

ACS Cancer Conference 2025

March 12-14 | Phoenix, AZ

Why Participate in Cooperative Group Clinical Trials through NCTN

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How to Develop Successful Accrual to Clinical Trials in a Community Center

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Disclosures: Throckmorton

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- Numerous spousal orthopedic disclosures (royalties, consulting fees, IP)



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Cooperative Group Trials – What are they?

- NCI - Federally funded cancer clinical trials through the National Clinical Trials Network (NCTN)
 - Efficiency and Effectiveness

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The Importance of Cooperative Group Clinical Trials

- Access to innovative, high-quality clinical trials
- Increase collaboration between institutions, researchers, and oncologists
- Facilitate large-scale, multi-institutional studies that would not be possible independently = practice changing
- Recognize the importance of diversity and minority recruitment for participation to assure all populations represented

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Benefits of Participation for Hospitals and Physicians

- Access to cutting-edge research that are NCI-Funded
- Expand treatment options
- Professional growth
- Enhanced institutional reputation

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Benefits for Patients

- Access to new therapies not yet widely available
- High quality care
- Hope for better outcomes

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Early Beginnings

- 1950s: Post- World War II scientific boom
- 1955: Concept of cooperative group trials conceived by Sidney Farber, Mary Lasker, and others
- 1956: Formation of the first cooperative groups
 - GALGB
 - ECOG
 - SWOG
 - CCG

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Growth and Development

- 1960s-1970s: Expansion of cooperative groups
- 1970s: Establishment of the National Cancer Institute (NCI) Clinical Trials Cooperative Group Program
- 1980s: Increase funding and more structured trials

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Major Milestones

- 1990s: Significant breakthroughs in cancer treatment through cooperative trials
- 2000s: Introduction of precision medicine and targeted therapies
- 2011: Merger of cooperative groups into 4 major groups

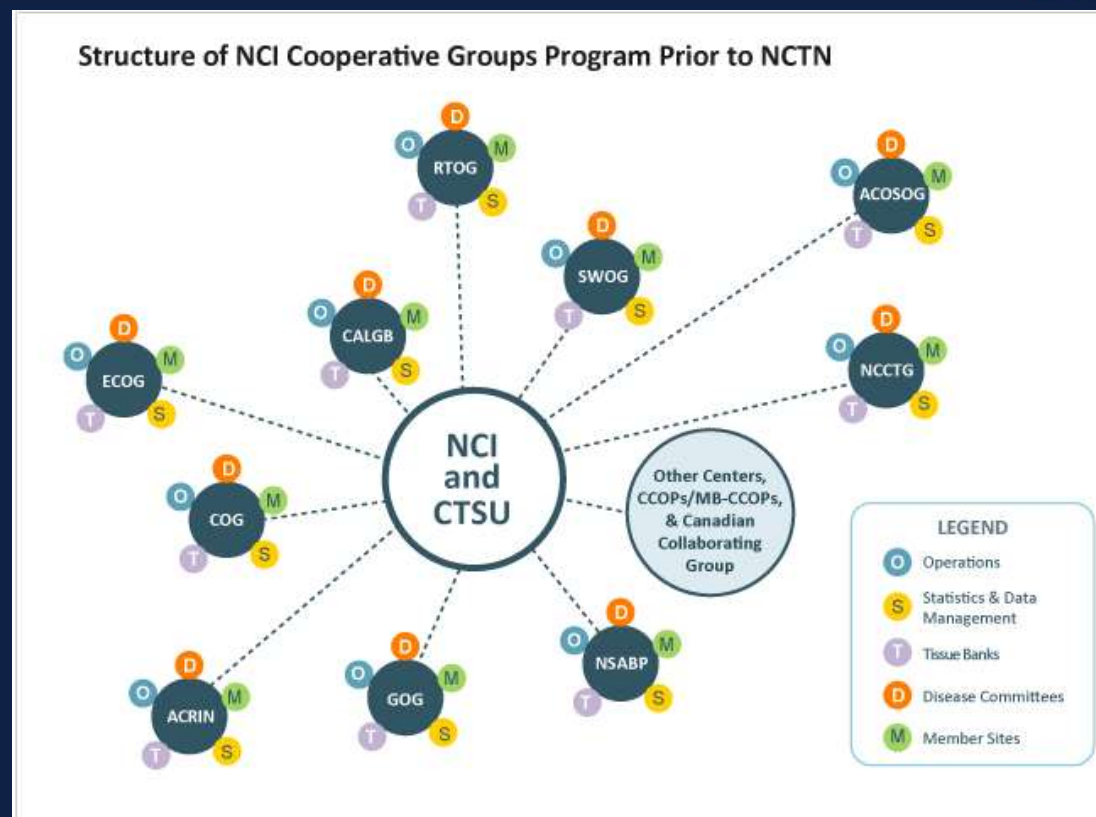
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Clinical Trial History

- Initially there were numerous independent trial groups focused on specific cancer types or treatment modalities

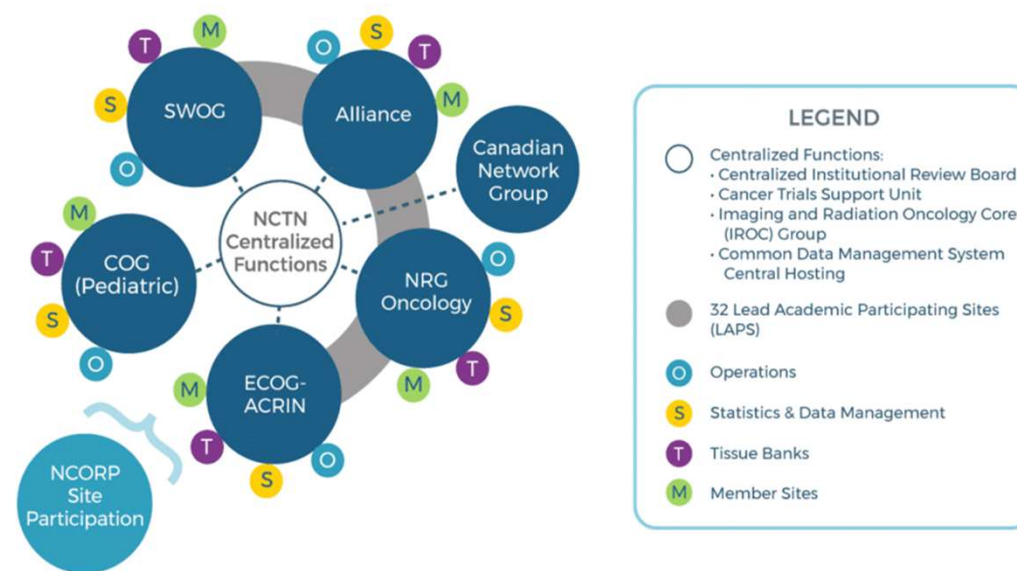


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Clinical Trial History

- Over time, these groups consolidated to streamline research efforts and resources

NCI National Clinical Trials Network Structure



cancer.gov

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Alliance for Clinical Trials in Oncology

- Cancer and Leukemia Group B (CALGB)
- North Central Treatment Group (NCCTG)
- American College of Surgeons Oncology Group (ACOSOG)



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ECOG-ACRIN Cancer Research Group

- Eastern Cooperative Oncology (ECOG)
- American College of Radiology Imaging Network (ACRIN)



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NRG Oncology

- National Surgical Adjuvant and Bowel Project (NSABP)
- Radiation Therapy Oncology Group (RTOG)
- Gynecologic Oncology Group (GOG)



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SWOG

- Originally Southwest Oncology Group
 - Remains a key cooperative group



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Modern Era

- 2014: Transition to the National Clinical Trials Network (NCTN)
- Current Focus: Emphasis on efficiency, collaboration, and precision medicine

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Laying the foundation

- Define the research vision and focus
 - Identify therapeutic areas of interest
 - Align with institutional goals and funding priorities
 - Short-term and long-term objectives



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Housekeeping: Regulatory and Ethical Framework

- IRB approval process
- Compliance with FDA
- Ethics considerations and patient safety
- Training and Certification
 - Good Clinical Practice (GCP) training
 - Human subjects research protection training
 - Standard Operative Procedures (SOPs) for staff



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Cooperative Group Participation

- NCI supports hospitals/institutions to participate in **multiple cooperative groups within NCTN**
 - Expand trial availability for patients
 - Access specialized research and expertise from different groups
 - Contribute to a broader range of scientific studies
- Requires dedicated resources
 - Compliance
 - Administration
 - Regulatory oversight to manage protocols effectively

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Practice Changing Trials

- NSABP B-06: Lumpectomy with RT vs. mastectomy vs. lumpectomy alone
- NSABP B-18: Impact of NACT on tumor size and surgical outcomes
- NSABP B-32: SLNB vs. ALND
- ACOSOG Z0011: Axillary nodal management de-escalation movement begins
- ACOSOG Z1071: Downstaging axillary nodal burden
- NRG B-51: De-escalation radiation – RNI omission

It takes a village to change practice...across the country...big and small!

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Why Clinical Trials in the Community?

- ~85% patients treated at community practices¹
- 7% CoC patients enroll on trials²
- 3-6% historical ethnic/racial minority enrollment³
- Improves generalizability/implementation of results
- “Bringing tomorrow’s treatments to our patient’s today”
- “Best treatment is a clinical trial”
- Potential to attract new patients

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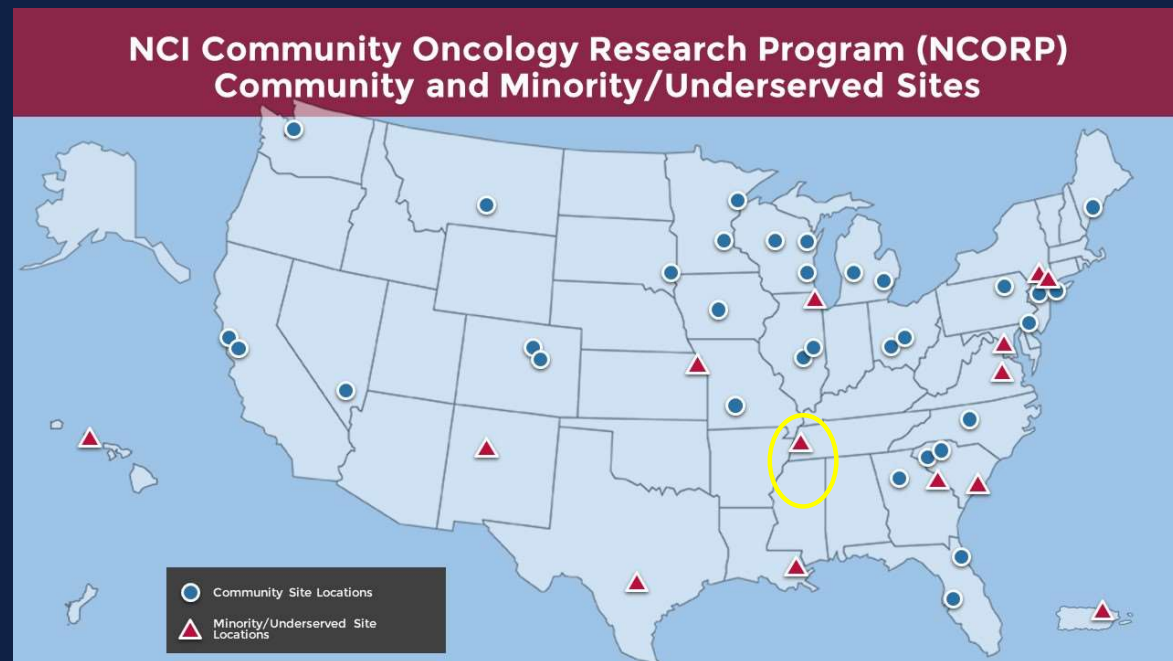
¹<https://ascopubs.org/doi/10.1200/JCO.23.01030>

²<https://www.cancer.gov/research/areas/disparities/Chanita-huges-halbert-clinical-trials-community-access>

³Nouvini R. Interventions to increase racial and ethnic minority accrual into cancer clinical trials: A systematic review. Cancer. 2022 Nov 1;128(21):3860-3869. doi: 10.1002/cncr.34454. Epub 2022 Sep

Baptist MU NCORP

- Urban/suburban/rural
- 47 rostered investigators
- SWOG/ECOG/Alliance/Wake Forest
- Ave annual accrual 300+
- Ave minority accrual 37%



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[NCORP_map-Community-and-Minority-sites.jpg \(1280x720\)](#)

What trials to consider?

- Trial origin
 - Cooperative Groups
 - Investigator Initiated
 - Industry
- Trial types
 - Cancer Control/Prevention
 - Treatment
 - Supportive Care
 - Cancer Care Delivery Research

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Building the Research Team

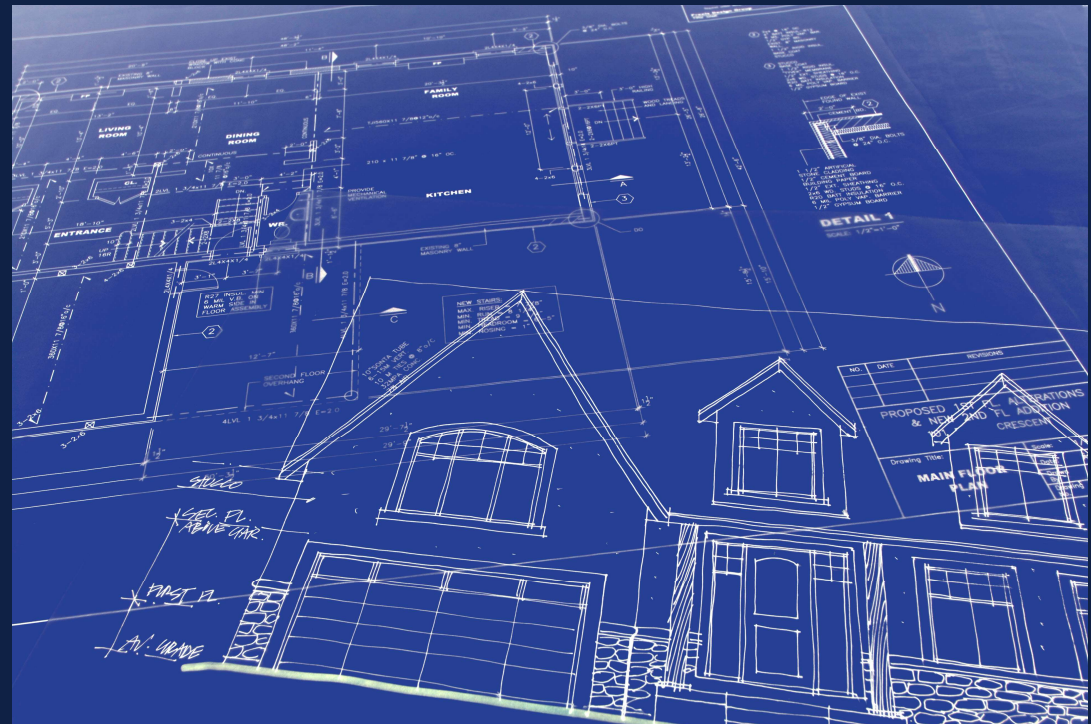
- Principal Investigators (PIs) and Co-Investigators
- Clinical Research Coordinators (CRCs)
- Regulatory and compliance specialists
- Data managers



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Starting from scratch

- Find an institutional partner
- Find a mentor
- Find a patient/community advocate
- Build the business case
- Get administration buy-in
- Pick easy trials first
- Market the program



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Requirements for primary and coinvestigators

- CITI training
- CTEP ID
- Protocol training
- Patient enrollment
- Adhering to protocol
- AE reporting/monitoring



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Trial selection in the community

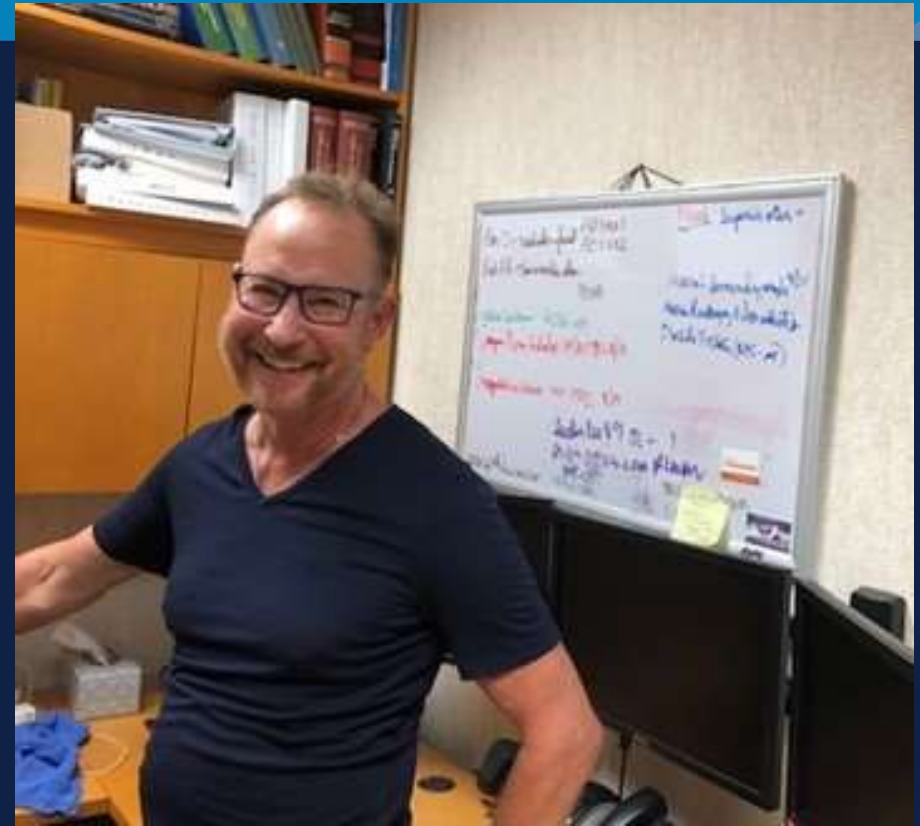
- Interest and eligibility of your patient population
- Interest to you/your colleagues
- Ease/feasibility/location
- Trial equity for your population (i.e. language, culture, barriers)
- Cost/credit
- Patient identification
- Trial promotion



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Learn from Others

- Attend trial webinars/calls
- Find an investigator at high accruing site
- Find an investigator with similar practice/patient population
- What Would Gary Do?



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Presenting to patients

- Talk about trials even if this patient isn't eligible right now
- Why clinical trials are important
- Participation is voluntary
- Acknowledge history with minority patients



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Presenting to patients

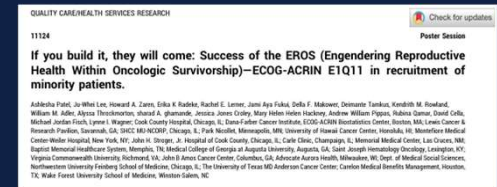
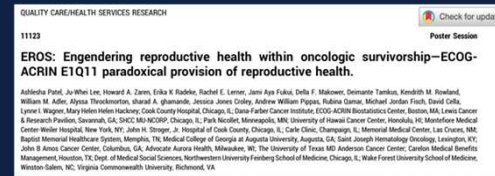
- Introduce any available trial
- Why this patient may benefit
- Identify potential barriers to participation
- Include trial discussion in communication to referring MDs
- Update patients as trial outcomes are presented/published



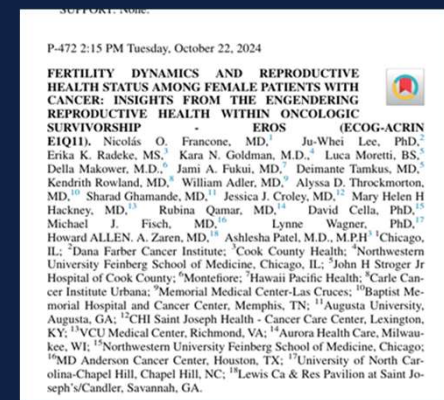
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Opportunities for involvement

- Local trial selection
- Local trial co-investigator
- Local trial PI
- Institutional program PI
- Cooperative group meetings
- Cooperative group community trial PI
- Cooperative group committees
- Cooperative board of directors
- NCORP/cooperative group rep to NCI task force or steering committee
- Publications



Nightingale CL, Dressler EV, Kepper M, Klepin HD, Craddock Lee S, Smith S, Aguilar A, Wiseman KD, Sohli SJ, Wells BJ, DeMari JA, Throckmorton A, Kulbacki LW, Hanna J, Foraker RE, Weaver KE
Oncology Provider and Patient Perspectives on a Cardiovascular Health Assessment Tool utilized during Post-treatment Survivorship Care in Community Oncology (Mixed Method Results from WF-1804CD)
Journal of Medical Internet Research. 18/01/2025:65152 (forthcoming/in press)
DOI: 10.2196/65152
URL: <https://preprints.jmir.org/preprint/65152>
PMID: 39854647



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Networking

- Colleagues at nearby institutions
- Attend cooperative group meetings
- Reach out to investigators re pilot trials, concepts
- Answer cooperative group surveys re trial design, feasibility



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Resources for investigators

- Study team
- Study print and online materials
- Cooperative group meetings
- NIH trial search engine
<https://www.ctsu.org/Master/SimplePage.aspx?ascx=ProtocolsReport>
- CTSU website <https://www.nccn.org/patientresources/patient-resources/patient-webinars/patient-webinar--clinical-trials>

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Resources for patients

- NCCN webinars <https://clinicaltrials.gov/>
- Patient navigators
- Study patient-facing print and online materials
- Study website

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Thank You

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