

eTable 1. Additional operational tools used in TIN consultations and trials

eTable 1 References

eFigure 1. Summary of TIN's dissemination

eTable 2. Selected TIN publications across the clinical trial lifecycle

eTable 2 References

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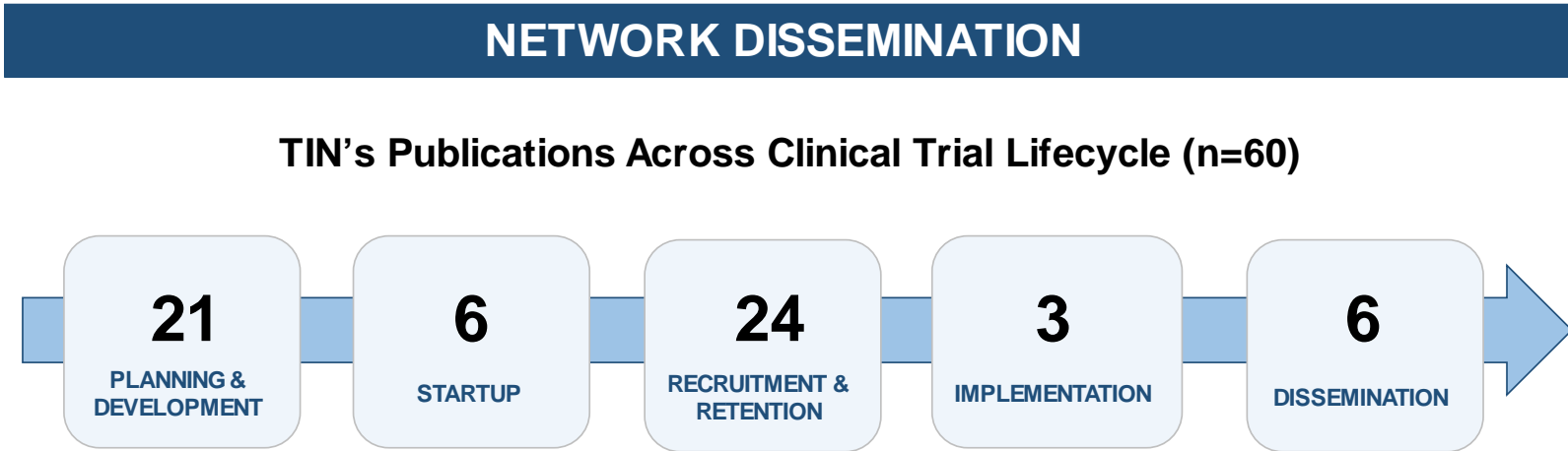
	Innovation	Description	Implementation
Study Design	Master protocol	Master protocol design, incorporating a single infrastructure and trial design that can evaluate multiple drugs and/or devices, or disease populations.	<ul style="list-style-type: none"> Used in two trials where 8 different drug/dose combinations have been tested. Lessons learned include understanding that the enrollment process may be more complicated with multiple drugs being studied. This may be mitigated by providing a streamlined description of each drug in the model informed consent form and by providing sites with aids, such as an informational video or flip chart to assist in the consent process.
	Adaptive design	A clinical trial design that allows for modification to a trial and/or statistical procedures of a trial after its initiation to maximize efficiency and/or speed up clinical development.	<ul style="list-style-type: none"> Used in two trials. In one, three arms were opened, and one arm discontinued. In the other trial, 6 arms have opened to date and 5 arms have been closed. Lessons learned include taking care to plan the opening and closing of arms with the protocol team as needed and the data management team and randomization team to insure a smooth transition.
IRB including Informed Consent	Single IRB Coordination during Study Startup¹	SIRB coordination includes the incorporation of personnel to help navigate and coordinate SIRB activities. This role may eliminate inefficiencies in the SIRB and HRPP review process by decreasing the time it takes participating sites to obtain site SIRB approval and HRPP activation prior to study enrollment.	<ul style="list-style-type: none"> Data has been collected on over 30 multi-center trials receiving SIRB coordination support.
	Informational video	Informational videos about clinical trials are used to explain the requirements of the trial, help recruit participants for the trial and assist with the informed consent process, either remotely or in person.	<ul style="list-style-type: none"> Trial informational videos were created for 8 studies. Lessons learned include obtaining IRB approval prior to any filming and being sure to account for potential protocol changes that could require video editing.
	iConsent	I-Consent is a web-based tool that works in conjunction with REDCap. It provides frameworks for investigators to customize the concise consent summary utilizing interactive techniques (e.g., videos,	<ul style="list-style-type: none"> A trial piloted the use of two iConsent methods (video versus infographic) for obtaining consent from patients for participation in a clinical trial. Our hypothesis is that iConsent may increase

		infographics) based on adult learning theories for use in real-world research studies within a user-friendly human-computer interface.	comprehension or improve participant autonomy.
Site selection and Start up	COVID Trials Rapid Study Startup in Under Two Weeks²	Emergency support for rapid study start-up was critical during the early outbreak of the COVID-19 global pandemic. By using expertise in various domains (data management, bioinformatics, site management, study management) at four academic medical centers, two large randomized clinical trials were developed and initiated to study the effects of a specific drug in outpatients with confirmed COVID-19 in under two weeks.	<ul style="list-style-type: none"> Timelines associated with rapid study start-up include 1) establishment of a DSMB and approved DSMB charter (3 days), 2) FDA-approved IND exemption (<90 minutes), IRB submission to approval (5 days), and 4) IRB approval to first patient in (5 days).
Enrollment	Guidelines for Developing Culturally Tailored Recruitment Materials³	Culturally appropriate, minority recruitment material (MRM) guidelines developed using a multi-layered approach. The literature related to application of cultural targeting strategies to develop recruitment materials served as the foundation for guideline development integrated with input of African Americans and Latinos on strategies to increase reach of recruitment materials in clinical trials.	<ul style="list-style-type: none"> Metrics under development
Study Conduct	The 3-3-3 Approach⁴	Risk Assessment and Risk Management (RARM) is a simplified tool designed to meet the demands of an academic medical center. It was developed to prioritize risk management activities around critical aspects of a research study.	<ul style="list-style-type: none"> Used in approximately 30 multi-center trials. Tool was developed through an iterative process of pilot testing and revising to achieve a simplified, seamless, approach to risk assessment and risk management.
	Risk-Based, Study-Specific Training Program⁵	A competency-based training program was designed to support high levels of competency and performance in clinical research coordinators (CRCs) working on a clinical trial. The training program, which incorporates Joint Task Force Competency Domains and ICH E6(R2) risk assessment processes, was targeted toward high- and moderate-risk protocol activities.	<ul style="list-style-type: none"> A focused approach helped CRCs feel competent in the high- to moderate-risk areas of the trial as well as standard areas of research.

eTable 1 References

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eFigure 1. Summary of TIN's dissemination



eTable 2. Selected TIN publications across the clinical trial lifecycle

TIN Publication	Planning & Development	Study Start-up	Recruitment & Retention	Implementation	Dissemination
CPCCRN Demo Lessons Learned from SMART IRB & IREx ¹	X				
Using Single IRB Consultations to Meet the Educational Needs of Investigative Teams ²	X				
Consent Builder: An innovative tool for creating research informed consent documents ³		X			
Key Lessons and Strategies for Implementing Single IRB in the Trial Innovation Network ⁴	X				
The IRB Reliance Exchange (IREx): A national web-based platform for operationalizing single IRB review ⁵		X			
Approach to Reviewing Local Context for EFIC Trials Using SIRB ⁶	X				
Development of a Risk Assessment and Risk Management Tool for an Academic Research Organization ⁷		X			
Using gamification to benchmark clinical trial site performance ⁸				X	
DSMBc in COVID-19 studies ⁹					X
Decentralized Clinical Trials: Perspectives for Clinical Research Professionals ¹⁰	X				
Broadly Engaged Team Science Comes to Life in a Design Lab ¹¹	X				
Bayesian Adaptive Design TIC-TOC ¹²	X				
Incentive Delivery Timing & Follow-up Survey Completion in a Prospective Cohort Study of Injured Children: A Randomized Experiment Comparing Prepaid & Postpaid Incentives ¹³			X		
Clinical Trial Agreements ¹⁴		X			
Impact of a Risk-Based, Study-Specific Training Program on Research Coordinator Competency ¹⁵		X			
Efficacy and Effectiveness Too Trials: Clinical Trial Designs to Generate Evidence on Efficacy and on Effectiveness in Wide Practice ¹⁶	X				
An example of medical device-based projection of clinical trial enrollment ¹⁷	X				

Efficacy-to-Effectiveness Clinical Trials ¹⁸	X				
REDCap on FHIR: Clinical Data Interoperability Services ¹⁹				X	
Creating and Implementing a COVID-19 Recruitment Data Mart ²⁰	X		X		
Using a multicultural and multilingual awareness-raising strategy to enhance enrollment of racially underrepresented minoritized communities – the PassITON trial ²¹			X		
Development and Validation of the Perceptions of Research Trustworthiness (PORT) Scale ²²	X		X		X
Selecting EHR-driven Recruitment Strategies: An Evidence-Based Decision Guide ²³	X		X		
Development and pilot implementation of guidelines for culturally tailored research recruitment materials for African Americans and Latinos ²⁴	X		X		
MyCap: a flexible and configurable platform for mobilizing the participant voice ²⁵	X		X		
Recruitment and Retention for Chronic Pain Clinical Trials: A Narrative Review ²⁶			X		
What we wish every investigator knew – Top 4 recruitment and retention considerations from the Recruitment Innovation Center ²⁷	X		X		X
“Send My Information”: Increasing Public Accessibility to Clinical Trials by Facilitating Participant Expression of Interest ²⁸			X		
How do Hispanics/Latinos Perceive and Value the Return of Research Results? ²⁹			X		X
EHR-based Cohort Assessment: A Fast and Flexible Model for Identifying Study Populations in Support of Multi-site Clinical Trials ³⁰	X		X		
Effects of financial incentives on volunteering for clinical trials: A randomized vignette experiment ³¹			X		
The Recruitment Innovation Center: Developing Novel, Person-centered Strategies for Clinical Trial Recruitment and Retention ³²	X	X	X		
Engaging smokers in research: Utility of Facebook in facilitating recruitment to a smoking cessation study ³³			X		

Design and implementation of a massive open online course on enhancing the recruitment of minorities in clinical trials – Faster Together ³⁴	X		X	X	
Opening doors to clinical trial participation among Hispanics: Lessons learned from the Spanish translation of ResearchMatch ³⁵	X		X		
A REDCap-based model for electronic consent (eConsent): Moving toward a more personalized consent ³⁶	X		X		
The Impact of an Educational Video on Clinical Trial Enrollment and Knowledge in Ethnic Minorities: A Randomized Control Trial ³⁷			X		
To end disease tomorrow, begin with trials today: Digital strategies for increased awareness of a clinical trials finder ³⁸			X		
Association of Health Literacy and Numeracy with Interest in Research Participation ³⁹			X		
Understanding What Information Is Valued By Research Participants, And Why ⁴⁰			X		X
Effective Engagement Requires Trust and Being Trustworthy ⁴¹			X		X
Connecting the public with clinical trial options: The ResearchMatch Trials Today tool ⁴²			X		

Table excludes study-specific publications

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