

Why the Rise of the Foundations within the NCTN

- Federal funds are limited and often do not support “special” trial components (e.g., translational medicine objectives)
- Foundations offer more agile funding support, as monies are raised on an annual basis
- Foundation funds support education (e.g., grant writing workshops) and new types of clinical trials, through own competitive grants

Why the Rise of the Foundations within the NCTN (cont.)

- Foundations can support additional use of data gathered on the primary, federally-funded trial (e.g., secondary analyses)
- Foundations support items desired by NCI but which are not yet well-funded (e.g., DEI, novel patient advocacy efforts)
- Foundation trials are not subject to the same NCI oversight
- Non-federal trials can be quite lucrative, supporting the overall network group effort

Network Trials: “Classic” NCI vs Public Private Partnership Studies

Responsible Party	NCI Classic	Public-Private Partnership
Clinical Trial Coordinating Center	NCI Network Group	Group Foundation (often an LLC)
Regulatory Sponsor	IND Holder: Network Group or NCI	Network Group
Approval Process	NCI (Steering Committees if large)	Group Executive Committee
Funding Flow for Accrual	NCI Grant to Group Chair Institution to sites	Contracted Funds to Group Foundation LLC to sites
Timelines	NCI-mandated	Per Network Group, if any
Data custody	Network group	Group; may share with company
Specimen custody	Group; widely shared through NCI	Group; sometimes shared with partner

Network Trials: “Classic” NCI vs Public Private Partnership Studies (cont.)

Responsible Party	NCI Classic	Public-Private Partnership
Conflict Resolution	Group Conflict Mgmt Committee	Group Conflict Mgmt Committee
Clinical Sites	NCTN Network Sites	Usually same; potential to add from outside network, especially internationally
Contracting/Legal	NCI Regulatory Affairs Branch/SWOG Legal	SWOG legal
Investigator Credentialing	NCI Registration and Credential Repository	Contracted private system
Institution Review Board	NCI-Central IRB	Western Connexus or academic center IRB

Network Trials: “Classic” NCI vs Public Private Partnership Studies (cont.)

Responsible Party	NCI Classic	Public-Private Partnership
Funding per patient	Fixed, with add-ons; penurious	Negotiable; generous
Ability to use grant-funded infrastructure	Yes	No, with some exceptions if NCI is a partner or time and effort are “bought”
Management system	Clinical Trials Support Unit	Private contracted system
Safety Reporting	CTEP Adverse Event Reporting System	Private contracted system
Scientific leadership	Network group	Same; sometimes include private partner

