Developing a consortium to study NASH: Lessons learned from NIDDK NASH CRN

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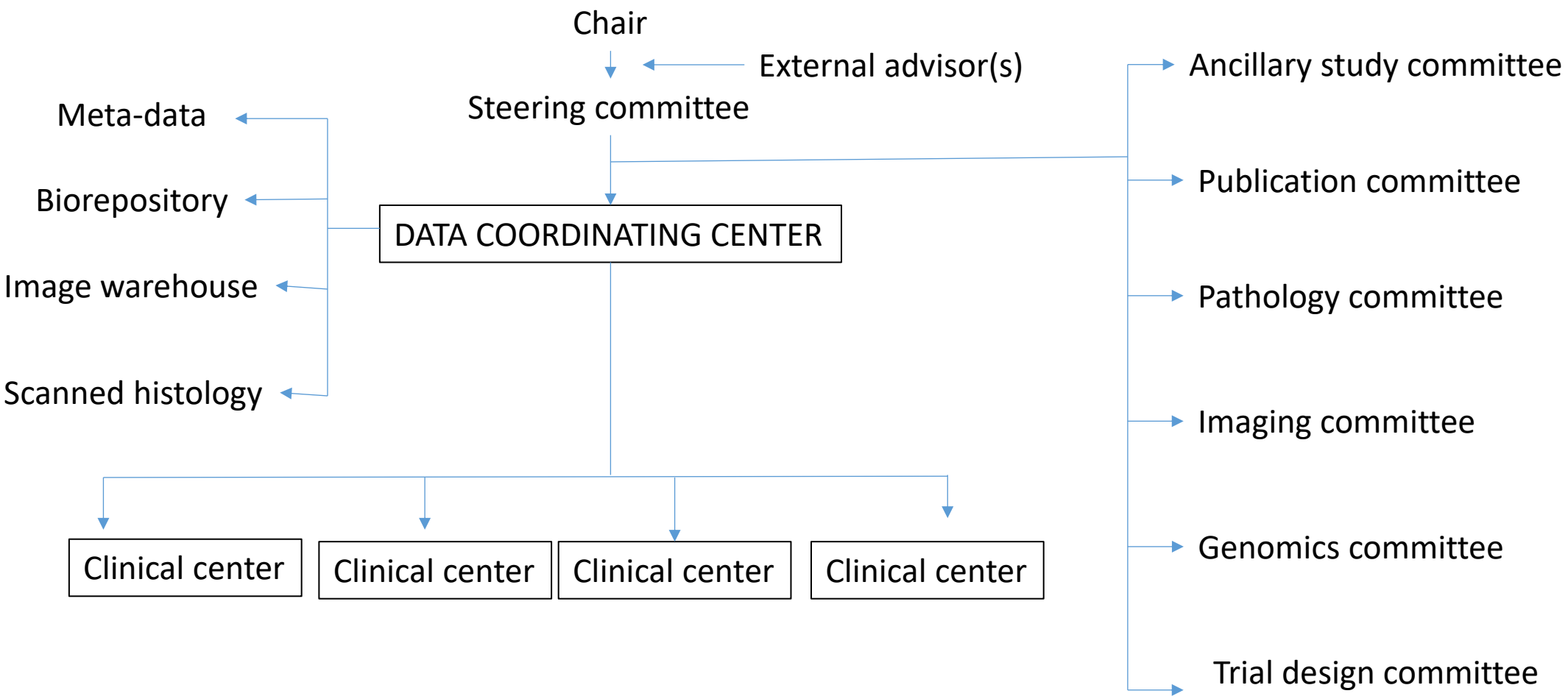
Step 1: Define the vision, goals and objectives

- To study the natural history of the disease
- To identify subpopulations with variable outcomes
- To perform translational studies to relate the biology of the disease to clinical phenotype and outcomes
- To develop biomarkers to facilitate assessment of the disease
- To perform clinical trials
- To be a platform to launch the career of junior investigators

Step 2: Agree on guiding principles

- Collaborations work only when everyone benefits from the collaborations
- Some general principles:
  - Shared responsibility with hierarchy
  - All key participants should have a key role
  - Transparency in conduct of the consortium
  - Every one is involved
  - Promote junior colleagues

Step 3: Develop an organizational chart



Function of the data coordinating center

- Data repository
- Connects all the different limbs of the program
- Organizes and integrates calls and actions of working groups
- Controls inflow and outflow of data and biosamples
- Communicates with biorepository
- Establishes contracts with external entities
- Helps with statistical design
- Analysis of data
- Preparation of reports for steering committee

Step 4: Develop actions and timelines

- Delineate timelines and milestones (strategic plan)
- Identify who is responsible for meeting milestones and timelines
- Developing working groups
- Communication is key- by web conference
- Create a Dash-board for self assessment and course correction

Community-Engagement and patient centered activities

- Critical to get a picture of real-life
- Critical to develop best practices for each region

External Advisory Committee (do not just include friends- important to have diversity of expertise)

- Chair- hepatologist
- Hepatology- 1-2
- Behavioral Scientist- expertise in nutrition, eating disorders, behavior, addiction
- Genetics- need a genetic epidemiologist with expertise in obesity, addiction and behavioral genetics
- Basic scientist- with expertise in systems biology
- Imaging expert- expertise in experimental-molecular-clinical imaging
- Biomarker development: expertise in science of biomarker development
- Community-engaged research expertise
- Data coordination
- Pathologist

Step 5: FUNDING

- To do it right it requires funding