



## Data Monitoring Committees Matter

United BioSource Corporation (UBC) provides administrative, statistical and data management support to effectively conduct Data Monitoring Committees (DMCs). From assessing the need for a DMC in initial protocol design to effective management and conduct of the meetings, UBC's professionals possess the necessary scientific and operational experience required to garner clear recommendations from thought leaders based on reliable statistical output.

### **Getting Started: Member Identification, Recruitment & Contracting**

Selecting the right mix of expertise in the appropriate global region is of utmost importance in DMC membership. Of similar importance is the vetting of DMC members for potential conflicts of interest, ensuring that they are fluent in standard DMC responsibilities and study-specific considerations, and providing guidance as to what data will be presented and in what format.

UBC supports our clients in the lead-up to DMC meetings by:

- Identifying potential DMC members from our database and from the experience of our personnel
- Managing contractual arrangements with DMC members, including grant negotiation, financial disclosure and liability considerations
- Conducting initial DMC member training tailored to naïve and experienced DMC members
- Drafting the DMC Charter to document the standard operating procedures of the DMC and establish the format of data presentation
- Developing a secure, web-based, DMC portal through which information is shared

### **Putting the Plan into Practice: Conducting Effective DMC Meetings**

UBC DMC Project Managers are skilled in coordinating meetings to satisfy the schedules of our clients and the DMC members. We routinely work with client meeting planners and travel offices to ensure that DMC members focus solely on their primary charge – review of data and formulation of recommendations. UBC data services provide both the timely coordination of data and statistical support to offer the objective and conclusive evidence for members to make the right decisions.

UBC provides a full suite of services to effectively manage DMC meetings including:

- DMC meeting coordination including selection of meeting location, member travel and lodging arrangements, grant payment and distribution of DMC materials
- DMC hosting and administrative support including minute taking and open-session facilitation
- Data presentation including data cleaning and formatting and statistical support (presenting statistician or committee statistician)
- DMC follow-up and resolution through dissemination of minutes and managing reconciliation efforts post-meeting

UBC has the expertise and a full suite of services to develop and execute DMC meetings.

Our services include:

### **DMC Assessment Services**

- Preliminary protocol review and statistical consultation
- Advisement in determining necessity for a DMC
- Advisement regarding frequency of review, data elements to review
- Determination of statistical stopping boundaries (regulatory support)
- Adaptive design/implementation
- Development of DMC-relevant protocol sections

### **DMC Planning Services**

- DMC charter and analysis plan development
- Development of sample data review packets/ data displays
- DMC Committee member identification, recruitment and contracting
- Development of secure web-based portal for DMC
- Facilitating DMC Kick-Off and Training Meetings

### **DMC Meeting Conduct Services**

#### *Coordination & Management*

- Meeting planning, coordination and facilitation
- Agenda preparation
- Distribution of meeting materials through secure web-based coordination hub
- Generation and distribution of minutes

#### *Statistical Consultation & Support*

- Supporting/presenting statistician
- Independent statistician to the DMC

#### *Data Management & Programming*

- Production of Data Packages for DMC Review
  - Oversight by independent statistical programming team
  - Coordination of multiple data sources (clinical database, safety database, central labs, IVR)
  - Full validation of all output and DMC data reports (blinded and unblinded)
  - Secure data and record retention

### **DMC Follow-Up Services**

- Distribution of Open Meeting Minutes
- Identification of ad-hoc expert consultants
- Generation, validation and dissemination of DMC-requested ad-hoc data reports
- Assist in implementation of DMC recommendations (protocol and charter modifications, randomization updates)
- DMC Summary for Clinical Study Report
- Archival

Our professionals' experience includes:

### **DMC Coordination & Management**

- Staff of professionals with scientific background and post-baccalaureate degrees
- Average of 16 years in industry
- Fluent in FDA and EMEA guidance
- Served in management capacity for dozens of studies with DMCs

### **DMC Statistical Consulting & Support**

- Experienced and highly-qualified team of biostatisticians
  - Average 21 years in industry
  - 50% MS, 50% PhD
- Independent/presenting statisticians
- Protocol design
- Committee-member statisticians
- Stopping boundary determination
- Bayesian and Adaptive design

### **DMC Data Coordination**

- Substantial (30+ employees) data programming group
  - Average of 12 years in industry
  - 50% with post-baccalaureate degrees (MS, MA)
- Expertise in coordinating multiple data sources (IVR, central lab, etc.)
- Flexibility in generating ad-hoc DMC requests

*For more information about UBC's specialty clinical solutions, call us in the U.S. at +1 215 591 2880 or in the E.U. at +44 (0) 208 834 0100. Or email us at [info@unitedbiosource.com](mailto:info@unitedbiosource.com).*