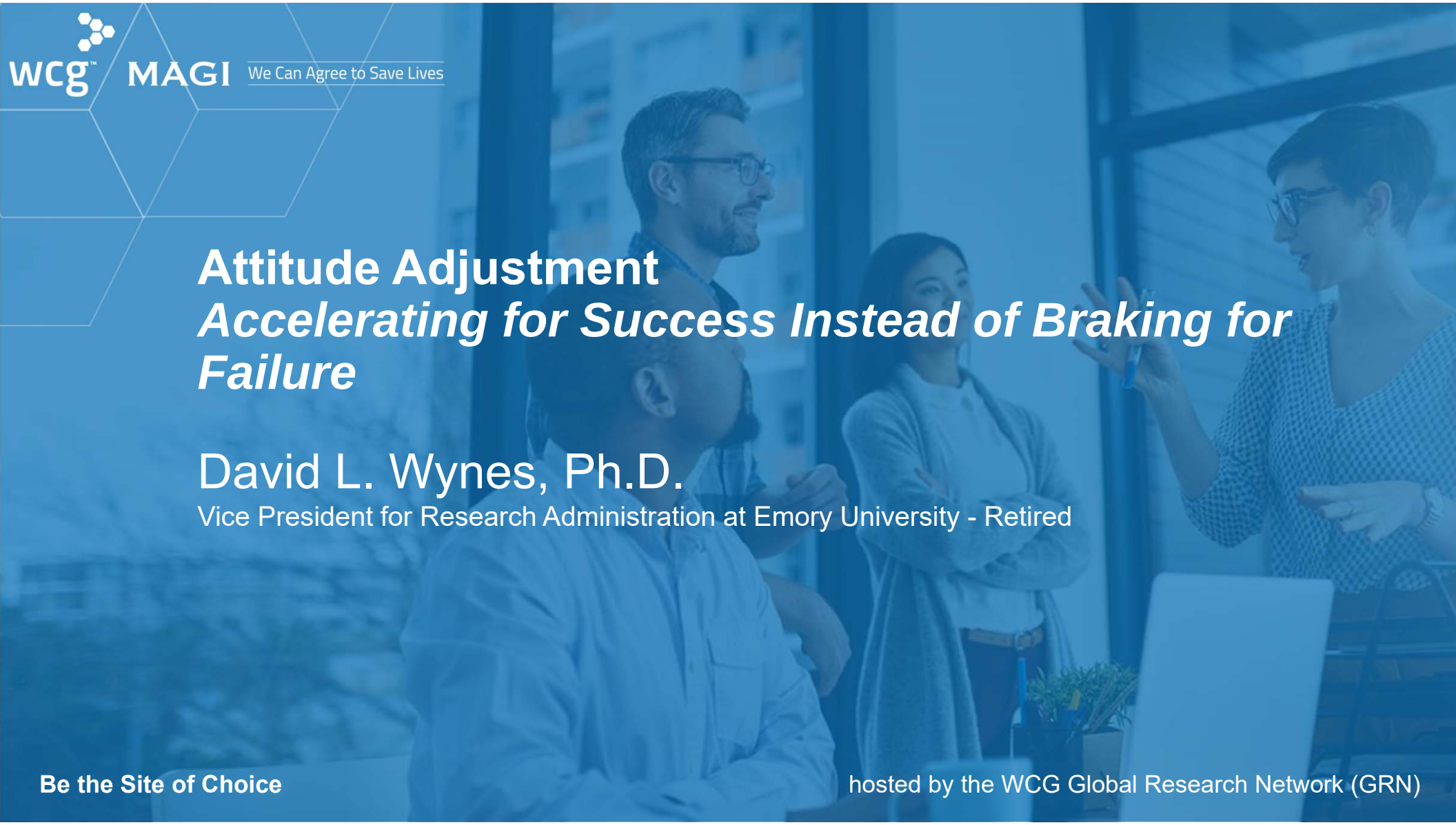


WCG MAGI We Can Agree to Save Lives

Attitude Adjustment
Accelerating for Success Instead of Braking for Failure

David L. Wynes, Ph.D.

Vice President for Research Administration at Emory University - Retired

Be the Site of Choice

hosted by the WCG Global Research Network (GRN)

If all is working well, why change?

- The IRB/clinical trial world of pre-1999
- OPRR (OHRP) actions
- Where did these universities turn for emergency assistance? Independent IRBs
- Call for legislative “fixes.”
- Formation of an accrediting organization (AAHRPP)
- Oh yes, and the development/expansion of the world wide web!

By 2019, accreditation is an accepted standard so clinical research is now fixed, right?

- NIH Single IRB Policy

- Does this really address all that is needed to accelerate the start-up, enrollment, and successful conduct of clinical research?

Industry Trials vs. Federally-Funded Trials

- Most Academic Medical Centers and other Research-Intensive Healthcare Organizations are designed to administer federally-funded research.

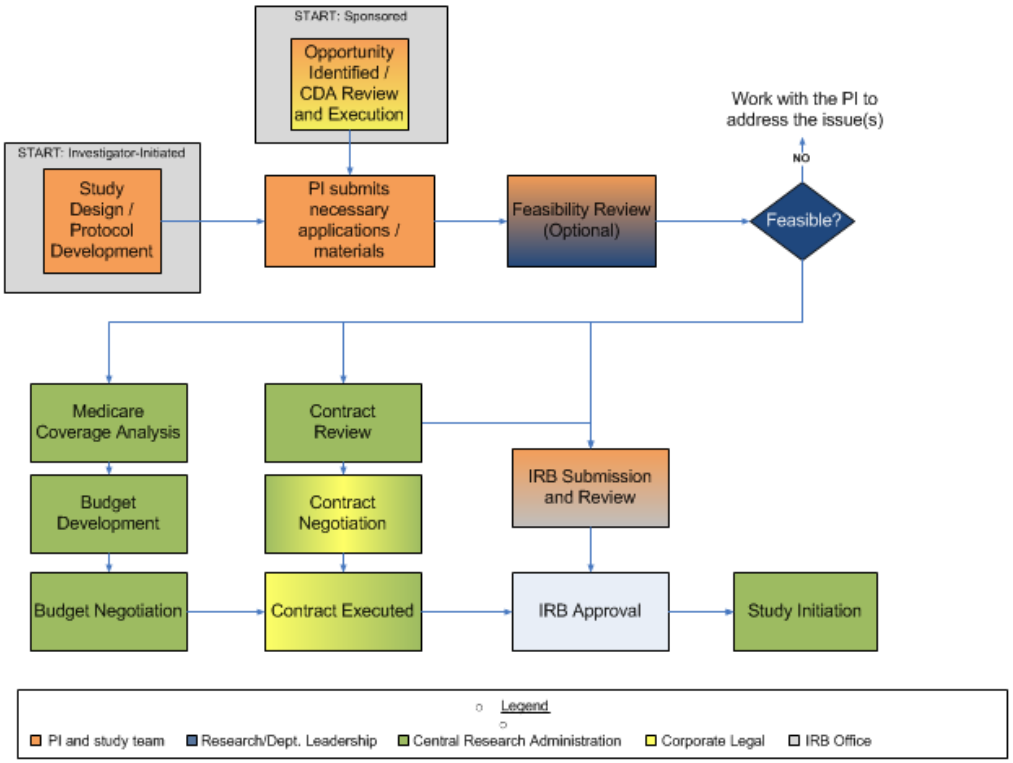
- Active vs. Passive engagement
- Protocol Development
- IRB Review
- Contract/Grant Review
- Billing

- Competitive Enrollment
- Recruitment Targets
- Payments per subject rather than salary lines

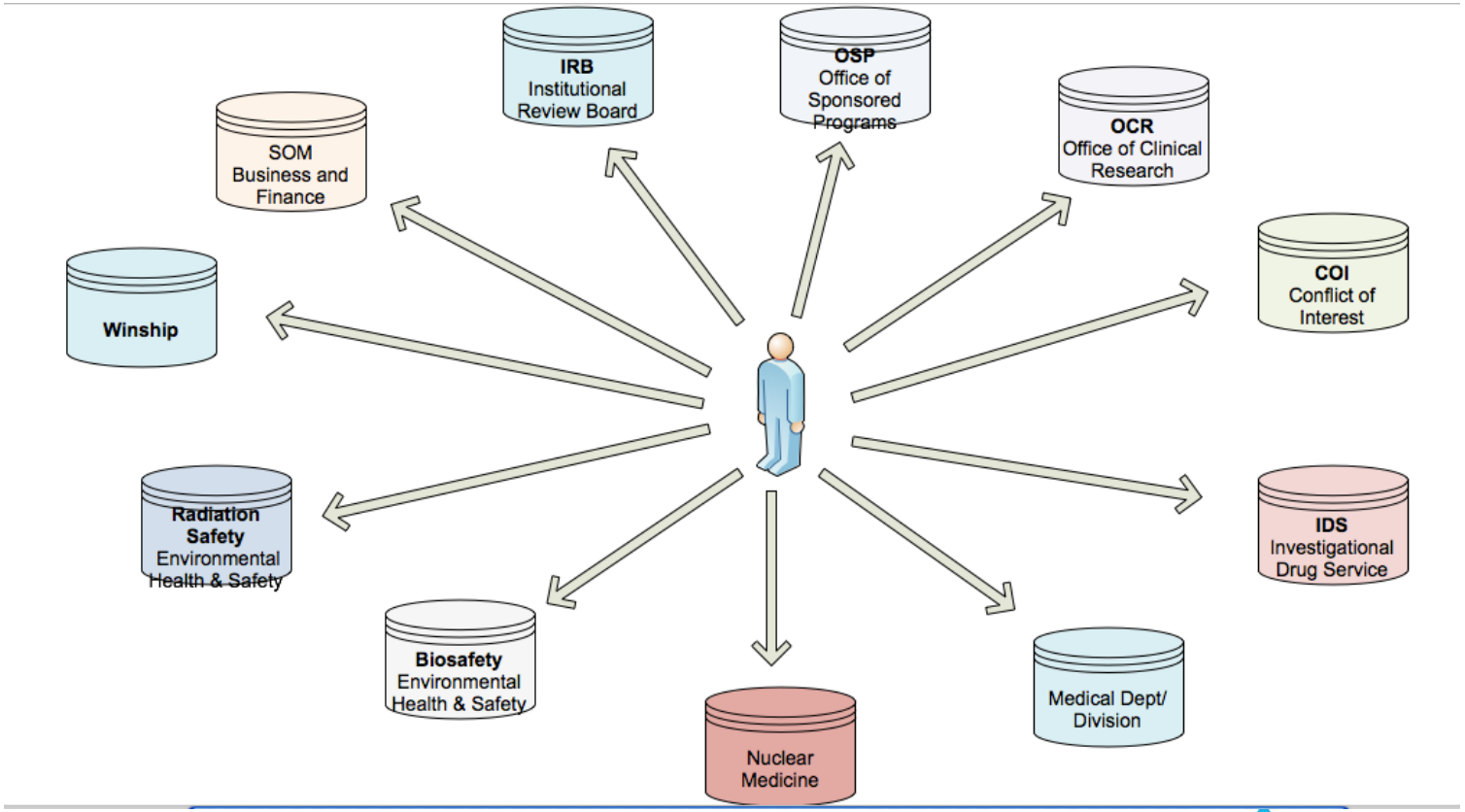
My Changing Perspectives

- University resources are limited – even at a large, “wealthy” university
- Increasing use of outsourcing across the research administration spectrum
- Greater use of metrics
- Recognition that the healthcare efficiency model of having medical professionals practice at the “maximum” of their licensing and training could be applied to other aspects of their work beyond clinic billing.
- Partnering with key sponsors

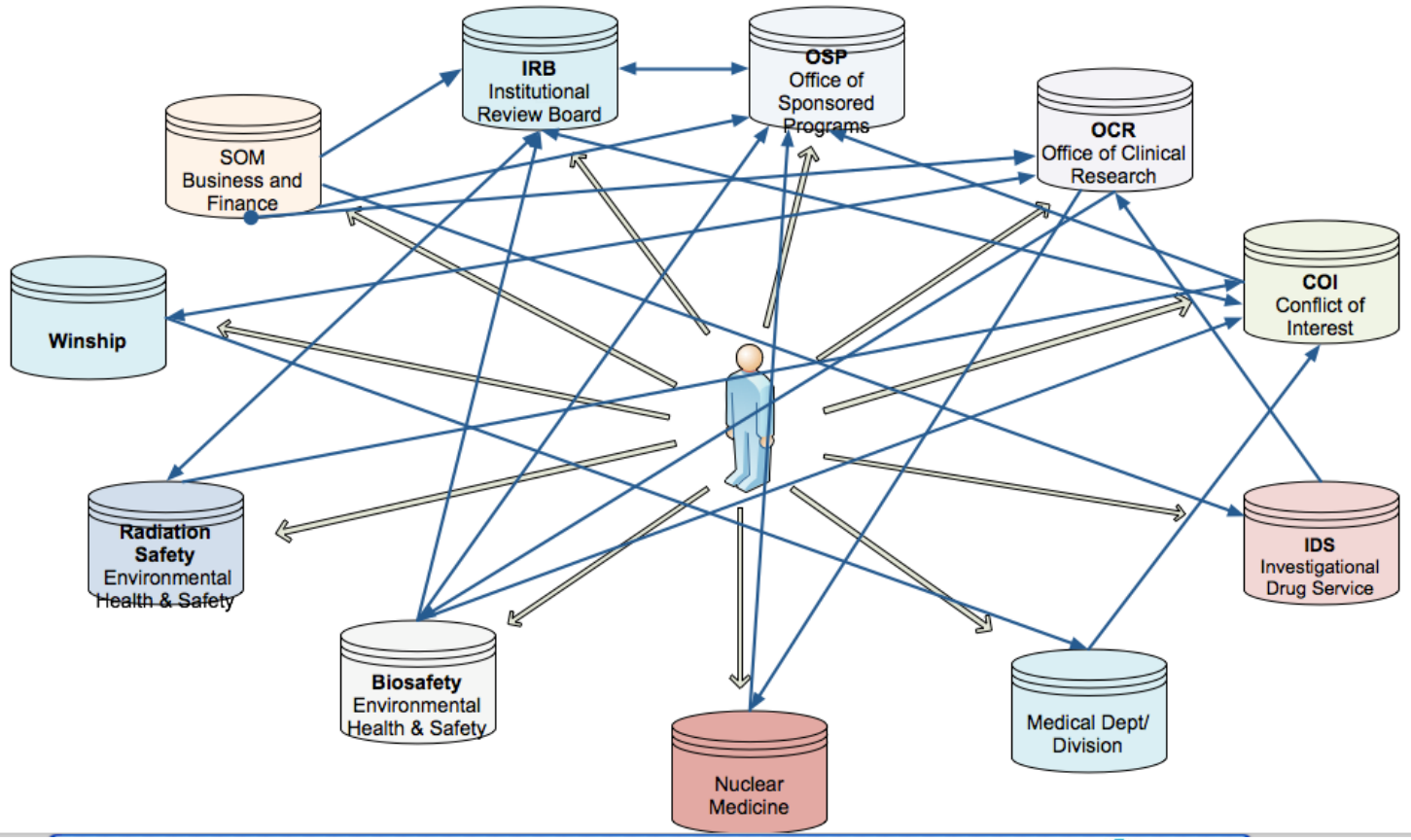
- Research Team Buy-in



Investigator Challenges



Challenges Compounded by Interdependencies



Efficiencies for Investigators: Outsourcing

- Single IRB review of multi-site studies
- Centralization of budgeting
- Use of EMR to streamline clinical trial billing
- Streamline contracting
- Electronic tools for identifying qualified subject pool
- Established mechanism for feedback

Managing the Cost of Clinical Trials to the Institution

- Sponsor and site success are closely linked
- Budget/MCA
- Enrollment
- Billing
- Compliance
- Metrics

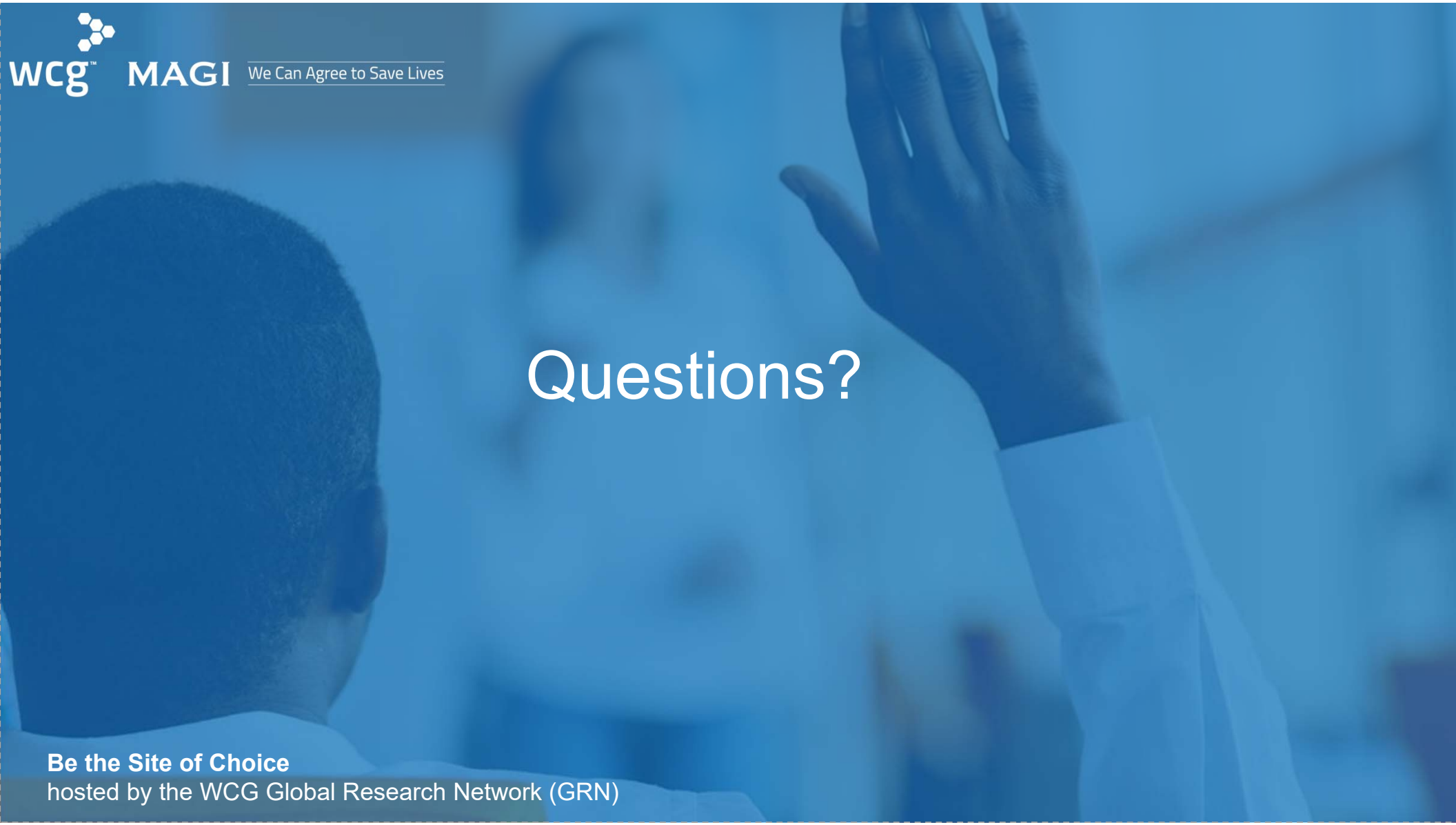
Steps to Change the Existing Paradigm

- Adopt a more active approach to initiating clinical trials
- Map systems and identify how to streamline steps
- Assure parallel processing
- Focus on how to relieve research team of administrative work that can be done more efficiently, consistently, and timely by others; Allow the clinicians to focus on the actual clinical research
- Outsource functions where there is no clear value added by internal efforts
- Be realistic about your potential subject pool
- Form partnerships with key sponsors

Success or Failure: It's up to you!

"When you're finished changing, you're finished."

Ben Franklin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