Accelerating Global Clinical Trials Conduct: Access, Decentralization and Technology

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ACCESS TO CLINICAL TRIALS CRITICAL RESULTS IN BETTER OUTCOMES

Shannon and his family

Photo and story with patient permission.

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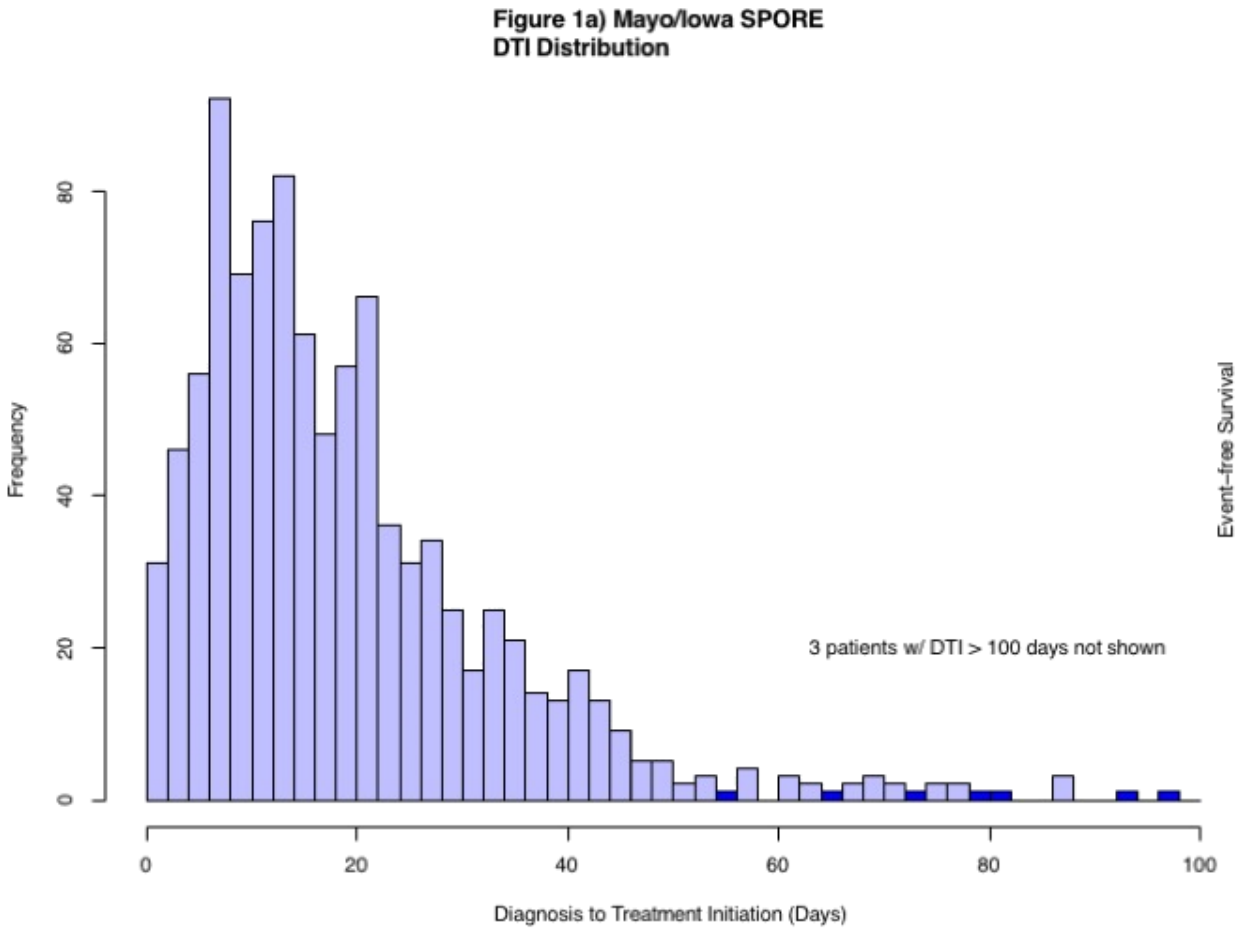
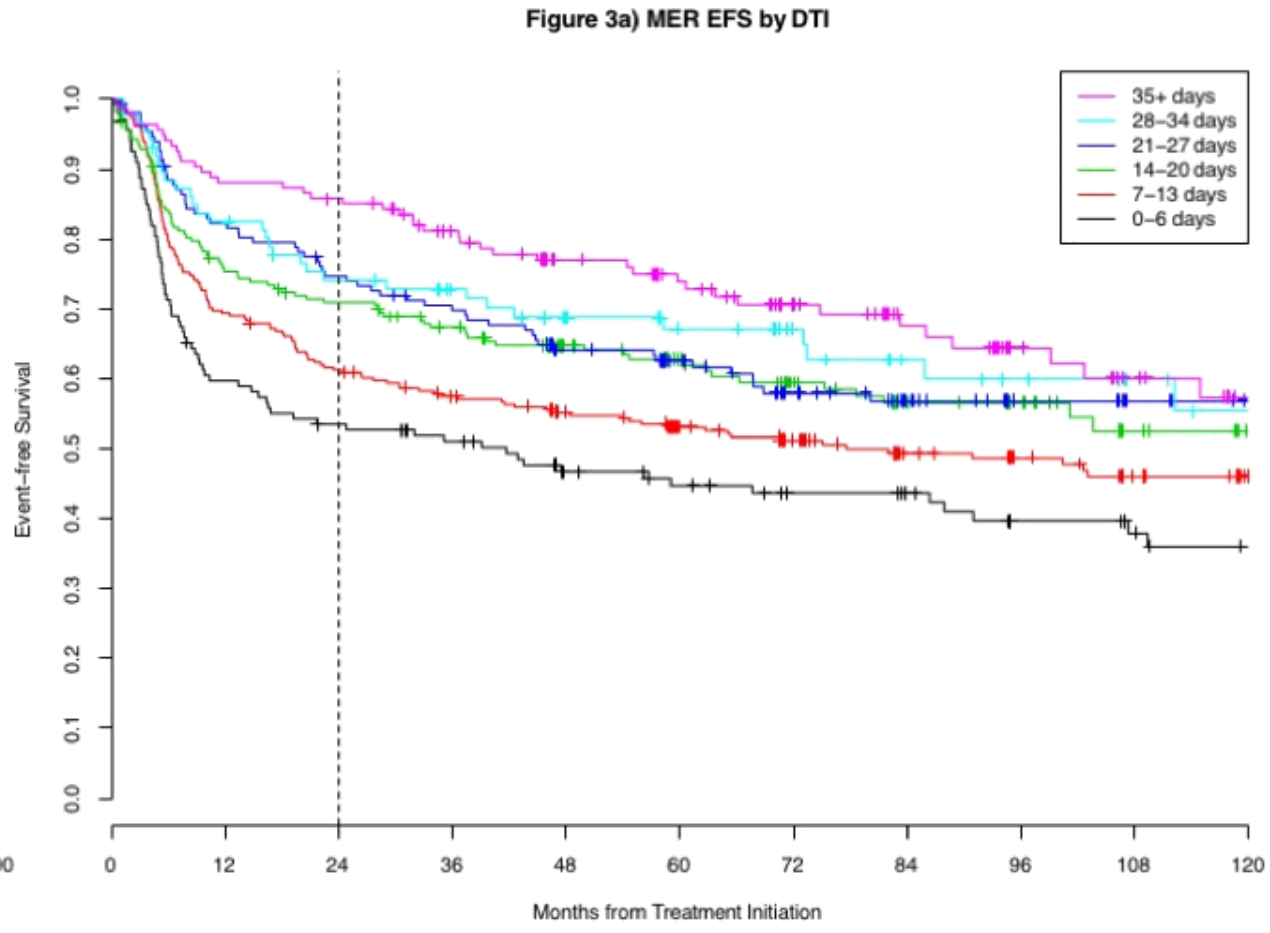
EASY ACCESS TO TRIAL…IMPROVES TRIALS





DLBCL, diffuse large B-cell lymphoma; DTI, diagnosis-to-treatment interval; EFS, event-free survival; MER, University of Iowa and Mayo Clinic Specialized Programs of Research Excellence Molecular Epidemiology Resource; SPORE, Specialized Programs of Research Excellence.

Maurer and Nowakowski, *J Clin Oncol*. 2018;36:1603-1610.

	Trial Availability	Trial Complexity and Requirements	Continuity of Care (Fields 4 & 6, FDA Form 1572)	Travel, Financial, and Time Toxicity (Fields 4 & 6, FDA Form 1572)	Costs and Convenience (Field 3, FDA Form 1572)
Patient Considerations	• Is there a trial available for me? • Does my local provider participate? • Will I be eligible tp participate?	• How often will I be required to go to the clinic? • How long is each visit? • How will this commitment, and potential side effects, impact my job, children/childcare, and family obligations?	• Can I continue care with my local oncologist? • If I transfer care to the research center, will there be linguistic and cultural alignment and understanding with their team? • Will I be able to trust my doctor and the research team? • How well does the research team know my medical or cancer history?	• What will be the financial and nonfinancial costs of participation? Is there someone who can help me understand and sort them out? • What will or will not be covered by insurance? • Will there be extra tests? • Will I have to travel to the research center for routine blood draws or can I go to the laboratory in my neighborhood? • Will I be able to have assessments at my local radiology imaging center? • How much do I have to budget for parking, tolls, gas, accommodations? • Who can accompany me on my research visits in case I don't feel well enough to travel?	
Community Practice/Provider Considerations (Limited or no Research Infrastructure)	• How do I identify available trials for my patients? • Is a suitable trial available onsite? • Am I able to provide my patients with access to a variety of treatment trials, including more complex trials? • Should I look into (do I have) a research partnership with a research center or network?	• How can I manage to offer (or support my patient in) the trial without protected research time? • How can I manage to offer (or support my patient in) the trial with limited or no research infrastructure? • What are the requirements (and the risks-benefits) for my patient to participate? • Will I have a reliable point of contact person who can answer questions in a timely manner?	• How will I be able to support my patient while they are participating in a trial? • How can I remain involved in my patient's care during their trial participation at the research center? • Will I be able to keep informed about my patient if they go to an academic center or research network to participate in a trial? • Will my patient return to my practice after they complete the trial? • What do I do if there is a treatment-related emergency?	• What will be the financial and time burden for my patients? • What will be the impact on my workload? • What will be the impact on my staff's workload?	• Will there be a financial impact on me and/or my organization, including a potential loss of revenue if my patient receives their care and testing offsite?
Investigator/Research Site Considerations	• Is there a community-based provider with whom I can partner to expand enrollment? • Does the local provider have research infrastructure? • Does the local provider have experience with clinical trials?	• What are the protocol requirements and is a research partnership feasible (e.g., respective responsibilities, oversight requirements, administrative burden on our staff)? • What support must I provide the local provider (i.e., training, expertise, central resources) • What regulatory documentation is required and how long will that take?	• Are there components of the trial that can be feasibly done locally (e.g., standard-of-care treatment, laboratory tests, and imaging)? • Can I trust the local provider and care team? • How do I manage the relationship with the patient's local provider? • How can I fulfill my oversight responsibilities without the ability to physically supervise?	• Can laboratory tests and/or imaging be done locally (some or all)? • How will I know if the local laboratories and imaging facilities will meet quality standards? Can I trust the results? How will I get the findings? • What is the financial impact on my research center?	• What are the costs-benefits of the partnership (burden vs. accrual)? • What are the regulatory requirements and risks? • How will I ensure regulatory compliance, with limited resources and workforce shortage? • What liability do I assume? • What is burden on staff and infrastructure?

Harvey, Nowakowski A call to action to advance patient-focused and decentralized clinical trials, Cancer, Volume: 130, Issue: 8, Pages: 1193-1203,

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1. Created by us – can be solved by us

2. Technology

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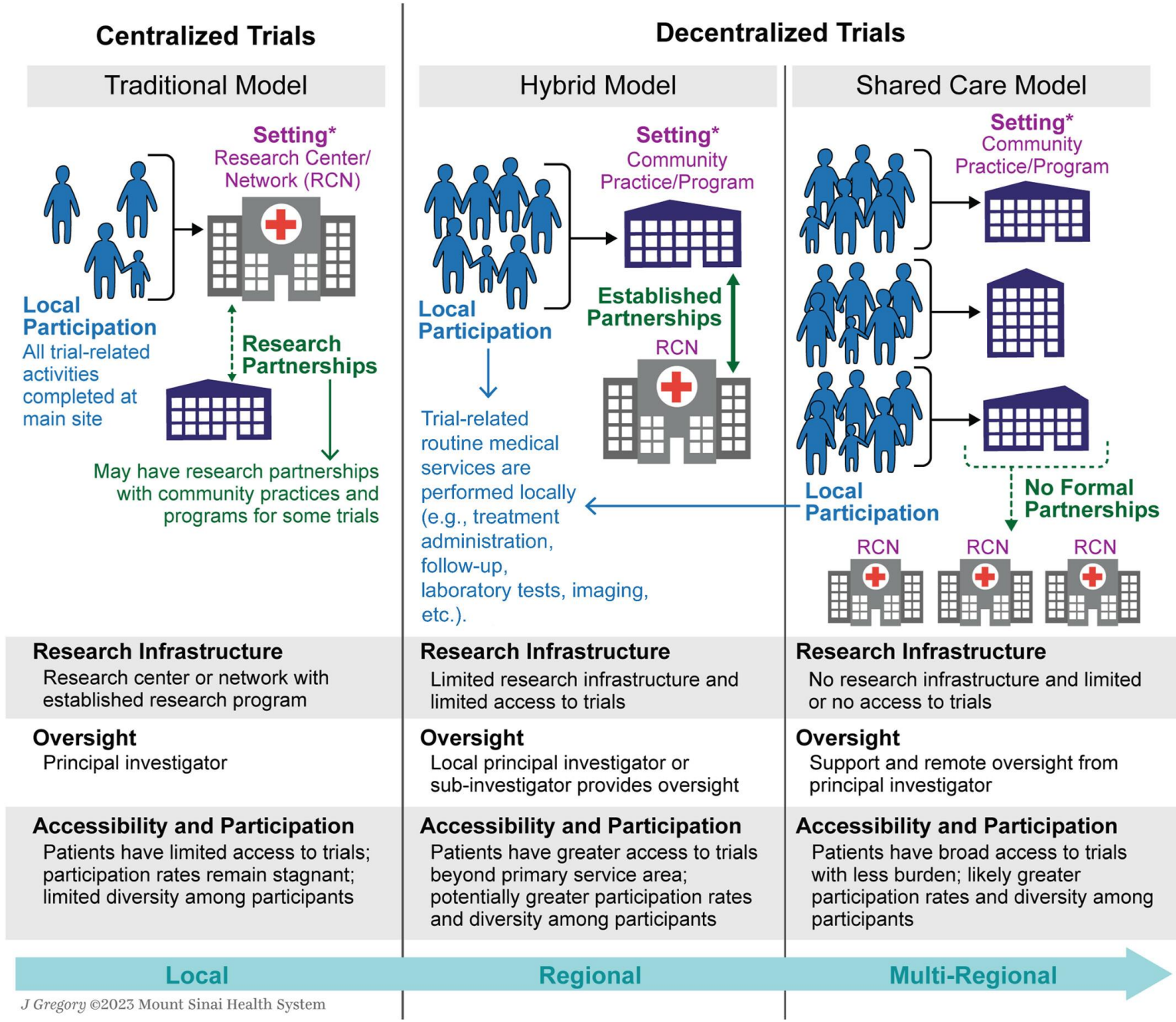

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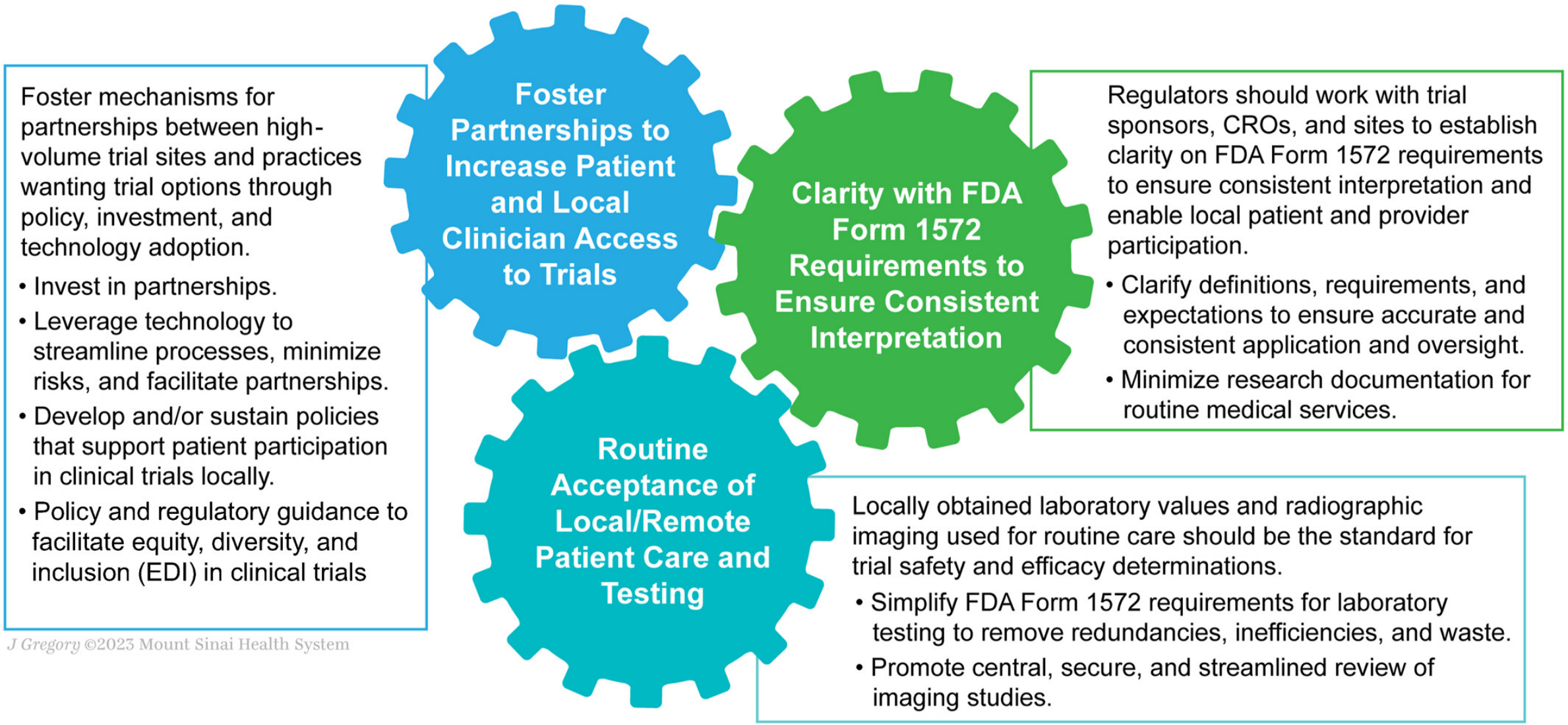

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MAYO CLINIC

#1 Health System in U.S. & World
15M Sq. Ft.; 1374 Beds (MCR)
U.S.: Highest Volume Proton Beam and Radiopharmaceutical Practice
1.4M Patients Annually (System)
76,000 Faculty & Staff (System)

Mayo Clinic in Rochester, Minnesota
St. Mary's and Downtown Campuses

Mayo Clinic Health System (MCHS): MN, WI, IA

60 Communities
Rural/Tribal
16 Hospitals
53 Clinics
Cancer Programs:
Albert Lea, MN
Mankato, MN
Eau Claire, WI
LaCrosse, WI

Mayo Clinic in Arizona
Phoenix and Scottsdale

Mayo Clinic in Florida
Jacksonville

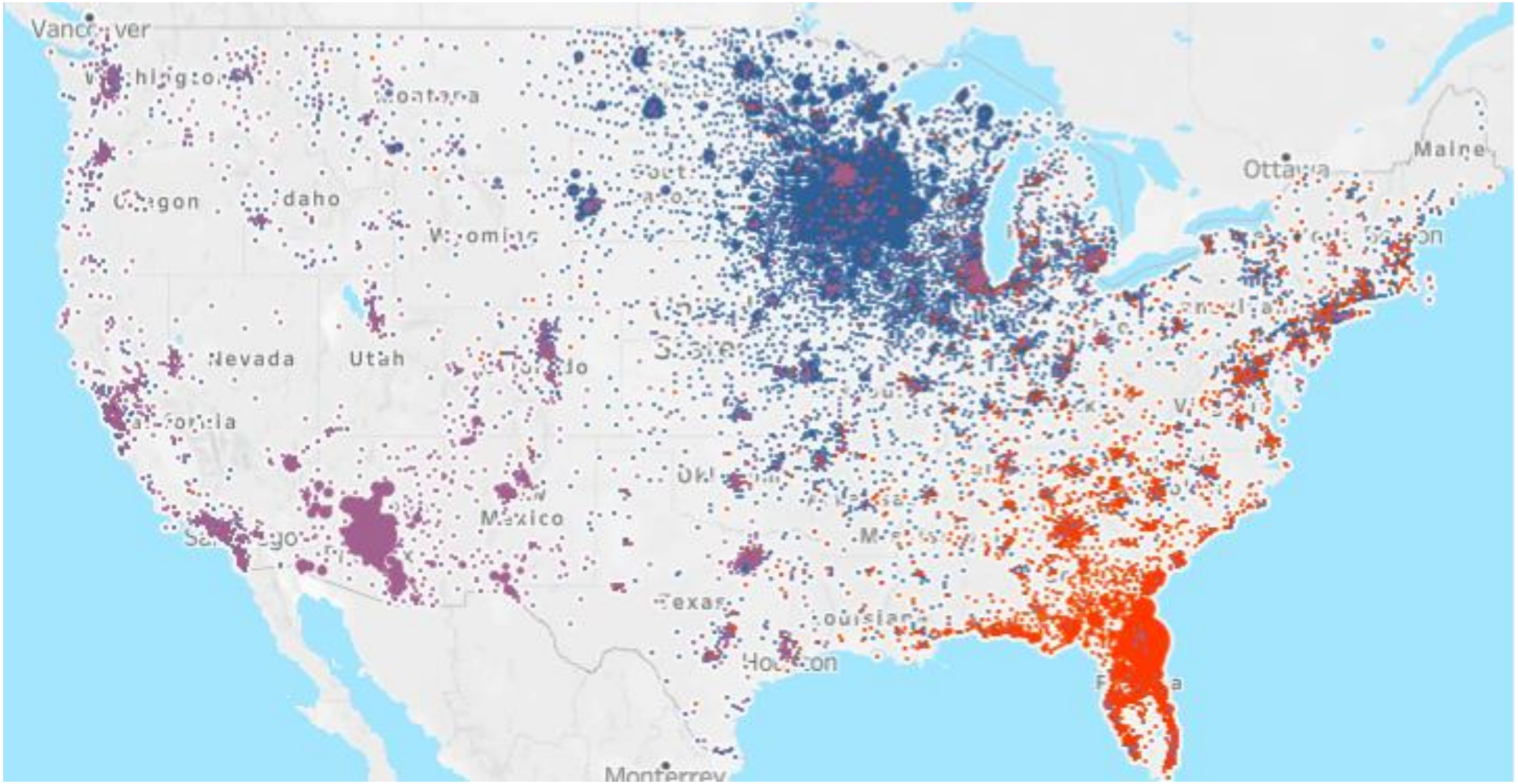
#1 Hospital – Arizona
U.S.: Highest Volume Solid Organ Transplant (>1500)
Strengths: Cancer/Transplant
ASU Partnership

#1 Hospital – Florida
First Site for Carbon Ion in the Americas
Cancer Vaccine Program
Virtual Care Delivery: Advanced Care@Home

Mayo Clinic Cancer Comprehensive Center: National Reach

2022: >122,000 Unique Pts; 20,627 Newly Diagnosed

2022: 3,629 Interventional Accruals (1,477 Therapeutic) and > 31,000 Interventional Accruals to Community-Based Screening/Intervention and Survivorship/Symptom Control Trials



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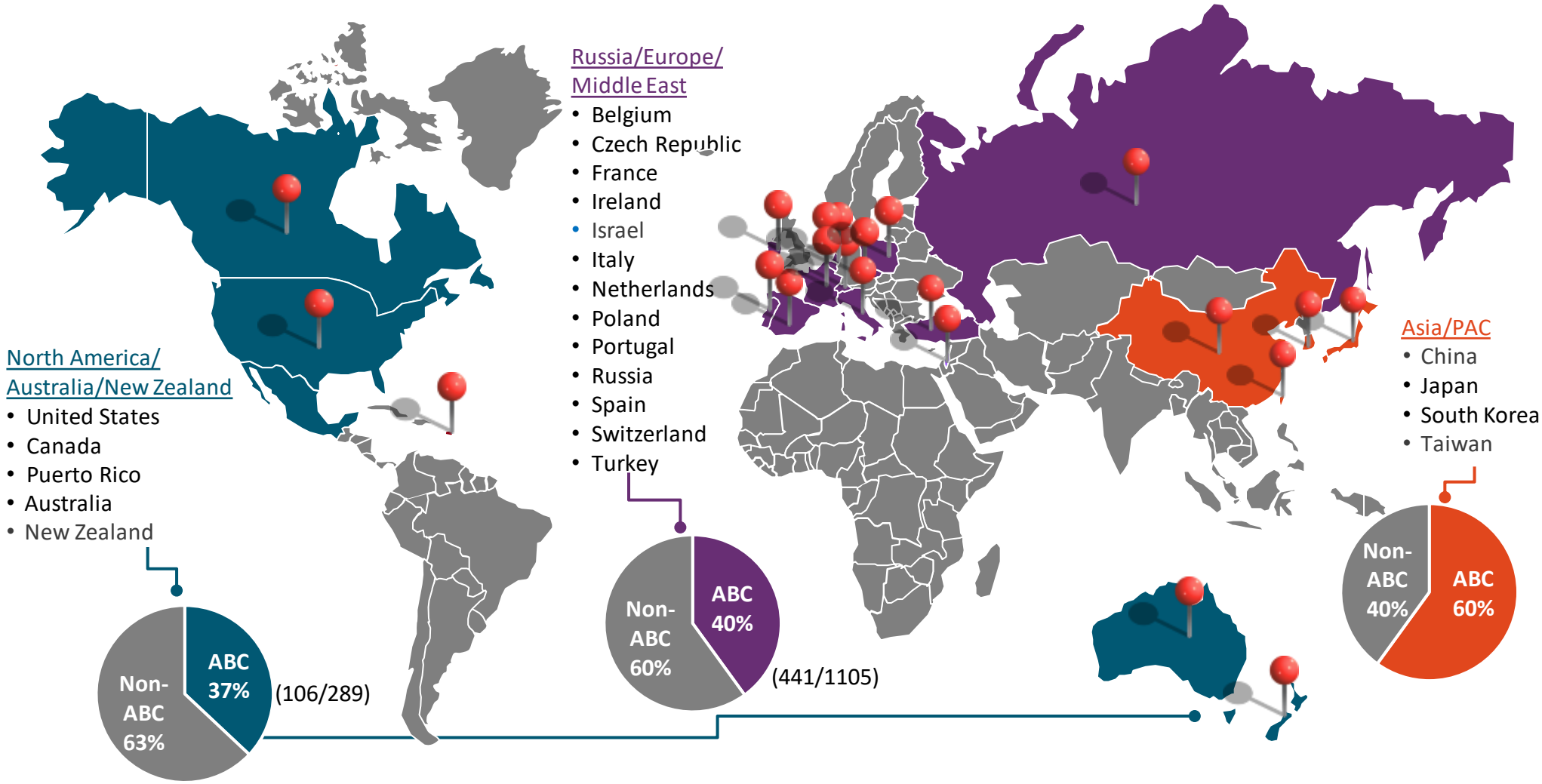
Molecular studies can allow for understanding of regional differences: geographical distribution of cell of origin in DLBCL



Nowakowski. Haematologica. 2020;105:e72.

Mayo Clinic Cancer CARE Beyond Walls

Mayo Clinic

Software Platform

Command Center

Supplier Network

Patient Home

Patient

Home Technology

Advanced Care at Home

> 5000 Patients Treated at Home
15-50% Reduction in Readmission
94% Patient Satisfaction

Care Beyond Walls: Managing the Entire Cancer Patient Journey

OUTPATIENT CARE AT HOME

- Telehealth (virtual visits, remote patient monitoring/RPM)
- Home healthcare
- Supportive care/home infusion

CHEMOTHERAPY AT HOME

- Home cancer-directed therapy (chemotherapy, immunotherapy) infusion
- Home labs
- Telehealth (virtual visits, RPM)

SUPPORTIVE CARE AT HOME

- Palliative care
- Non-medical home care
- Virtual visits with other members of the care team (e.g. nutritionist, social worker)

Global clinical conduct – opportunities

- Improving and simplifying study conduct
  - Improve outcomes of patents
  - Improve study – real world population
- Regulatory changes and changes fostering collaboration critical for accrual friendly and decentralized trials
- Technology provides platform
  - Remote and decentralized study conduct
  - Understanding of regional differences in outcomes based on molecular profiling

CAR, chimeric antigen receptor; RWD, real-world data; TCE, T cell engager.

Thank you

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