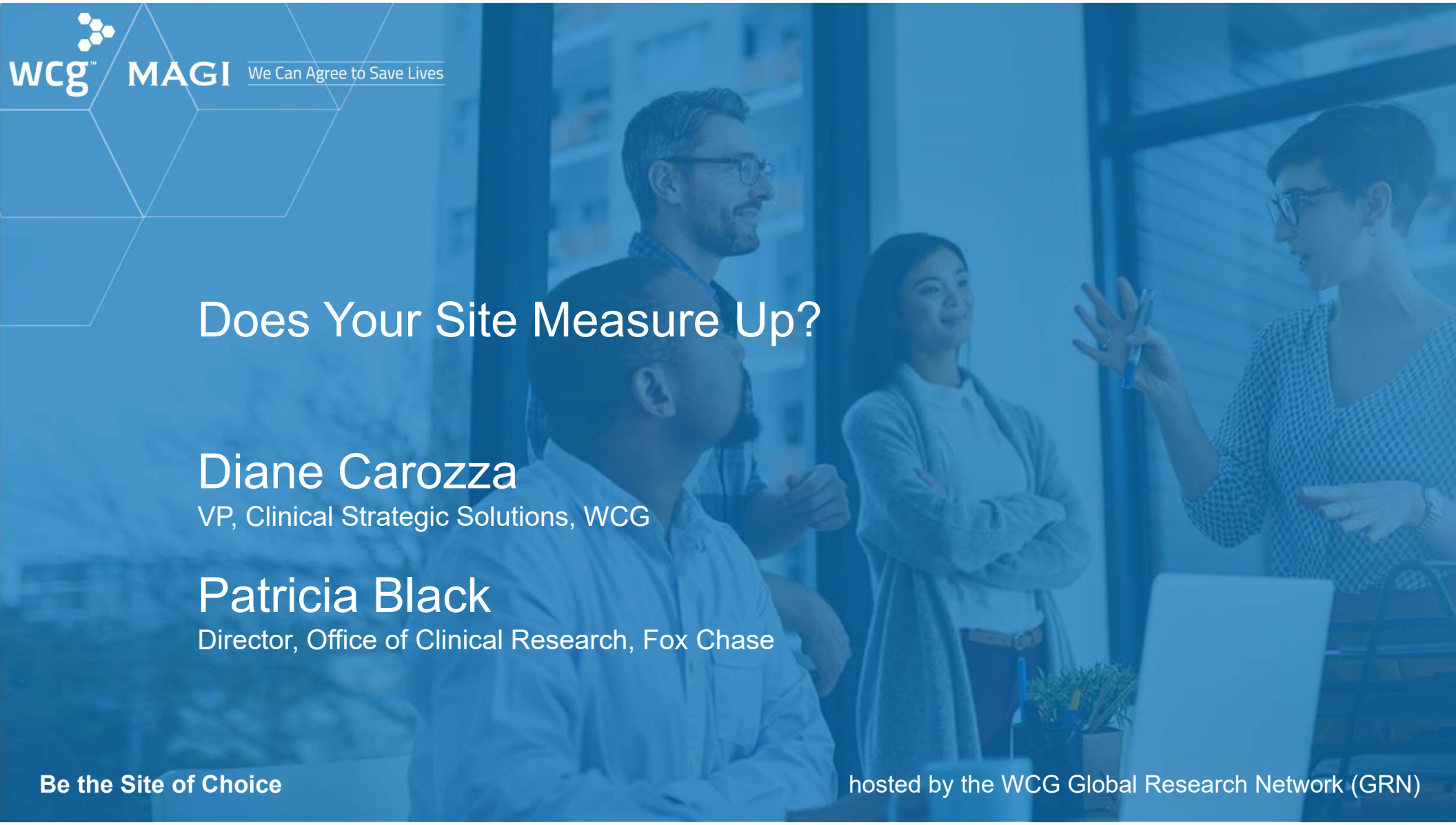


WCG MAGI We Can Agree to Save Lives

Does Your Site Measure Up?

Diane Carozza
VP, Clinical Strategic Solutions, WCG

Patricia Black
Director, Office of Clinical Research, Fox Chase

Be the Site of Choice

hosted by the WCG Global Research Network (GRN)

The Business of Clinical Research: Sponsor/Vendor View

- Sponsors approach the Study Planning / Feasibility Lifecycle with the following objective criteria in mind when assessing the ideal site:
  - Start-Up Timelines
  - Enrollment Capability
  - Data Quality

- Significant shift toward data-driven study design and feasibility within last 5 yrs

- Sponsors/CROs seek data and service providers to support objective study planning processes
  - Data trends
  - Indicators of historical performance
  - Indicators of potential study success

Study Start Up Time

- Contracts/Budgets Turnaround Time
  - Managed at the institution level or investigator level?
  - MSA in place?
  - Are contracts and budgets managed by the same department/Individual?
  - **WCG Standard**: Top quartile investigators <65 day turnaround time

- Use of Central IRB
  - Central vs Local IRB
    - If local only, most sponsors will not select under tight start-up timelines
  - Does your institution require additional review board approval?
    - If so, what is the review cycle for the secondary panel review?
  - **WCG Standard**: Top quartile investigators always able to use central IRB

Clinical Research Budgeting & Contracts

- Budgets: Managed by Office of Clinical Research, Budget Financial Analysis Unit
  - Budget Development & Negotiation – Approx. 3 weeks
  - Tools and Best Practices
  - Negotiations, # of iterations = 3 (Sponsor, Site, Counteroffer)

- Contracts Managed by Research & Development Department
  - Status and timelines communication is key among all parties
  - Contract turnaround time – Approx. 2-3 weeks (R&D Alliances & TUHS Health System Legal Departments)

Central IRB Use

Oversight by QA & Compliance Division:

- Commercial, largely utilized to identify and vet required safety, privacy, scientific and contractual submissions
- Benefits to site - Pool of faculty serving on IRB is shrinking
- For underfunded studies, internal IRB is an option

Enrollment Capability

- Historical Performance Metrics
  - How well has investigator performed in trials of similar indication/ phase within the last 5 years?
    - Total number of studies in indication in last 5 years
      - Indicator of experience in contemporaneous trial designs
    - Total number of enrolling studies
      - Indicator of clinical research infrastructure adequate for participation
    - Number of times the investigator has been re-selected by a sponsor (s)
      - Indicator of ability to meet enrollment targets
    - Number of patients consented vs. enrolled vs. completed
      - Indictor of investigator's ability to recruit viable subjects

Enrollment Capability

- Patient Availability
  - EHR as indicator of historical prevalence
    - Supports protocol feasibility / study design
    - Indicators of trends in patient population
  - What evidence exists for # of patients in active disease state that are eligible for recruitment?
    - Indicates potential ability to achieve enrollment target
  - Identify site personnel dedicated to finding and maintaining patients in study
    - Indicates capacity for study conduct

Enrollment Capability

Cottman Avenue

Temple – Broad Street

East Norriton

Enrollment Capability

- Historical Performance Metrics
  - Data Warehouse analytics for historic eligibility criteria
  - Focus also on exclusion criteria – downstream impacts on staffing and finances

- Patient Availability
  - PI-led Disease Site meetings
  - Feasibility Committee
  - Assessing U.S. patient availability by ICD-10 code
  - Sponsor Accrual targets

Enrollment Capability

Clinical Research Coordinators

- Managed by Clinical Operations Division
- Staff 3X in size!
- Association of Clinical Research Professionals (ACRP) Certifications
- Disease Site operational management responsibilities, leadership tiers, Committee membership

Investigator-Sponsored Research Unit (ISRU)

- Support for Investigators
- Investigator-Sponsored Trials:
  - Study Development
  - Study Operations

Data Quality

- Number of data corrections / data queries
  - How many data corrections were made after CRF entry?
    - Indicator of data accuracy / attention to detail

- Number of protocol deviations
  - How many deviations were noted for an investigator?
    - Indicator of investigator's ability to follow protocol
    - Indicator of investigator's ability to assess appropriateness of protocol

- Number of days from site visit to data entry
  - How many days, on average, does it take the site personnel to enter CRF data?
    - Indicator of capacity of site for additional studies
    - Indicator of appropriately resourced site

Data Quality

- Dedicated Clinical Research Data Specialists (CRDS) for data entry
- Robust CTMS for tracking, particularly with patient visits
- Business Operations Systems Coordinators (not IT) responsible daily data operations
  - Certification
  - Deliver training and education:
    - Comprehensive 2-week training for Oncology, specialized role-based
    - Teaching data awareness
  - Weekly reports to Clinical Operations leadership
  - ‘Data Quality is everyone’s concern’

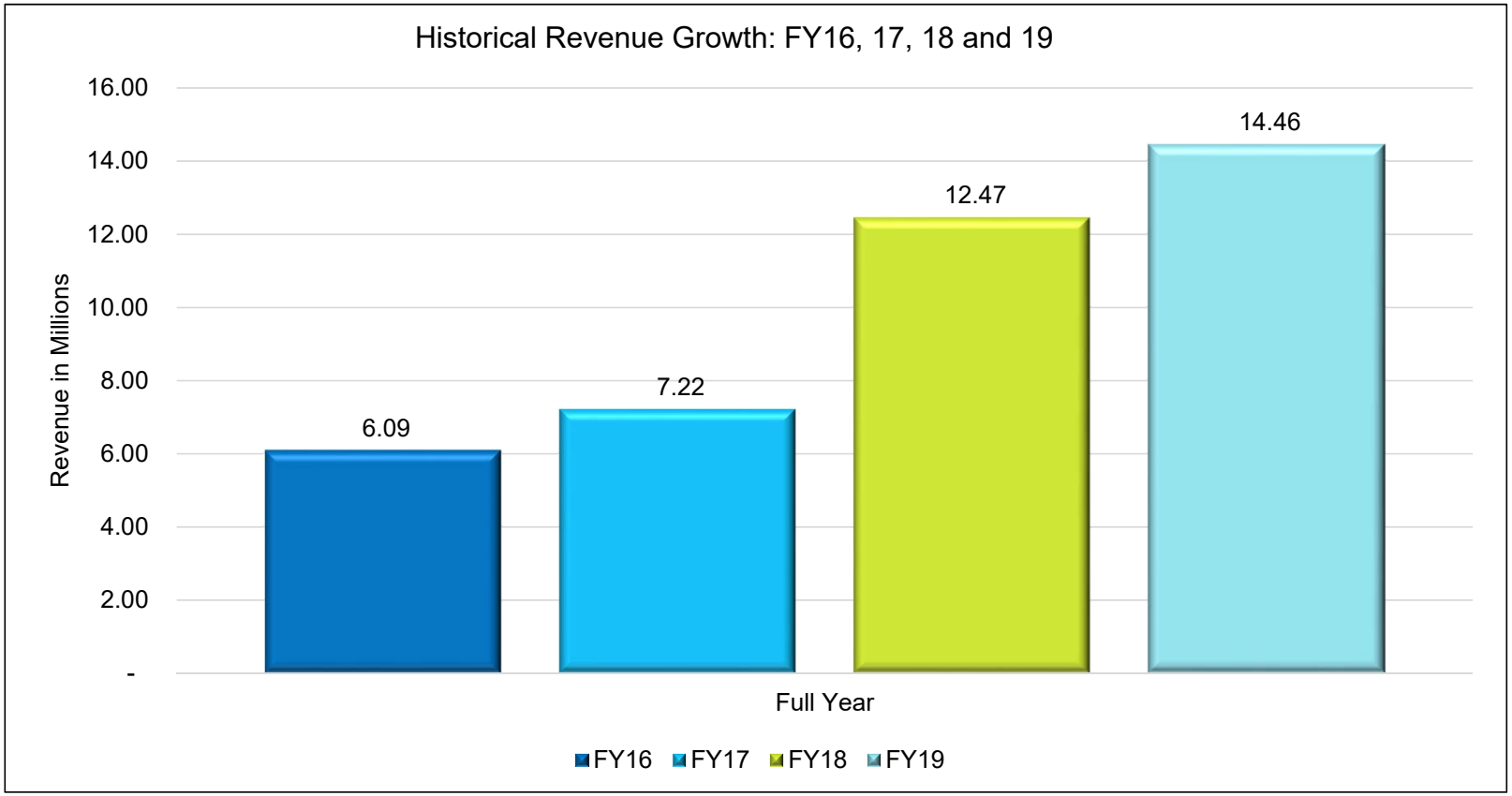
The Business of Clinical Research – The Sites' Perspective

- Business Operations Division - Financial and Operational leadership
  - Financial Management Unit
  - Patient Financial Counseling Unit
  - Patient Navigation Unit

- Community Outreach Programs - FCCC Office of Community Outreach
  - Biospecimen Research Participation

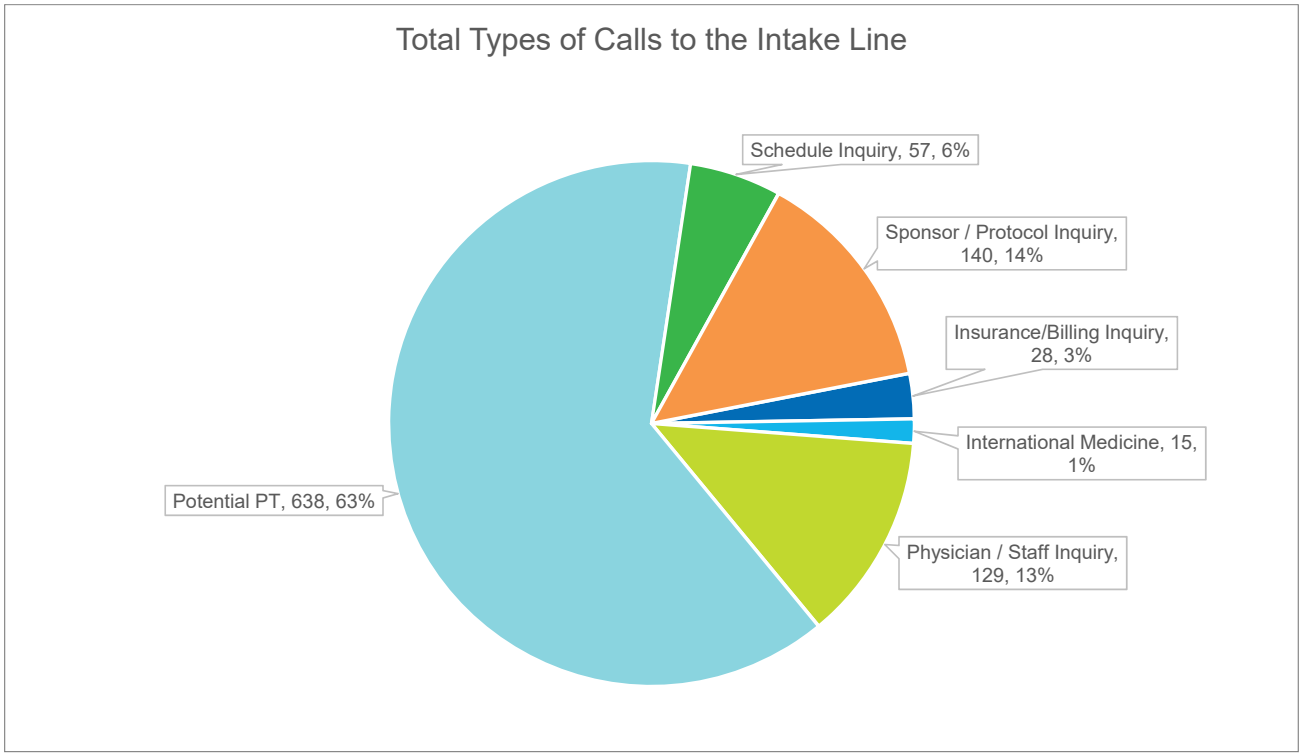
- Technological Enhancements
  - Biospecimen Module (BSM)

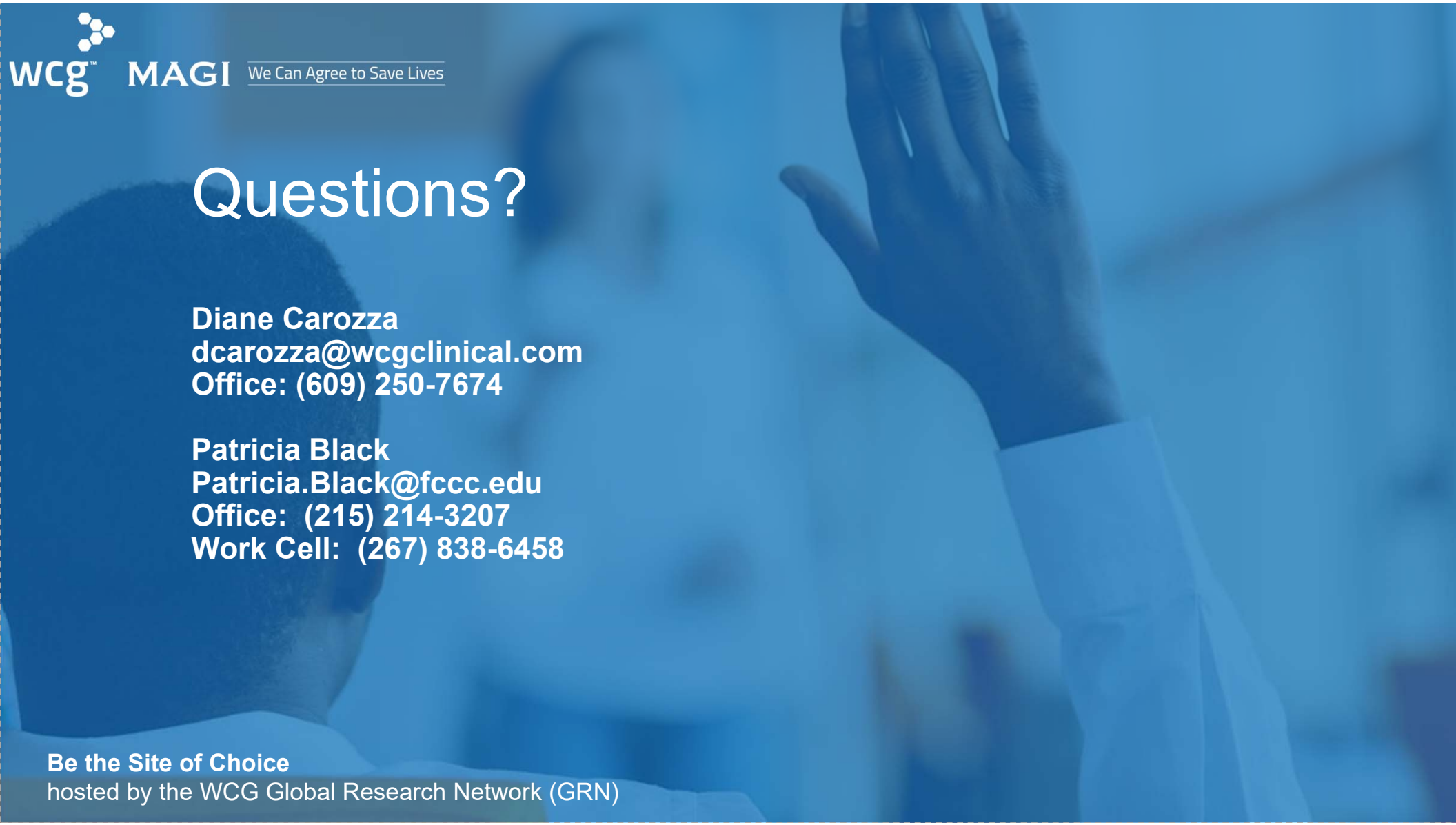
Business Operations Division: Financial Management Unit



Business Operations Division: Patient Navigation Unit

Aligning callers with available clinical research studies





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Questions?

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