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## Biostatistics, Epidemiology & Research Design (BERD)

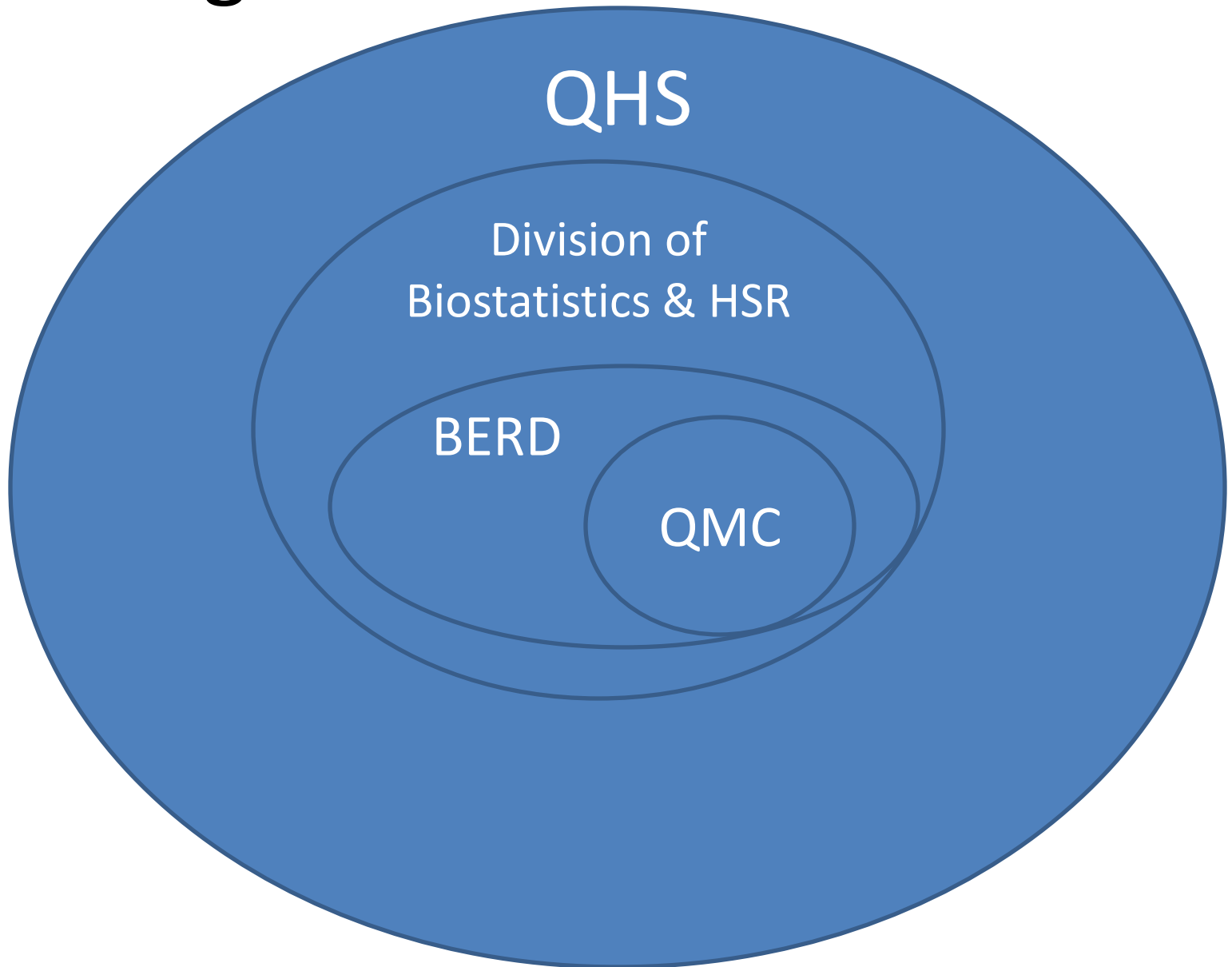
Item Type	Presentation
Authors	Ash, Arlene S.;Barton, Bruce A;Kiefe, Catarina I.
DOI	<a href="https://doi.org/10.13028/zb1s-py96">10.13028/zb1s-py96</a>
Rights	Copyright the Author(s)
Download date	2026-06-17 06:58:57
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# UMass Center for Clinical & Translational Science (CCTS) Seminar Series – Biostatistics, Epidemiology & Research Design (BERD)

Arlene Ash, Ph.D.  
Chief, Division of Biostatistics and Health  
Services Research  
BERD Director  
December 2, 2011



# Organizational Structure



# Quantitative Methods Core – A Progress Report

Bruce A. Barton, Ph.D.

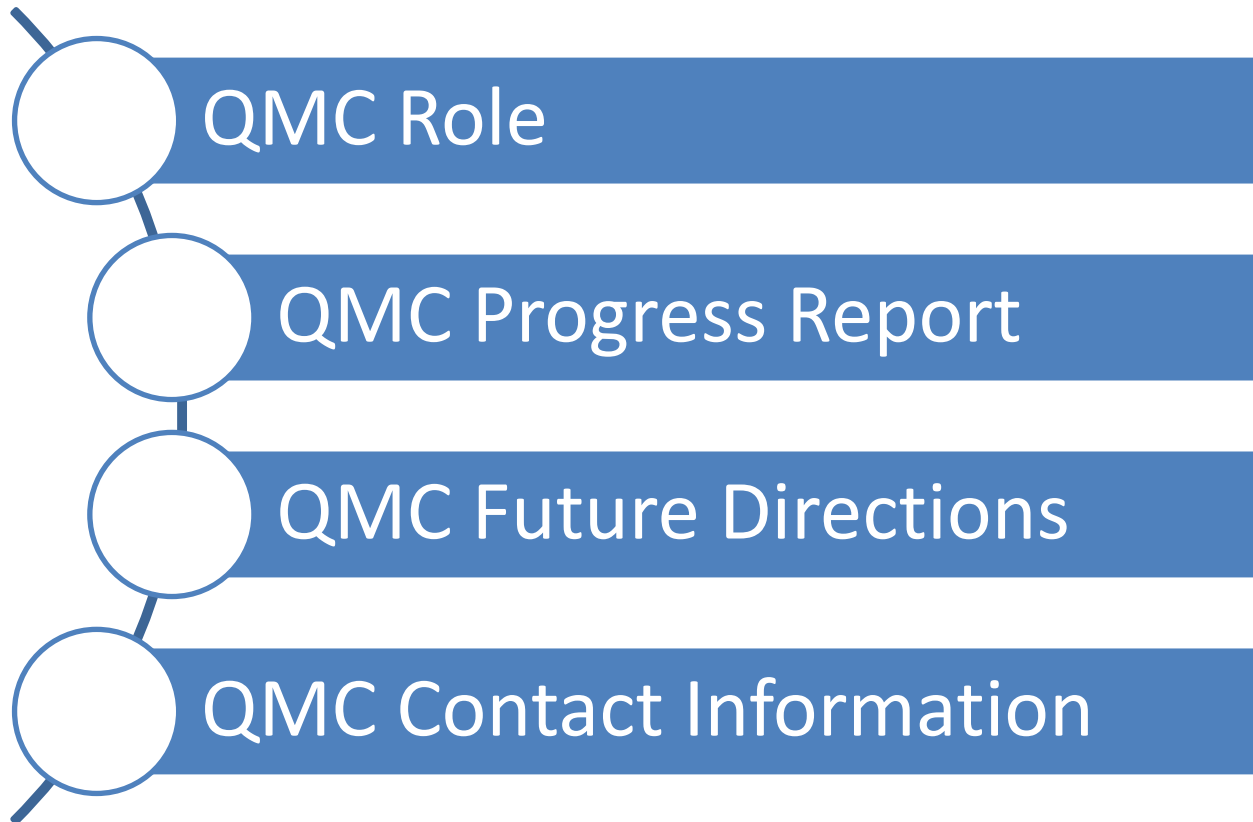
Director

Quantitative Methods Core

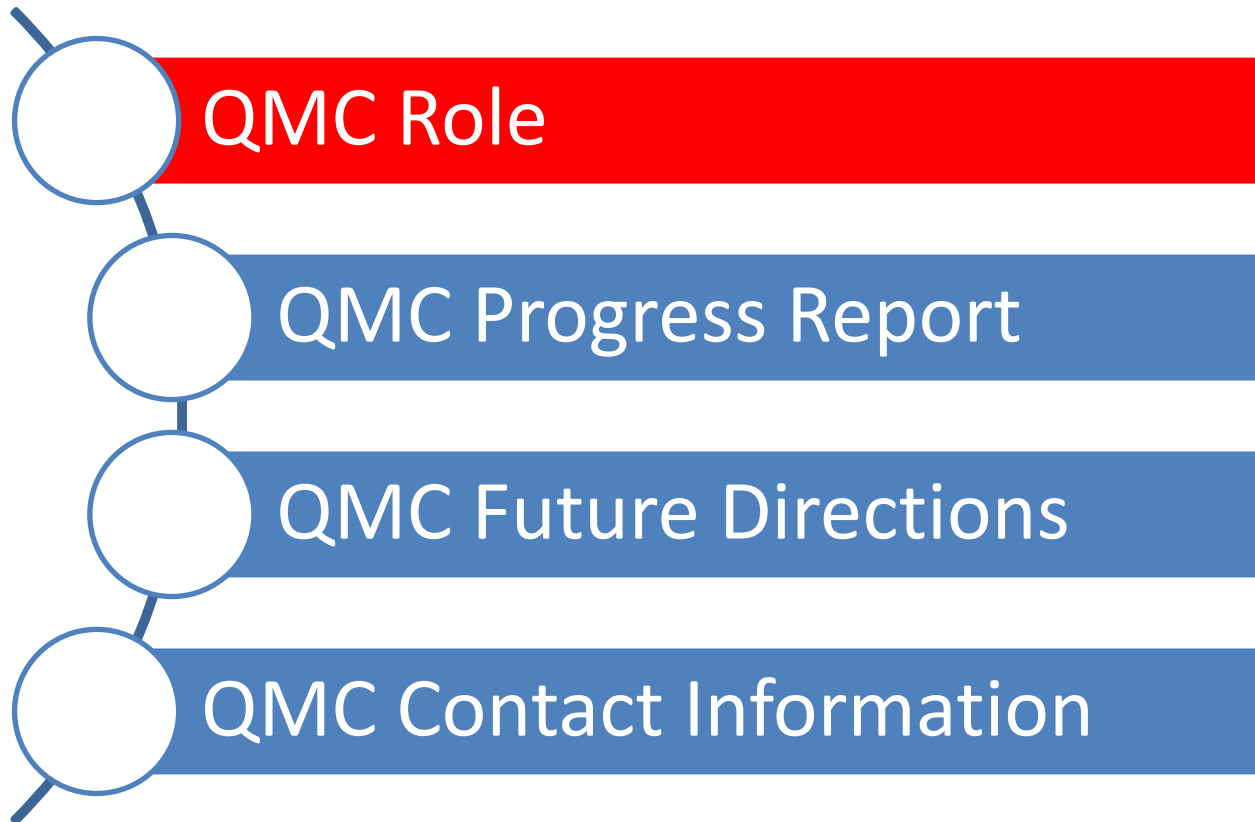
December 2, 2011



# Purpose



# Purpose



# Quantitative Method Core Mission

- To provide the highest caliber of professional expertise to researchers in the design, conduct, analysis, and reporting of medical research
- Established within Division of Biostatistics and Health Services Research in the Department of Quantitative Health Sciences

# QMC Services

- Analysis of existing data
- Study design
- Grant preparation
- Data management
- Data and safety monitoring
- Study conduct

# Analysis of existing data

- Prep data for analysis
- Can accept almost any format (e.g., Excel)
- Work with you to determine best analytic approach and actually run the analyses
- Help with tables, listings, figures
- Help with write-up
  - I.e., Stat methods and Results sections

# Study design

- Randomized clinical trials
- Cohort studies
- Case-control studies
- Retrospective studies
- Quasi-experimental designs
- Single- or multi-center
- Adaptive and accelerated designs
- Clustered designs

# Grant preparation

- Sample size/power
- Analysis plans
- QA/QC
- Data management plans
- Data and safety monitoring
- Data/resource sharing
- Innovation, innovation, innovation
- Review and editing
- Key statistical personnel

# Data Management

- Design and implement systems for data entry, data processing, and integration with statistical programming
- Multiple approaches
  - REDCap
  - Fax-Entry
  - QuickBase
- Developing area

# Data and Safety Monitoring

- RCTs require Data and Safety Monitoring Boards (DSMBs)
- Observational studies require OSMBs
- Both single center and multi-center studies
- Large and small
- Developing area

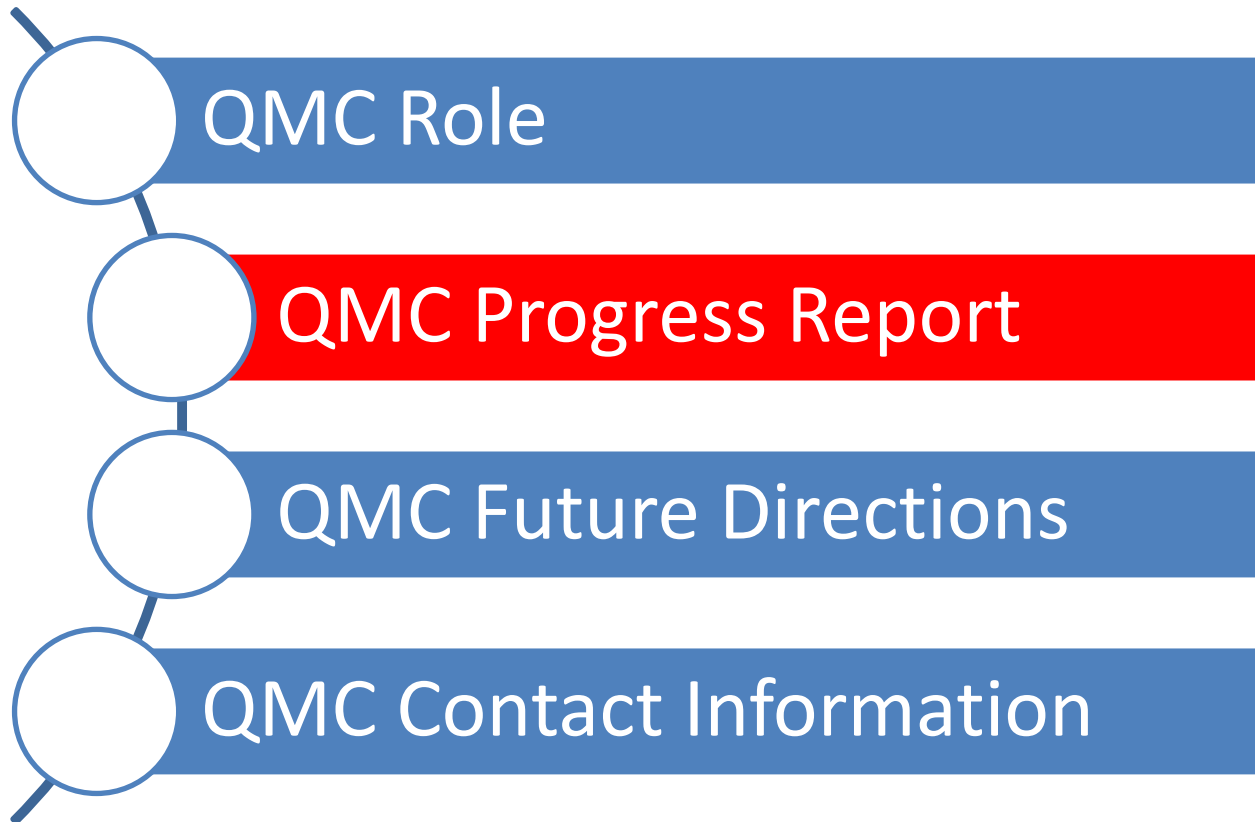
# Study Conduct

- Currently providing services as described above
- Future area for development
- Eventually evolve into a Data Coordinating Center (DCC)
- DCCs (independent) required for multi-center studies

# Other services

- Epidemiology
- Informatics
- Health services research
- Outcomes research

# Purpose



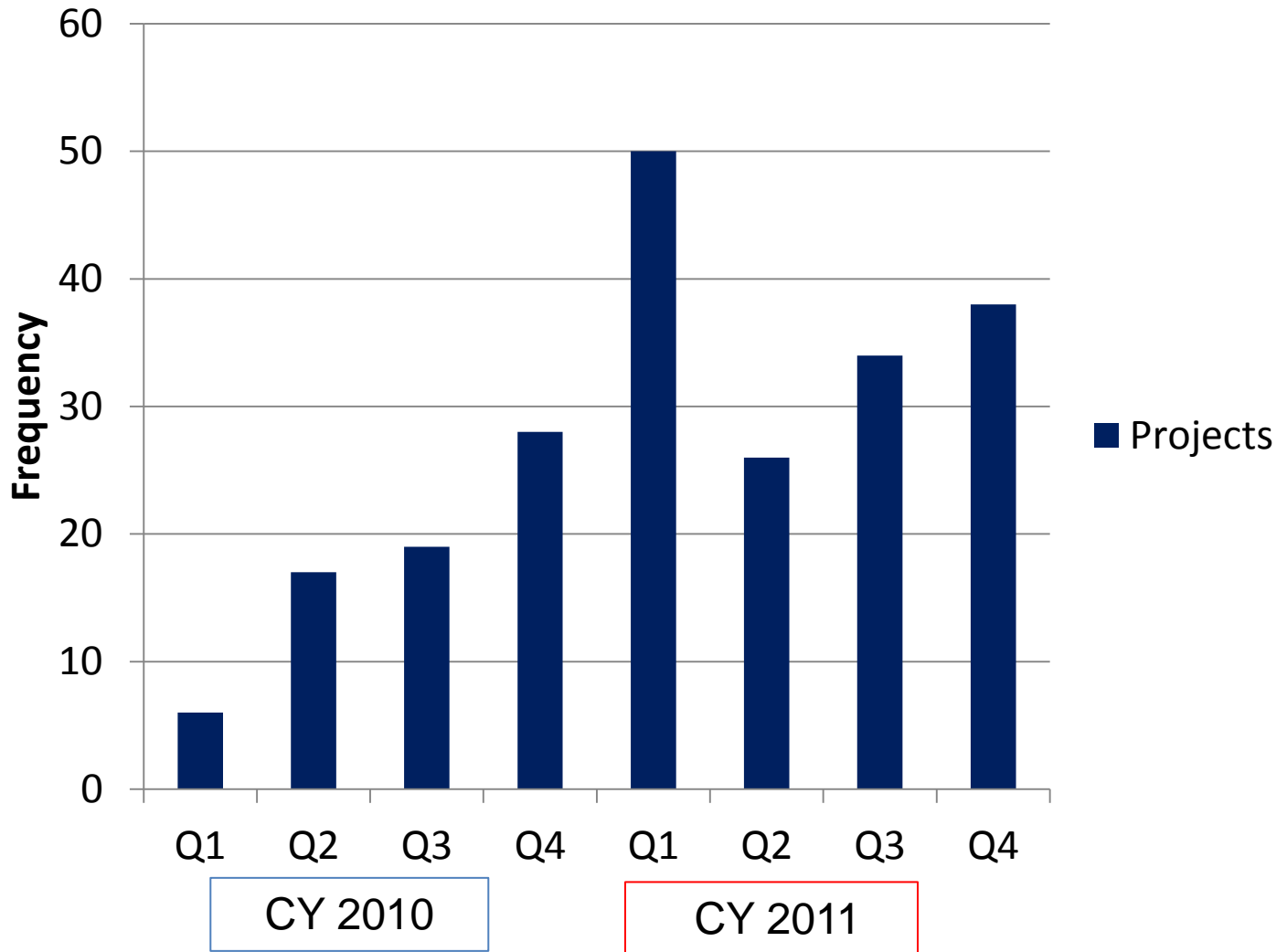
# Progress Report

- Unofficial start – 2/1/2010
- Official start – 5/1/2010
- Substantial – and rapid – growth
- Staffing has grown to accommodate
- Review of what we have done and who is the QMC

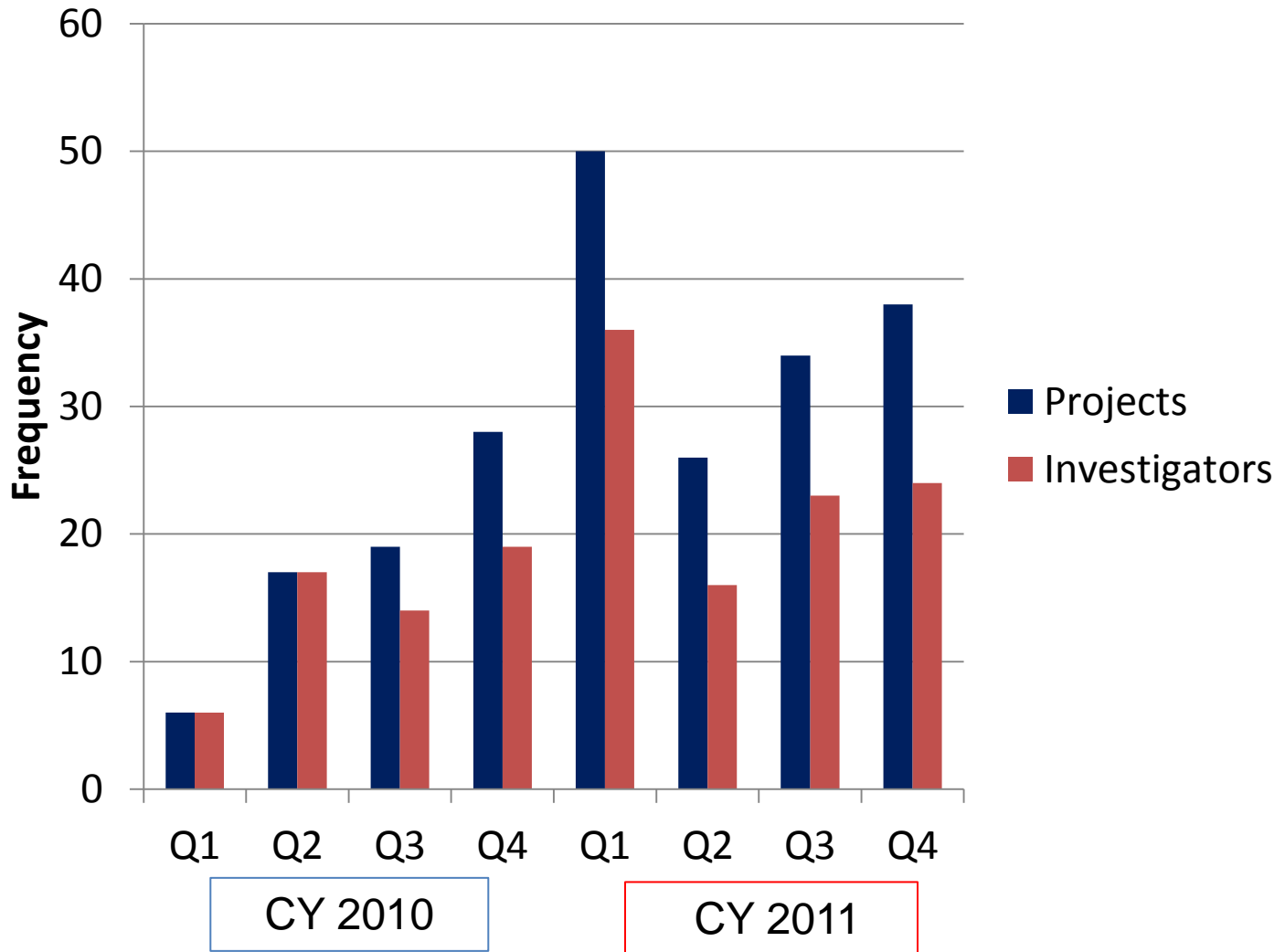
# Progress Report – As of 11/30/2011

- Initial investigator meetings: 155
- Initial project meetings: 218
  - Currently, about 1/3 of new projects are with “repeat” investigators
- Departments involved: 28
  - Divisions involved: 20
  - Includes animal labs, cell biology, molecular biology, pathology

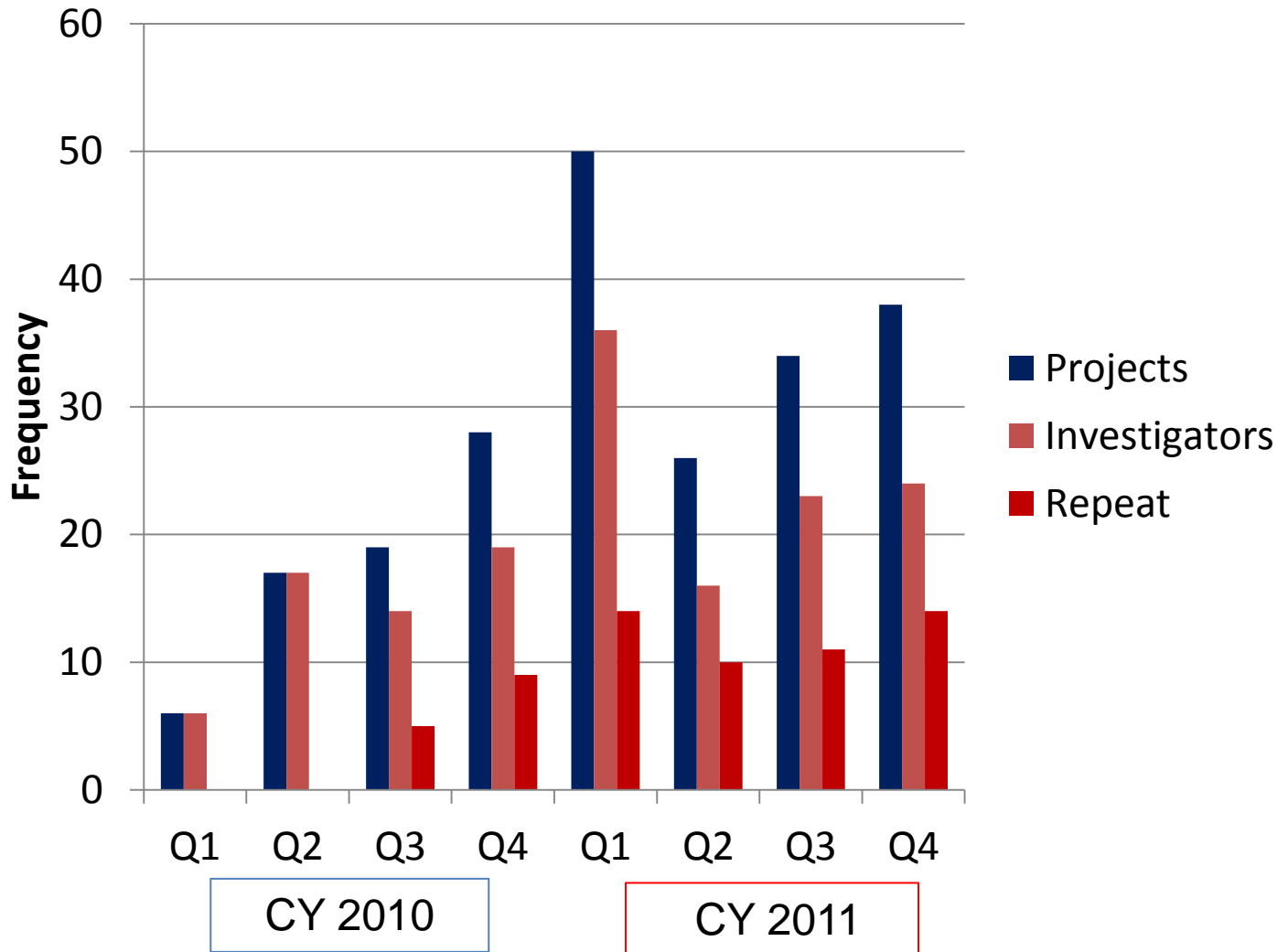
# Project Meetings by Quarter



# Project Meetings by Quarter



# Project Meetings by Quarter



# Progress Report - Results

- Purpose of Meeting
  - Grant Applications: 82 (38%)
  - Analysis: 78 (36%)
  - Study Design: 35 (16%)
  - Study Support: 17 (8%)
- Articles/Abstracts Submitted: 32

# Progress Report - Results

- Grants submitted: 82
  - NIH R-level grants: 55
  - NIH K-level grants: 6
  - NIH P-level grants: 3
  - Foundations/Other: 14
  - CTSA: 4

# Progress Report - Results

- U Mass Cross-Campus Collaborations: 6
  - U Mass Lowell: 3
  - U Mass Boston: 1
  - U Mass Dartmouth: 2

# Progress Report - Education

- QMC Seminars/Workshops
  - 1<sup>st</sup> and 3<sup>rd</sup> Tuesday each month at 12 noon in AC7-211
  - Cover wide variety of topics:
    - Clinical trial evolution
    - Power analysis for genetic studies
    - Bootstrap (non-parametric) confidence intervals
    - Multiple testing
    - Probability sampling in health research
    - Better statistical graphics workshop (January)

# Current Faculty

- Bruce Barton, Ph.D.

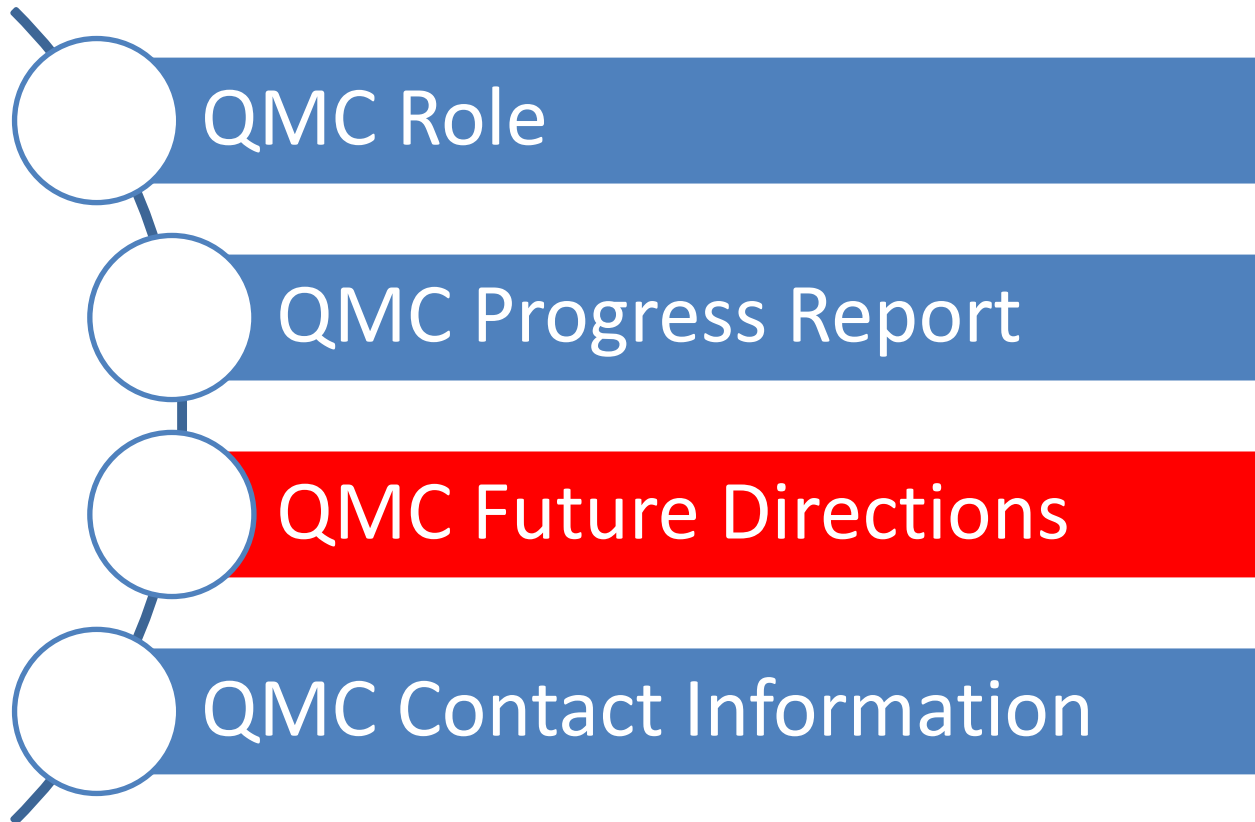
# Current Faculty

- Bruce Barton, Ph.D.
- Arlene Ash, Ph.D.
- Stephen Baker, M.Sc. P.H.
- Julia (Hua) Fang, Ph.D.
- Phil Gona, Ph.D. (12/15/2011)
- Sharina Person, Ph.D.
- Sowmya Rao, Ph.D.

# Current Staff

- Connie Barysaukas, M.S.
- Aimee Kroll-Desrosiers, M.S.
- Stephen Kurtz, M.S.
- Dane Netherton, Ph.D.
- Recruiting additional statisticians and database programmers

# Purpose



# QMC – The Future

- Continue basic approach with expanded services
  - Particular interest in finding a health economist, a “Quality of Life-ist”, and a statistical geneticist
  - Many applications could/should have a Specific Aim in one or more of these areas
  - Experience exists, but not the obvious credentials

# QMC – New Frontiers

- Data management
  - Based on both REDCap system and new “Fax-Entry” system
  - REDCap system has been described in this forum earlier this fall
  - Fax-Entry system based on Teleform software to design, publish, and process CRFs
  - Essential element is to integrate elements of a system into the “stream of research”

# QMC - Data Management Progress Report

- REDCap systems routinely designed and implemented as are Fax-Entry systems
- Currently, 8 projects use (or are about to use) QMC Data Management – with numerous grant applications proposing to use a QMC system
- Challenge is to build the infrastructure

# QMC – New Frontiers

- Data and Safety Monitoring Board Reports
- All RCTs – and observational studies – must now have a DSMB/OSMB
  - Leads to the requirement for substantive reporting
  - Includes study conduct, safety, and possibly efficacy
- Specialized programming to turn DSMB/OSMB reports into production

# QMC – Data Monitoring

- Produce hard-copy/PDF reports for distribution
- Integrate with cube (“drill-down”) technology to provide additional information if DSMB members request
- Formal interim analyses if study requires
- Integrated with QMC Data Management systems to provide direct data access

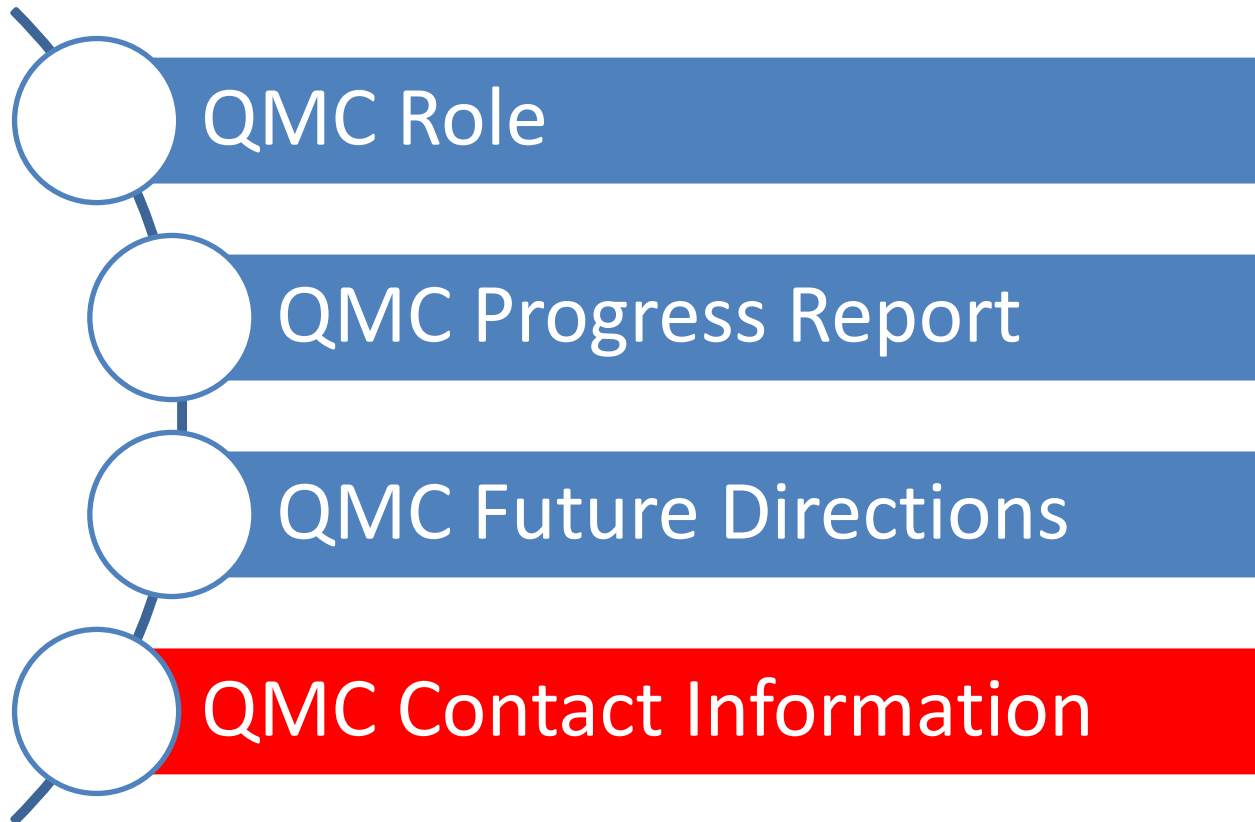
# QMC Data Monitoring Progress Report

- Currently, providing Data Monitoring for two studies with one more about to start
- Numerous grant applications propose to use QMC Data Monitoring
- Hiring statistical staff experienced in this type of programming to develop standard, yet flexible, approaches to data monitoring

# QMC – Final Frontier

- Data Coordinating Center activities for Multi-Center Studies
  - Study documents
  - Data management systems
  - Systems integration (randomization, drug and specimen inventory management, ePRO systems)
  - Logistics
  - QA/QC
  - Data and Safety Monitoring
  - Analysis and Reporting

# Purpose



# What to expect

- Meet with a faculty-level biostatistician
- Discuss what you need with informed discussion of options
- Formulate an Action Plan
- Form a collaboration to get your project done in the best possible way
- Teamwork!!!
- Polished final product

# How to Contact the QMC

- E-mail (easiest): [QMC@UMassMed.edu](mailto:QMC@UMassMed.edu)
- URL: [www.UMassMed.edu/QHS/QMC.aspx](http://www.UMassMed.edu/QHS/QMC.aspx)
- Phone: 6-8798 (Kelley Baron)
- Set up a time to meet and talk about what help you might need
- Send out an Information Sheet to gather some information about your project before we meet

# Cost

- Partially supported by the CTSA
- Junior investigators and short consults are generally at no cost (CTSA)
- Grant applications are generally at no cost assuming QMC staff/support included in grant budget
- Long-term analyses projects need to be supported – various mechanisms
- P01 program/project grants – let's talk

# Questions?

- Now or later

# Dept. of Quantitative Health Sciences – Background and Status

Catarina Kiefe, PhD, MD  
Chair, Dept. of Quantitative Health  
Sciences

December 2, 2011

# Dept of Quantitative Health Sciences (QHS)

- QHS, an academic dept with a broad mission
- Includes all CCTS Biostatistics, Epidemiology, and Research Design (BERD) Specific Aims and much more

# QHS: The Youngest UMMS Dept

- Conceptualized by UMass leadership in 2007, during CTSA planning
- Viewed as pivotal in
  - Strengthening T2+ translational research
  - Providing expertise campus-wide in the quantitative health sciences: statistics, epidemiology, “and more”
  - Providing a model for “breaking down silos” and collaborative research

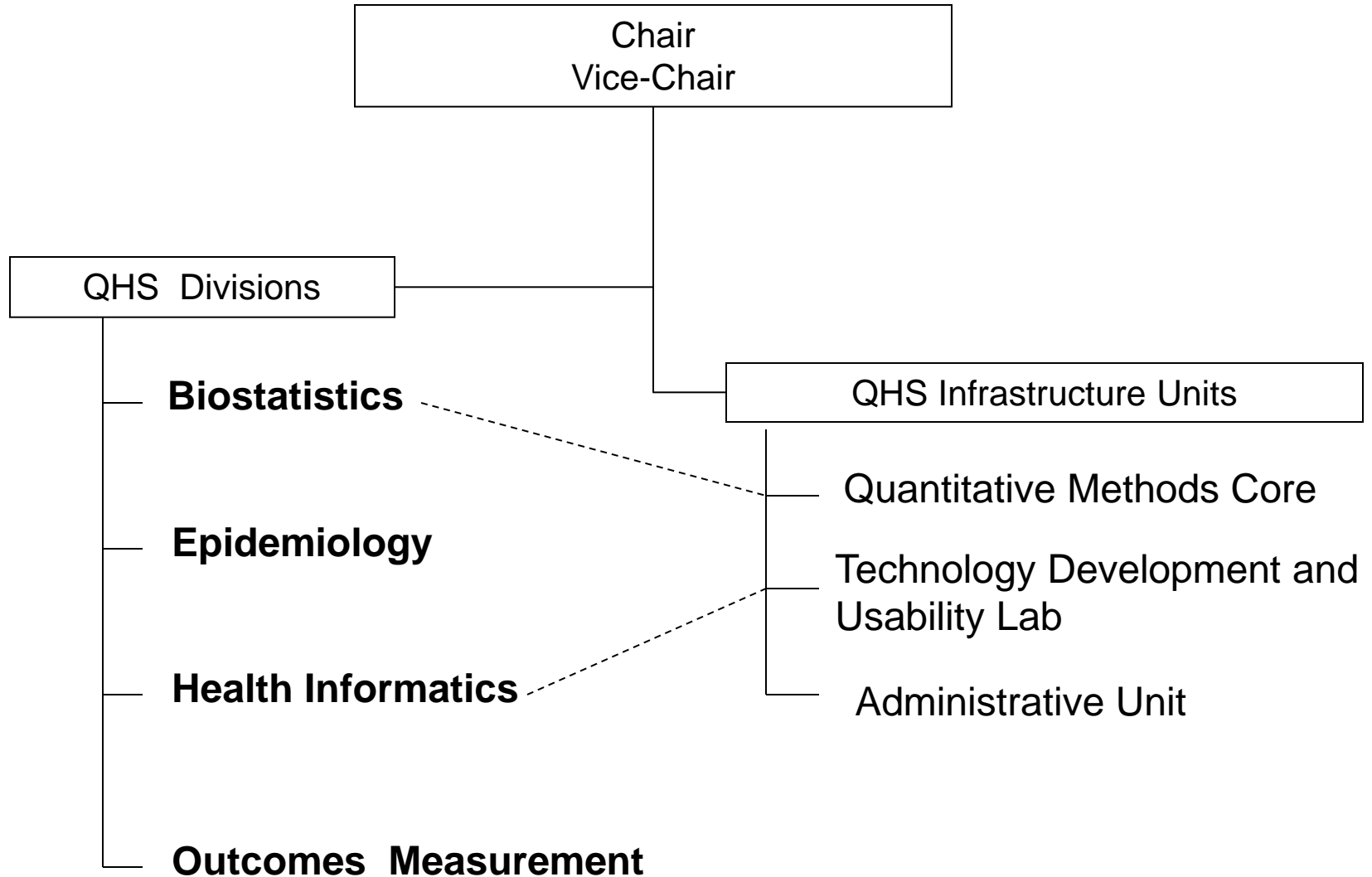
# QHS History

- Inaugural Chair and Vice-Chair arrive on campus June 2009
- 4 Division Chiefs recruited by October 2009
- Strategic planning retreat held Spring 2010
- Quantitative Methods Core opens May 2010
- UMCCTS funded July 2010

# QHS Vision

- **Vision:** We will be leaders in the science of moving from discovery to improving individual and population health
- **Values:**
  - Science that makes a difference
  - Integrity and scientific excellence
  - Collective creativity
  - Diversity and mutual respect
  - Social justice through improved health

# Department of Quantitative Health Sciences (QHS) Org Chart



# QHS Senior Faculty

- Chair: Catarina Kiefe, PhD, MD
- Vice-Chair: Jeroan Allison, MD, MScEpi
- Division Chiefs:
  - Arlene Ash, PhD: **Biostatistics and Health Services Research**
  - Rob Goldberg, PhD: **Epidemiology of Chronic Disease and Vulnerable Populations**
  - Tom Houston, MD, MPH: **Health Informatics and Implementation Science**
  - John Ware, PhD: **Outcomes Measurement Science**
- Director, **Quantitative Methods Core**: Bruce Barton, PhD

# QHS Current

- 33 Primary Faculty total
  - Goal: Steady state of about 40 Primary
- 23 Faculty with QHS primary salary commitment (18.8 FTE):
  - 7 Professors, 6 Assoc Profs, 8 Asst Profs, 2 Instructors
  - Average 76% effort extramurally funded
- 3 Adjunct/voluntary Faculty
- 26 secondary faculty from 12 Depts/Divs

# QHS Teaching and Enrichment

- Masters of Science in Clinical Investigation
  - Targets mostly MDs becoming clinician-scientists
  - Being reorganized; Goldberg, Director
- Doctoral Program in Clinical and Population Health Research
  - Transitioned to home in QHS
  - Currently ~6 new students/year
  - MD/PhD track to be expanded

# Questions?