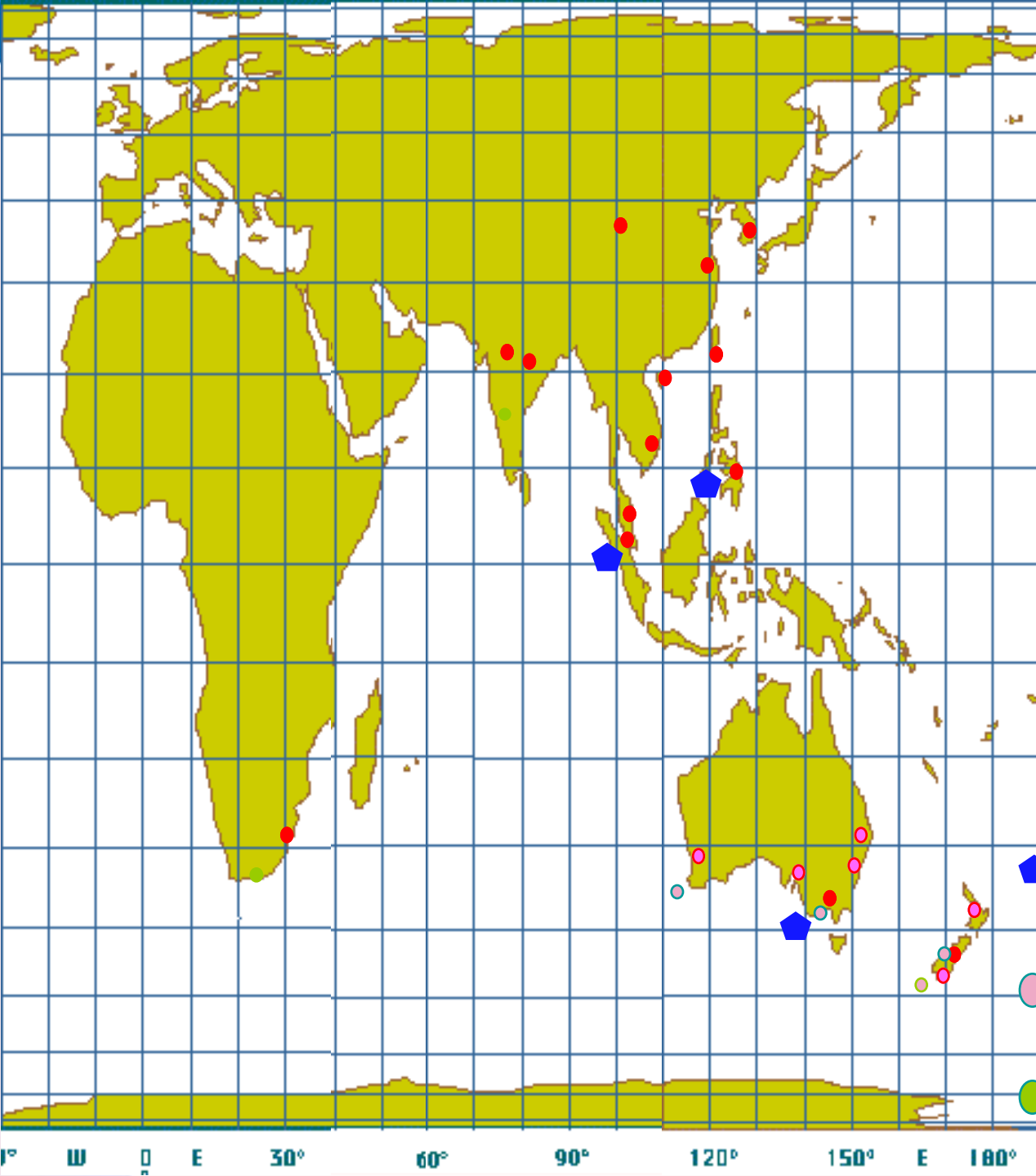
Points of Emphasis



European Network

27 countries, over 100 centers for recruitment





Asia-Pacific Network
15 countries

Vast geographic area
Many cultures
Transfer and sharing
Intellectual Property

Different Countries, Cultures, and the Ethical, Legal and Social Issues (ELSI) Committee

Responsible for promoting the ethical and legal conduct of this research study

- Draft model informed consent form templates
- Recommend policies for minimum requirements to meet ethical standards
- Advise Regional Networks on adapting informed consent forms to local requirements
- Advise the Steering Committee regarding intellectual property issues
- Address other general legal and ethical issues that arise and are within the competence of committee members to consider

Model Informed Consent Form

Purpose, Description

Consent for DNA, cell lines, samples (layered)

Ownership of samples, data

Risks, Discomforts/Benefits

Alternatives, Right to Withdraw

Confidentiality

Costs, Compensation, Treatment

Parent consent, teenage/child assent

Recontact

Publications and Presentations Committee

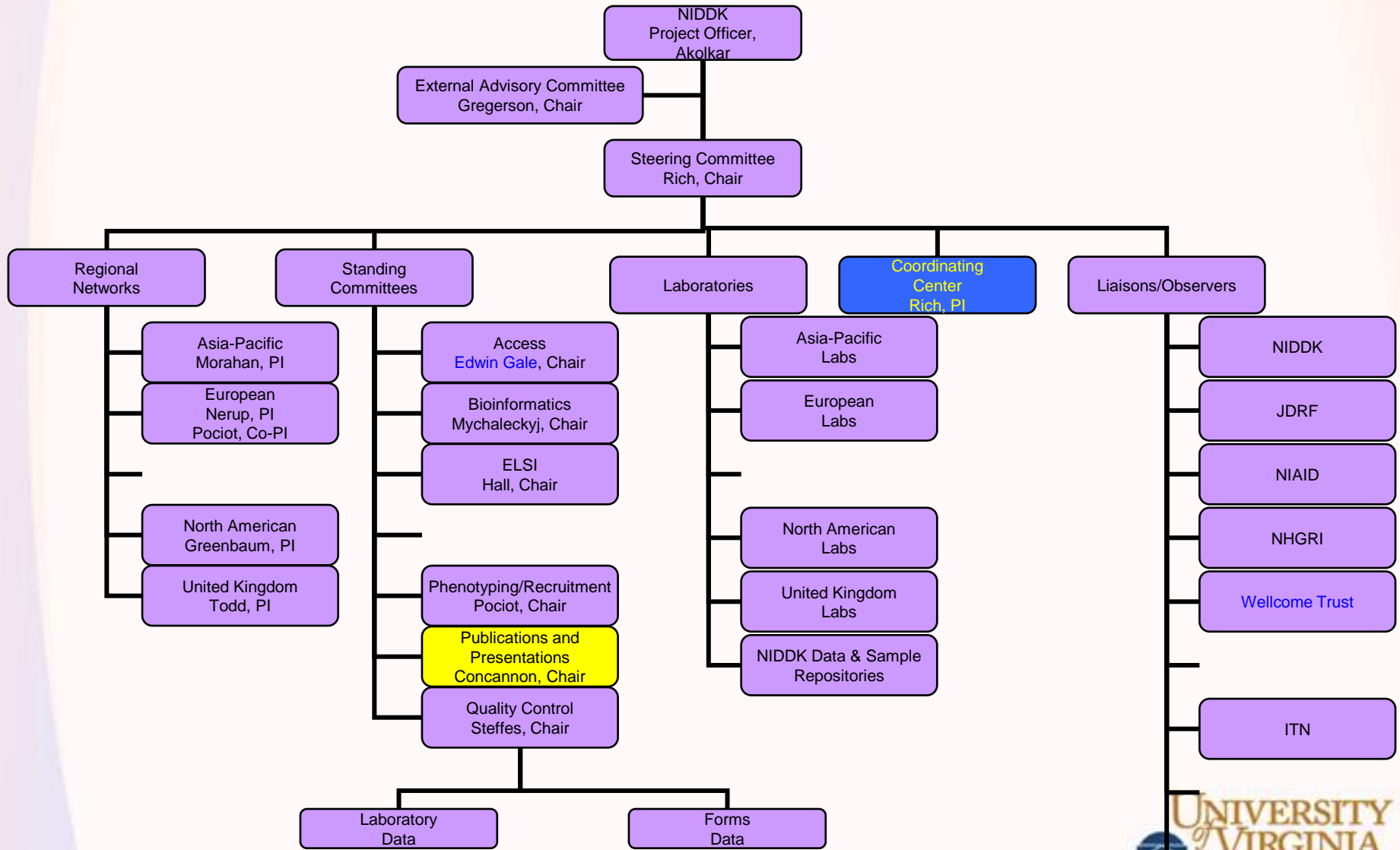
Assure and expedite orderly and timely presentations and publications

Assure that all investigators have the opportunity to participate in the study-wide presentation of T1DGC papers

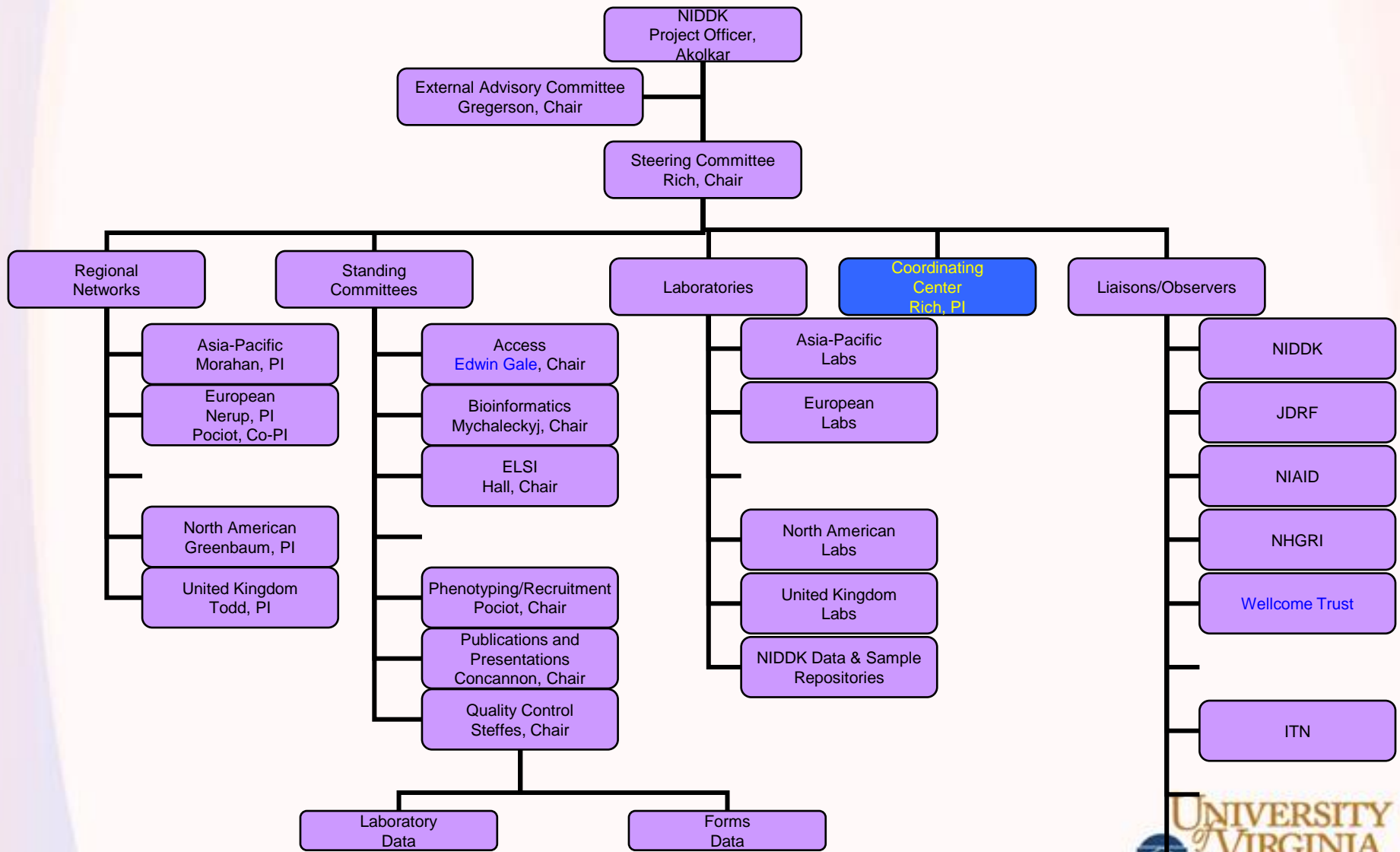
Assure that presentations and publications of T1DGC study materials are accurate, objective, and do not compromise the scientific integrity of this collaborative study

Assist in maintaining a complete up-to-date list of T1DGC Study presentations and publications on the study web site

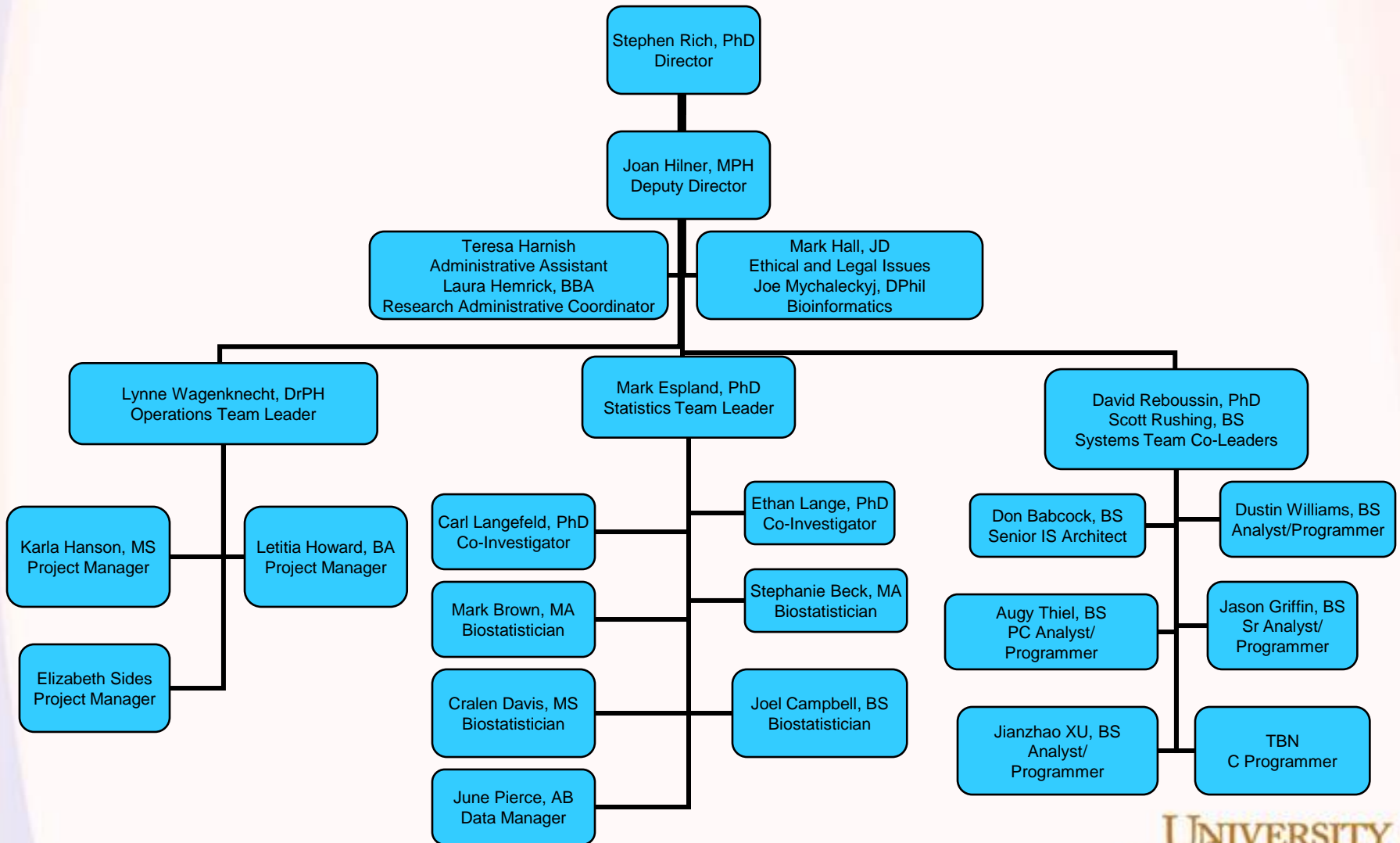
Points of Emphasis



Final T1DGC Study Organization Chart



T1DGC Coordinating Center





Type 1 Diabetes Genetics Consortium (T1DGC)

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Key T1DGC Documents:
[Consortium Agreement](#)
[Access to T1DGC Data and Samples](#)
[Publications and Presentations Policy](#)

T1DGC Networks:
[Asia-Pacific](#)
[European](#)
[North American](#)
[United Kingdom](#)

T1DGC Bulletin Board:
[Update on Recent T1DGC Developments](#)

Welcome to Type 1 Diabetes Genetics Consortium

This website is designed with different visitors in mind. Which visitor are you?

Family Interested in Study



Recruitment for the T1DGC has started in the four regional networks. If you would like more information about participating in this important study, click here.

Investigator Interested in Joining Consortium



T1DGC is organizing international efforts to identify genes that determine an individual's risk of type 1 diabetes. For further information, click here.

Consortium Member (please log in below)





a world of
understanding

T1DGC DATA & SAMPLES
NOW AVAILABLE!!

[click here >>](#)

Key T1DGC Documents:

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[Publications and Presentations Policy](#)
[Required T1DGC Acknowledgement](#)
[T1DGC Members List](#)

T1DGC Networks:

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T1DGC Bulletin Board:

[Update on Recent T1DGC Developments](#)

T1DGC Bioinformatics Resources:

[T1DBase](#)



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Family Interested in Study



Families with at least two siblings (brothers and/or sisters) who have type 1 diabetes are unique. If you are part of such a family, you have a great opportunity to contribute to this important research.

- [Find out more about the study](#)
- [Where is the study being conducted and who do I contact?](#)
- [See the article in the Fall 2005 issue of the JDRF publication *Countdown* and learn about a family that participated in T1DGC](#)

Investigator Interested in Joining Consortium



T1DGC is organizing international efforts to identify genes that determine an individual's risk of type 1 diabetes. For further information, click here.

Consortium Members Login: ([Login procedures and password requirements](#))

User Name:

Password:

Consortium Membership

Request via Website (www.t1dgc.org)

Consortium agreement (participation, access)

Participation

- Recruitment of new families
- Contribution of existing families (IRB permitting)
- Resource contribution (genetic, clinical, methodologic)
- Participation in committees (working groups)
- Data Analysis, Publication

Leverage of Consortium resources

Contributor Benefits

Groups providing (new/existing) data to T1DGC

- Retain rights to analyze and publish own data
 - Request data immediately
 - Request data after “Q/C and cleaning”
 - Request assistance from Coordinating Center
- Consortium analyze/publish data only in aggregate
- Access to interim Consortium results (secured website)
- Request access to all Consortium data and resources

Funding opportunities through the Consortium

Technology transfer (workshops, resources)

Some Examples

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NHLBI Exome Sequencing Project

NHLBI Exome Sequencing Project (ESP)



National Heart Lung and Blood Institute
National Institutes of Health

Program Officer: Deborah Applebaum-Bowden

<p>Heart GO</p> <p>PI: Stephen Rich University of Virginia</p>	<p>Lung GO</p> <p>PIs: Michael Bamshad U. of Washington Kathleen Barnes, Johns Hopkins University</p>	<p>Women's Health Initiative Sequencing Program</p> <p>PI: Rebecca Jackson Ohio State University</p>
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UNIVERSITY of WASHINGTON

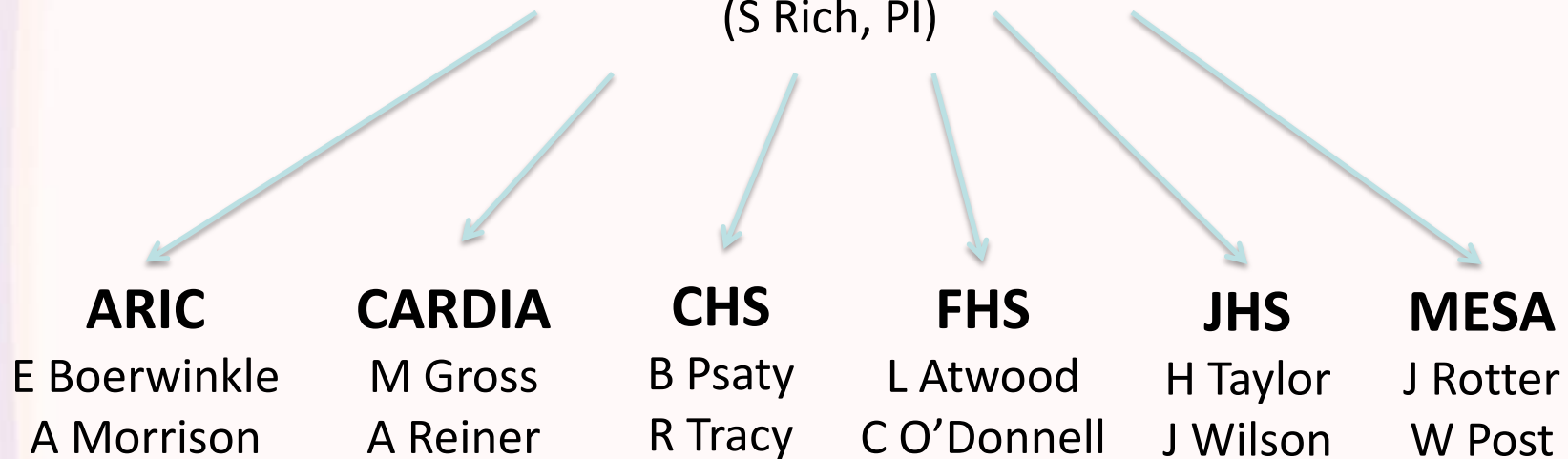
PIs: Debbie Nickerson,
Mark Rieder,
Jay Shendure, & Phil Green



PIs: Stacey Gabriel &
David Altshuler

HeartGO Structure

HeartGO Coordination
University of Virginia
(S Rich, PI)



Integration, communication and transparency within HeartGO
Communication and coordination with ESP Steering, Executive, NHLBI
Communication and coordination with contributing cohorts
(each with its own structures)

Project Teams and Writing Groups are the focus of work

Writing Groups are phenotype specific (CHARGE model)

Broadly inclusive membership

- Team leader/moderator (may/may not be lead author) sets agendas, coordinates calls, assigns responsibility for minutes
- Representation from cohorts, sequencing centers, other Phenotype Working Groups
- Phenotype experts within cohorts encouraged to participate

Integration and communication within HeartGO

Integration and communication within ESP

Responsibilities

Phenotype Working Group

- Prioritize phenotypes
- Recommend capacity between phenotypes
- Coordinate across phenotypes
- Define samples
- Coordinate delivery

Project Team

- Identify team members
- Select team leader/moderator
- Develop analysis plan
- Create/post timeline of deliverables
- Coordinate, merge, analyze data
- Develop paper proposals
- Report progress to Steering Committee
- Communicate results through publications, meetings

Summary

Time for organization and development of processes

Coordinating Center functions in support

Development of common goals, aims, deliverables

Representation from interested parties

Transparency

Communication

Coordination

Early determination of study regulations, publications, sharing

mobile, agile but not hostile