



Multinational Retrospective Chart Reviews

Real-world patient level data are essential to most burden of illness evaluations or study of the potential impact of novel therapies or devices in the actual practice setting. Medical record data are wholly naturalistic and present an opportunity to examine current care and its outcomes. Traditional paper-based approaches to the collection of medical record data and routine on-site monitoring visits can be cost and time inefficient. In contrast, remote web-based data collection and study monitoring can provide a practical, consistent and efficient means of collecting high quality, multinational outcomes data without the need for costly site visits and local monitoring.

United BioSource Corporation's (UBC) Multinational Retrospective Chart Reviews (MRCR) are designed by a team of senior scientists and implemented by an international team of experienced project managers using innovative, state-of-the-art, web-based data capture technology. Site-based investigators and staff are trained to abstract and enter medical chart data into a user-friendly, secure and study-specific website, permitting centralized, real-time monitoring, cleaning and analyses of study data. This approach offers timeline and cost efficiencies by allowing for simultaneous, multinational data gathering without the need for burdensome local oversight. MRCR facilitate the rapid collection of clinical and health care utilization data, providing tailored international datasets that are ideally suited as inputs to a wide range of health economic analyses.

A research solution that is:

UBC's senior scientists and international project managers use innovative state-of-the-art technology to provide MRCR and other Health Care Data Capture solutions.

Quality controlled	<ul style="list-style-type: none"> Every MRCR study is carefully designed to withstand rigor of peer review Employs data validations at point of data entry Enables scientifically valid chart sampling and disposition tracking
Practical and convenient	<ul style="list-style-type: none"> Eliminates paper-based data collection and data transmittal Avoids need for local site monitoring and oversight
Efficient	<ul style="list-style-type: none"> Facilitates site and data monitoring in real-time Permits a clean data set within days of database closure Data are gathered simultaneously across multiple countries
Consistent	<ul style="list-style-type: none"> Employs a standard e-CRF resulting in standardized local or multinational data
Valuable	<ul style="list-style-type: none"> Quantifies real-world variability in relation to patient characteristics, patterns of medical care and health outcomes Informs clinical trial design, costing and other burden of illness or health economic analyses Highlights unmet medical need, and informs development of treatment guidelines

UBC Provides Standards and Innovation in MRCR

<p>Scientific rigor across all electronic data capture methodologies and infrastructures to ensure that quality data are available for analysis in real time</p>	<ul style="list-style-type: none"> ▪ Global team of specialists providing scientific leadership in study design, conduct and analyses ▪ Data may be used to populate health economic analyses, but all studies are designed to stand on their own ▪ Numerous studies published in top-tier, peer-reviewed journals
<p>Innovative study designs, methodologies, and technologies for efficient and practical national and multinational data collection</p>	<ul style="list-style-type: none"> ▪ In-house tools to support large-scale project management and data gathering (web-based tools, IVRS, call center teams) ▪ Site-specific algorithms and tools to identify site-based chart sampling frame and to facilitate random selection when appropriate ▪ Analytical methods tailored to naturalistic data ▪ Study designs applicable to any number of patients or sites (studies ranging from 100 to over 10,000 subjects), therapeutic area, country or geographic region
<p>Coordinated, centralized project management to ensure that study design aligns precisely with data requirements and product value propositions</p>	<ul style="list-style-type: none"> ▪ Single point of contact, full-service solution with no sub-contractors <ul style="list-style-type: none"> - Study design, planning and management - Site recruitment and training - Analyses and dissemination ▪ Central management; remote real-time monitoring of study sites and data ▪ Research experience that has resulted in a number of disease-specific networks of study sites and world-class investigators.

MRCR is an advantageous approach whenever real-world data are needed to document patterns of care and to associate resource utilization with clinical outcomes in the actual practice setting. Chart data may include demographics, disease history, medication use, physician and emergency room visits, hospitalizations, diagnostic test results, adverse events and co-morbidities, alongside patient-level health outcomes data.

Product Development Challenge

MRCR Opportunity

<p>To study real-world patterns of care in relation to disease severity or clinical outcomes.</p> <p>Health economic analyses often require outcomes data by specific sub-groups of interest defined by severity of disease or particular clinical outcomes.</p>	<p>Medical charts typically contain disease severity and clinical outcomes data that administrative databases or other claims datasets do not.</p> <p>MRCR permits quantification of real-world rates of outcomes and/or events across different treatments and patient populations.</p>
<p>To estimate complete treatment costs</p> <p>Micro-costing may require information related to medical supplies and consumables, medication wastage, or in the case of transfusion, type and quantity of blood products administered.</p>	<p>Medical charts can contain some information about medical supplies and can reveal the difference between what is paid for by a hospital and what is actually administered to the patient (wastage).</p>
<p>To evaluate the impact of an FDA mandated Risk Evaluation and Management Strategy (REMS)</p>	<p>Medical charts of REMS subjects may be reviewed to determine if physician prescribing practices align with the REMS when subject disease history and clinical characteristics must be taken into account.</p> <p>MRCR data may serve as useful evidence to the FDA in the context of a REMS review.</p>

Multinational Retrospective Chart Reviews Frequently Asked Questions (FAQs)

In general, MRCR is an advantageous approach whenever real-world data are needed to document patterns of care, and to associate resource utilization with clinical outcomes in actual practice settings. The following frequently asked questions provide further detail regarding UBC's capabilities and may help to determine whether MRCR is the right solution to meet your data capture needs.

Are UBC's MRCR capabilities limited to particular countries or regions?

UBC's capabilities are not constrained geographically. Although access to the Internet is required when using our web-based tool to collect and manage the study data, we have a number of alternative approaches that can be implemented where web access is limited, or where sites prefer a more traditional paper-based process. An international team of project managers utilizing innovative and flexible project management techniques and approaches allows our team to overcome any potential linguistic challenges.

What are some of the countries and regions that UBC has experience with?

UBC has implemented chart review and abstraction research in the United States, Canada, the United Kingdom (UK), France, Germany, Greece and Australia. In addition, chart reviews are currently ongoing or in the preparatory phase in several other European countries. UBC has also routinely implemented other study designs involving primary HEOR data collection in most other European countries.

What are some of the disease areas that UBC has experience with?

UBC's principal research areas have included thalassemia, sickle cell disease, MDS, multiple myeloma, lymphoma, stroke, atrial fibrillation, chronic liver disease, thrombocytopenia, leukemia, c-difficile, hypertension, break-through cancer pain (opioid tolerance) and Alzheimer's disease.

How is Institutional Review Board (IRB) approval obtained and does UBC typically interact with the IRB?

UBC's approach is completely tailored to the needs of the study and/or study sites. In cases where an ethics review is required for a chart review study (e.g., most countries with the exception of the UK), sites have usually already prepared and submitted their own documentation. UBC may interact with the IRB, but it has typically been the preference of the local study principal investigator to manage the submission with only minimal support from the UBC team. UBC can also manage and assist with other required submissions, such as privacy protection schemes (e.g., CNIL in France). In the U.S. and other countries where it is typically easier to use a single, central IRB, the UBC team will prepare and conduct the submission on behalf of the study sites and sponsor.

Does UBC have country-specific standard operating procedures (SOPs) in place to manage various privacy concerns, regional approvals and fees (e.g., Italy), etc.? Who determines and acts upon any regulatory requirements, as they may be different according to country?

Over the last decade, UBC's European team of scientists and project managers have gathered and centralized intelligence relating to country-specific ethics, privacy protection issues and legislation. Country-specific site recruitment and project managers identify and track all process issues from the outset of each project. Research experience and ongoing communication with local principal investigators and their study nurses ensures that challenges are identified proactively and resolved as required.

Who performs the data abstraction and how are they trained?

Generally, site-based study staff (e.g., local principal investigators, study nurses, medical residents, research fellows) have performed the data abstraction and data entry into the study website. In the rare instance where this has been prohibitive for the sites, UBC staff or other third-party collaborators have participated. Site staff members may be trained by UBC using detailed manuals, web-ex and conference calls, which avoids the need for costly on-site or centralized training sessions.

How are sites selected?

UBC's approach to site selection is custom tailored to the needs of every project. In the past, sites have been recruited according to the preference of the study sponsor (e.g., sites associated with priority key opinion leaders [KOLs]), or via use of the extensive network of study sites that UBC has built over the course of many years of research collaborations. When new sites are needed, UBC is able to identify potential study sites through medical literature or other search strategies.

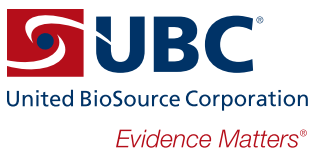
How much country-to-country variation exists in medical charts?

The lack of standardized reporting requirements in the usual care environment presents a sizeable challenge for any chart review study. Although reflective of actual practice, the quality of documentation can vary from country to country and potentially even from site to site within a given country. Electronic Medical Records (EMRs) have improved the quality of documentation in most cases; however, EMRs are more common in the U.S. than in other countries, therefore this improvement is not often widespread.

UBC has been successful in all studies to date by creating a case report form (CRF) that streamlines the data collection process and results in a standardized dataset. This CRF then becomes the property of the study sponsor. Generally, UBC has designed CRFs with simplicity in mind, minimizing site burden, reducing pass-through site costs and timelines, and ensuring that all variables of interest will be available at most sites. Prior to launch, principal investigators have the opportunity to review the CRF, and this feedback can be incorporated and managed proactively. UBC has not yet experienced a situation using this approach in which large data gaps have emerged.

Is it possible to pool data from several countries?

UBC is able to aggregate or disaggregate study data in any fashion. Such analyses are documented in the statistical analysis plan at the outset of each study. The analysis plan may be revised following the completion of data capture when the content of the analytical data set is reviewed. UBC has frequently pooled clinical outcomes across countries, but for obvious reasons usually analyze patterns of care (i.e., health economic outcomes) by individual country.



For more information on MRCR or other Health Care Data Capture solutions, please call us in the U.S. or Canada at +1 514 422 8271, in the E.U. at +44 (0) 207 299 4550, email us at analytics@unitedbiosource.com, or visit our website at unitedbiosource.com.