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## SCIENCE & POLICY OPINION

### Evidence Solutions for Medical Device Clients



By Isabella Sledge, MD, MPH

Medical device clients have some specialized evidence requirements to support their product development and marketing initiatives. This article outlines some of the research, regulatory, reimbursement and adoption challenges faced by these companies. Examples of specific solutions to help companies assess and communicate their products' relative values in improving health care outcomes and/or cost effectiveness are described.

#### Issues Encountered in Research Synthesis for Medical Device Literature

The use of research synthesis to support the development and adoption of new technologies is associated with certain practical and methodological hurdles. Additionally, reimbursement challenges require multifaceted solutions.

#### Quality of Medical Device Literature

Because many devices are utilized during an interventional procedure, it is often difficult or even impossible to have a placebo or sham treatment control group. There are fewer randomized trials for medical devices as compared with pharmaceutical trials. The lack of controlled trials means that most of the literature is class 3 or class 4 evidence based upon standard evidence classification schemes. A study's classification by quality is a measure of internal validity. This clustering of evidence class makes it difficult to meaningfully sort literature by quality and thereby compare the validity of different trial results. Additionally, the quality of the medical device literature is diluted by the large number of retrospective case series that are published relative to the smaller number of controlled trials.

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### Global Reimbursement: Essential to Every Step of Clinical Development

By Beth Hahn, PhD, Ruth Brown, MS, MHSA,  
and Diane Simison, PhD

Reimbursement is viewed slightly differently and the terminology is not the same in the US compared with Europe, but regardless of the location, reimbursement is all about market access and the components supporting it. Traditionally, emphasis on reimbursement has come prior to the launch "of a product and has not been considered within every stage of clinical development. At what stage of development should reimbursement research be conducted and how global must the research be? Ideally some research is needed at all phases,

however, if the bulk of the research is not conducted during Phase II and is delayed until Phase III, it may be too late to take corrective action prior to launch and may postpone market access.

We recommend a methodological approach with some research beginning in Phase I and a continued building of the evidence in Phase II and Phase III, such that there is a clear vision of reimbursement issues identified and addressed by launch.

#### Phase I

Virtually all new products will face some market access challenges at launch. Some of these challenges stem from the increasing experience of the market with competitor products between now and the launch date, and some will be a result of reimbursement environmental changes. Challenges in the US and Europe include:

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## Global Reimbursement

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- **U.S.:** The Medicare Part D drug benefit is a major change to the US reimbursement environment, providing a drug benefit for the majority of U.S. citizens age 65 and above for the first time in U.S. history. The extent to which changes in the drug benefit, such as management and formularies, will have on the non-Medicare (or the commercial segment) of U.S. managed care organizations (MCOs) is yet to be determined and is evolving.
- **Europe:** The health care payment systems in European countries are undergoing changes reflective of growing health care costs and government efforts to control expanding expenditures. For example, Germany and Italy have adopted Diagnosis-Related Group (DRG) systems and France is revising their system. The UK has primary care trusts (PCTs) which act similarly to the MCOs in the U.S. The budgets for drugs in the outpatient setting are increasingly becoming the responsibility of the health care gatekeeper (usually the GP). Changes in the systems are confusing and upsetting to many of the health care providers and, in some cases, limit the availability of drugs within the national health system.

While product profiles are rarely tightly defined at Phase I, there is a need for policy research to anticipate shifts in the reimbursement landscape. Research includes examining reimbursement decision-making for those regulatory bodies frequently considered to be the standard and should encompass likely reimbursement level and restrictions, if any, based

**While product profiles are rarely tightly defined at Phase I, there is a need for policy research to anticipate shifts in the reimbursement landscape.**

on existing competitors. It should also include an examination of country requirements for cost effectiveness, quali-

ty of life, and budgetary impact data and analyses beyond evidence of safety and efficacy, as well as an exploration of other market access hurdles such as prescription restrictions and treatment guidelines and special funds to pay for medicines. The data also provides important information for the creation of the initial reimbursement strategy.

During Phase I, manufacturers may also consider an independent evaluation of clinical study designs against payer data requirements to facilitate reimbursement and planning post-approval studies. This work involves review of regulations and policies and an identification of data and endpoints relevant to reimbursement decisions.

### Phase II

At the completion of Phase II, the product profile is refined and can be used in primary research with payers, health

authorities, and influencers. Desired data include the reaction to the profile (unique, similar to existing, etc.), identification of missing information needed to evaluate the drug, current barriers, and the likely impact of restrictions, if any, on the drug. We recommend research in the U.S. and the top five European markets at this stage. These data are used to supplement and refine the reimbursement strategy. Conducting reimbursement research at this stage informs the Phase III activities, allowing time to collect and prepare information required at launch.

### Phase III

If the lapse between Phase II and III is a number of years or the market has experienced changes, augmenting the previous primary research may be useful. A second review with payers, health authorities, and influencers can be quickly completed following the groundwork at Phase II. We also recommend reviewing the reimbursement data, the drug value statements, and the supporting data with country affiliates to assess, challenge, and ultimately validate the final reimbursement strategy to be certain that there are no unanticipated issues prior to launch.

Global reimbursement data is as important as pharmacokinetic data in the development of a compound and ultimately more important to the long-term success of the drug in the marketplace. As most manufacturers have experienced, registration is not always an accurate predictor of reimbursement or market success. Waiting until Phase III to conduct reimbursement research may impede reimbursement decisions due to a paucity of data and poor planning, resulting in delaying market access and hindering profitability.

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## A Systematic Review of Budget Impact Analyses

*By Noémi Muszbek, BSc, MSc, John Hutton, BScEcon, BPhil*

Although affordability is a major concern to decision-makers as health care costs grow, few economic submission guidelines explicitly require a budget impact analysis (BIA). A BIA is part of the reimbursement submission in Australia, Belgium, Canada, England & Wales and for managed care organizations in the U.S. An overall health system BIA is also included in the pharmacoeconomic guidelines of Switzerland, Hungary, Italy and Poland and is an essential part of pricing discussions in France. In spite of attempts to distinguish BIAs from economic evaluation proper, and to develop guidelines to standardise practice, (e.g., Trueman, Drummond, Hutton, 2001), the content and use of BIAs remains varied by country.

The quality of BIAs varies greatly, partly due to the different expectations of users. We undertook a systematic review of

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## SCIENCE &amp; POLICY OPINION

# Evidence Solutions

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## Searching the Medical Device Literature

Unlike pharmaceutical trials that are often indexed under both the drug name and the disease indication, device trials are often indexed according to the procedure used to implant the product. If a device is used in multiple procedures or therapeutic areas, identifying a complete evidence base can be quite challenging. Multiple search strategies may need to be attempted and samples of abstracts reviewed in order to maximize the search yields. Because of these indexing issues, manual bibliography searches of references obtained from the original electronic search are a critical step in the systematic review of device literature. Manual bibliography checks can be expected to yield up to 25% of relevant papers in any device review. In contrast, reviews of pharmaceutical trials usually have fewer than 10% of citations found manually.

## Impact of Regulatory Environment on Literature Quality

Regulatory requirements for devices are substantially different from pharmaceuticals. Many new devices seek regulatory approval through a 510(k) process. A 510(k) is a pre-marketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective as a previously marketed device. Unlike the pre-market approval (PMA) process that requires more substantial clinical evidence of safety and effectiveness, a 510(k) requires much less evidence to substantiate equivalence. The result of the lower regulatory bar for many new devices is lower quality and/or fewer clinical trials evaluating safety and efficacy.

## Impact of Regulatory Environment on Need for Literature Synthesis

In May 2006, the FDA released a guidance document on the use of Bayesian statistics in medical device trials. Through the 510(k) process, clinical effectiveness information on a new device is necessarily based in part on information obtained from clinical studies on earlier devices. Bayesian statistics use formal methodology to incorporate prior information with current information so as to obtain data on a new device through smaller size or shorter duration trials. Part of the Bayesian process is quantifying the prior information. Often the best source of information is a synthesis of published literature via a systematic literature review. As Bayesian analyses become more common, the need for rigorous evidence synthesis using unbiased and transparent methodology will increase.

In addition to the above issues with the medical device literature, reimbursement and adoption challenges also impact evidence-based decision making with regard to medical devices.

## Evidence Needs for Reimbursement Challenges

Reimbursement challenges often present a higher bar for success of new medical device products than does regulatory approval. Device companies often must approach both regional and national decision makers for both public and private insurers. Obtaining reimbursement for a product may require explication of overall budget impact, assessment of cost-effectiveness, and longer term clinical data than required for FDA approval. There are multiple stakeholders involved in the reimbursement decision-making process, from medical directors to benefits managers to hospital administrators, and each stakeholder may have different evidence requirements for decision making.

An example of a new evidence requirement is the Centers for Medicare and Medicaid Services' (CMS) new coverage determination, released in July 2006, that allows for coverage determinations to be contingent on the collection of additional evidence. The requirements of additional data are outlined in the guidance document on the CMS website: [http://www.cms.hhs.gov/mcd/ncpc\\_view\\_document.asp?id=8](http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8).

## Evidence Needs for Technology Adoption Challenges

Unlike new pharmaceutical products, new medical devices sometimes require entirely new or adapted procedures or interventions. Such changes often mean altering established practice patterns. These changes have ripple effects with

**As Bayesian analyses become more common, the need for rigorous evidence synthesis using unbiased and transparent methodology will increase.**

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## SCIENCE &amp; POLICY OPINION

## Evidence Solutions

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regard to medical training, hospital and operating room procedures, and individual as well as inter-physician practice norms. Adoption of new technology can feel like a seismic change, and thus barriers to broad adoption of new technology can often be higher than the regulatory and reimbursement hurdles faced by device companies.

### Summary of Challenges

The above challenges to evidence-based decision making for medical devices can be summarized as follows:

- Overall poorer quality literature as compared with pharmaceutical trials, with a clustering of class 3 and 4 literature, makes it difficult to organize the literature by quality.
- A comprehensive literature base to assess a particular device may be difficult to assemble because of challenges with indexing and searching.
- Regulatory requirements may allow approval with substantially less evidence than for pharmaceutical products, particularly with regard to longer term outcomes; thus the evidence base for product support may be thin.
- Growing use of Bayesian statistics in device trials create demand for evidence synthesis to obtain robust prior information.
- Reimbursement decisions are made by multiple stakeholders with different evidence needs.
- New CMS coverage with evidence development may require ongoing data collection.
- Adoption of new technology may require substantial changes in practice and training patterns, thus evidence required to support such change may be substantial.

### Solutions to Meet These Challenges

#### ■ Literature Catalog

A literature catalog can help clients overcome some of the difficulties in finding and assessing device studies. A catalog is a searchable, current database of all studies of a particular device in one or more therapeutic areas. Basic information on study design, accrual years, treatment characteristics, and efficacy and safety outcomes reported are organized in a relational database that can be sorted with customizable filters. In addition to tracking current literature and meeting abstracts, the database can be used to plan further analyses or to assemble a dataset quickly to respond to a regulatory or market challenge. Optimally, the database should be updated every six months.

#### ■ Web Portal

Creating a web portal that allows multiple stakeholders to access a single comprehensive evidence base derived from a systematic review of the literature is a way of promoting evidence-based decision making. For example, a portal has been created in the field of bariatric surgery. This web portal offers access to a relational database with information extracted from over 800 studies. The intent of the portal is to discourage ‘cherry picking’ of studies by allowing decision makers to examine all published literature relevant to a particular question. The bariatric surgery portal was presented at the Cochrane Collaboration North American conference in May 2006 in an abstract titled, “Integrating a Systematic Review of the Bariatric Surgery Literature into a Web-Based Portal to Facilitate Evidence-Based Decisions in the Surgical Management of Morbid Obesity.”

#### ■ Analytic Capabilities

In addition to competence in traditional meta-analysis methodology, having an array of analytic capabilities that incorporate a variety of data sources is vital. These capabilities should include Bayesian statistical methodology as well as access to and experience with large claims databases.

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### ▪ Combined Solutions

Addressing the various needs of multiple decision makers in the reimbursement and technology adoption process for medical devices is critical. A systematic literature review/meta-analysis complemented with a cost-effectiveness analysis and budget impact model addresses many of the evidence needs for multiple stakeholders. A patient registry may be a logical second step after a literature review highlights the lack of longer term outcomes. It is vitally important to keep up with and meet the evolving evidence needs throughout the product life cycle.

### Strategic Consulting/Publication Strategy

Device companies must think strategically about coordinating evidence generation and translating this evidence into a publication strategy. Because of the difficulties with technology adoption described above, publication strategy becomes an essential component of product support. Significant changes in practice patterns will only be adopted if supported with substantial evidence. Thus publication strategy for device technology often requires a two-pronged approach: the documentation of cost-effectiveness and budget impact for payers, and proof of superiority of clinical outcomes for providers. Clients should not focus solely on the cost implications of new technology. The practice of medicine needs to evolve before a new technology is adopted, and targeted peer-reviewed publications and influential podium presentations are essential in this process.

In summary, medical device clients are faced with unique challenges as they develop and market new products, however, there are solutions to these evidence needs that will help device companies meet their reimbursement and marketing goals.

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## Budget Impact Analyses

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published BIAs to assess the characteristics of the studies; the extent of the variation in practice; and possible explanations.

PubMed and EMBASE were searched for articles with the search terms “budget impact” or “budget analysis” limited to the English language. Between 2001 and 2006, 16 studies were found, most of them relating to pharmaceuticals in a US setting. All studies relating to France and the US had a BIA as their main aim; in other countries, the BIA tended to be a subsidiary part of full economic evaluation. Industry funding was stated for 63% of studies, and industry affiliation was present for a further 13%.

Understandably, the payer perspective was chosen in all of the studies, complemented in a few cases by a patient or societal perspective. Epidemiological data was mainly drawn from the literature, and adoption rates were based on assumptions. Most studies addressed only direct medical costs (63%) but 19% included only drug costs. The most frequent time horizon was one year (44%). A breakdown of the sources of budget change was reported in only six studies (38%), even though the majority (56%) was either cost-saving or had cost-saving scenarios. A sensitivity analysis was conducted on the budget impact in only half of the studies.

From the limited number of published BIAs identified, it is clear that the methods used were much less sophisticated than for full economic evaluations. Because a BIA is specific to a single decision-maker or health system, few are considered to be of sufficient interest to be published in mainstream clinical and pharmacoeconomic journals. The reduced exposure to peer-review has not helped to raise interest and methodological standards. On the other hand, the low expectations of some decision-makers provide little incentive for manufacturers to invest in more sophisticated studies.

Many BIAs are carried out internally by health care funding organizations and are not publicly available. Those which are accessible, e.g., those carried out for NICE in England and Wales, show no improvement in methods over time. In fact the authors of more recent NICE assessment reports have shown greater reluctance to estimate any budget impact figure, as they have recognized the difficulty of conducting good quality BIAs but have insufficient resources to do them well. If affordability was not important to decision-makers, the current BIA might be adequate. However, if the current BIAs are actually influential in the decision-making process, there is cause for concern amongst those who support decisions based on sound analysis.

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## Qualitative Data Analysis in PRO Research — Philosophical and Practical Issues

By Donald E. Stull, PhD

The measurement, analysis, and interpretation of qualitative data are complex processes. How does a researcher move from hundreds or thousands of pages of field notes or transcripts of interviews or focus groups to the final conclusions that are read in a journal article or become the basis for a product claim? How do we take comments about item content made by our subjects in cognitive interviews and make decisions about developing or modifying our instruments?

Qualitative methods have become an increasingly important, in fact necessary, part of patient-reported outcomes (PRO) instrument development. The richness of the patient experience is captured best in words and actions that are grounded in those very patients' lives. The challenge for health outcomes researchers is to transform those qualitative data into meaningful interpretations that can lead to better understandings of the patient experience, link our PRO instruments more closely to the patient experience, and allow for the emergence of important concepts and their inter-relationships.

The qualitative researcher has been described as a jack-of-all-trades<sup>1</sup> who uses many different tools, methods, and inquiry paradigms. The final products of our efforts are collages that reflect the multiple methods and perspectives used as we attempt to gain an in-depth understanding of a phenomenon. This understanding, or collage, is an emergent construction that changes or takes new forms as we employ new tools, methods, or perspectives.

Philosophically and practically, qualitative research is an interpretive endeavor that favors no single methodology over another. The choice of research questions and the methods of data collection and interpretation will be shaped by the perspective or inquiry paradigm the researcher uses. As an example, patients recently diagnosed with heart failure can be studied using several inquiry paradigms (Table 1). The kinds of questions asked, the analytic approaches and methods, and the ontological product itself (i.e., What do we know? What have we learned?) all vary as a function of the paradigm used.

Analysis of qualitative data involves a transformation.<sup>2</sup> Qualitative data are summarized; coded; broken into themes, clusters, and subcategories. They are described, classified, and connected in new ways such that patterns and processes and relationships emerge that were not immediately apparent before. One consequence of this process is the creation of a “thick description.”<sup>3</sup> A thick description goes beyond merely reporting facts. Instead, it presents the context of an experience, states intentions and meanings that organized the experience, and it reveals the experience as a process.

There are several practical implications of these philosophical issues for health outcomes researchers. First, the process of transforming qualitative data allows new understandings to emerge from the data. Thus, our methods must not be prescriptive. Specifically, the interview guide must not determine the themes that emerge. Specific questions are often asked but we must not limit our interpretations to the content covered by those questions. Those questions and the responses to them represent the text of the interview. Upon deeper exploration, however, there may be sub-text, themes, concepts, or processes that emerge, yielding a richer understanding of the patients' experiences. This can increase the face and content validity of our items and instruments.

Second, the use of qualitative data analysis software has revolutionized analysis in several ways. We can have multiple electronic versions of the same textual passage coded in different ways while leaving the original text unaltered. Some programs allow the analyst to make visual linkages between codes or categories, increasing the opportunity for underlying themes, concepts, or processes to emerge. While these programs have greatly streamlined an otherwise labor- and paper-intensive coding process, this still does not eliminate the need for qualitative researchers to immerse themselves in their data.

**Table 1: Comparison of Qualitative Approaches for Patients with Heart Failure**

Method	Research Question	Analytic Approach	Product
<b>Grounded Theory</b>	How do patients cope with their diagnosis and new identity?	Constant comparative analysis leading to emergent themes and relationships.	Theory about the basic processes involved in becoming a patient with heart failure and developing this new identity.
<b>Ethnography</b>	How is heart failure understood and managed in different social, cultural, gendered, or economic contexts?	Representation, rhetoric, translation, and transformation of culture into writing.	Cultural descriptions and interpretations of variations in the experience of heart failure.
<b>Phenomenology</b>	What is the lived experience of having heart failure?	Phenomenological reduction; hermeneutic analysis.	Descriptions of the essential elements and structure of the experience of heart failure.
<b>Narrative</b>	How do patients with heart failure come to know and understand their experience?	Generating, interpreting, and representing patients' stories in narrative form.	Narrative accounts of patients' explanations, understanding, and interpretations of their experiences with heart failure.

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Third, many qualitative data analysis programs have emerged out of specific inquiry paradigms. Thus, they lend themselves more easily to particular analytic approaches. Just as statistical software has varying capabilities requiring the researcher to use specialized programs for certain statistical techniques, each qualitative data analysis program handles data and coding in different ways.<sup>4,5</sup> Qualitative researchers should explore these features so they use a program that maximizes the richness of their data and fits well with their inquiry paradigm.

Finally, writing is as much a part of the analysis and interpretation as is coding and categorizing.<sup>6,7</sup> With writing, we begin to reconstruct a representation of the phenomenon of interest, along with emergent themes, concepts, and processes. It is at this point that we begin to create a “thick description” that allows for a “thick interpretation.”<sup>8</sup> These help contextualize patients’ experiences and locate phenomena socially, historically, and experientially. When we write, additional questions often arise and we may find that we must return to our data to explore these questions, leading to a richer analysis. In qualitative research, our writing often extends beyond a write-up of our “results” to include narratives of our processes, speculations, and the potential for alternative interpretations. Researchers should maintain documents that contain these accounts as they reflect the thoroughness of our efforts.

Awareness of these philosophical and practical issues can help health outcomes researchers ensure that their instruments are grounded in the patients’ experiences. It can help researchers discover additional relevant concepts or

processes that can be incorporated into PRO instruments. Moreover, full narratives of the steps taken, processes carried out, and additional speculations or interpretations will add detailed evidence for validation reports and applications to regulatory agencies for labeling claims. Finally, these documents can lead to further publications and refinement of PRO measures.

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## Considerations When Training for an International Audience *By Alan Kott, MUDr.*

Many clinical trials include endpoints whereby study investigators are required to rate outcomes. This is quite common in trials focused on mental health, neurology, some oncology trials, as well as other areas. Training the investigators through a comprehensive training program can lead to a more successful study outcome. A training program can promote more consistent scoring competency among raters, improve interview techniques, reduce placebo response rates and, ultimately, reduce the sample size required for a study due to better data collection.

A typical comprehensive training program will train the raters on the scales being used in a trial, how to successfully conduct an effective research interview, and how to score on the scales properly. These training sessions are often held at the trial sponsor’s Investigator Meeting (IM). A trained expert presenter will use didactic presentations to coach the raters on the scales and then assess their rating skills through an audience response system (ARS). It is very helpful to incorporate videos of actual patient interviews to show the raters the proper way to conduct a patient interview and score the scales. Due to the subjective nature of the material, this overall approach has been proven to be very effective in rater training.

The training approach just described is typical for most clinical trials, but multi-centre trials generally involve a large number of investigators in different countries, and in recent years, it has become standard to run multi-centre clinical trials with an international group of investigators and participants/patients. This presents a significant challenge to standardizing data collection.

In these multi-national studies, it is important that training programs for investigators and participants are designed to accommodate the special considerations needed for an international audience, such as training and certifying several hundred raters across multiple countries, in multiple languages and on multiple protocols. There are several factors a sponsor must consider when evaluating a multi-national training program.

### Promoting Consistency across Countries and Languages.

Cultural and clinical perspectives can vary from country to country which may affect scoring and, ultimately, the outcome of a study. In the planning stages, it is essential to design programs that reflect cultural sensitivity throughout both the

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## CASE STUDY

## The Pharmacists' Role in Access to Physicians and Patients

By Abbe Steel

### Leveraging the NCPA for Patient Recruitment: A Case Study

Recently, UBC incorporated a focused pharmacy-driven recruitment program to support the patient recruitment efforts for a Phase IV Study for an FDA-approved gastrointestinal product. There were approximately 30 investigative sites that were ideal candidates for proactive patient recruitment outreach efforts to support a challenging protocol that required patients to already be on therapy to qualify for participation in the study.

#### Targeting the Right Pharmacists and Pharmacies

A series of filters was established for identifying the “best” pharmacists in targeted geographic areas to work with the 30 investigative sites to recruit the right patients. UBC, together with the NCPA, identified approximately five pharmacies within a 10 mile radius of each investigator site.

Pharmacies were solicited that had the following credentials:

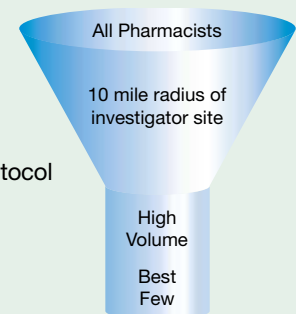
- ▶ **Data segmentation by defined mile radius**
  - Pharmacies that met filter criterion and fell within 10 miles of an investigative site
- ▶ **Prescription volume for therapeutic class(es) of prescribed treatment**
  - Targeting pharmacies based on their prescription utilization by brand, therapeutic class, etc.
- ▶ **Store Volume**

#### Targeted Patient Enrollment: The Pharmacist's Role

Pharmacists were asked to perform a query of their database to identify targeted patients based on a type of Rx (the drug list was supplied to the pharmacists). In this study, there were approximately five drugs that qualified for this query. Community pharmacies maintain up-to-date databases of prescription and other demographic information on their patients. They can sort these databases by product and therapeutic categories. These databases are a vital tool in targeting patient populations for trials and research. This approach is HIPAA compliant and all materials receive Institutional Review Board (IRB) approval before sent to patients.

The pharmacist then mailed a letter and study pamphlet along with the name and contact information of the investigator to the patient. UBC wrote the letter, wrote and designed the study pamphlet, and obtained the necessary IRB approval that was sent to the patients by the pharmacists. Each pharmacist was responsible for mailing up to 75 letters to patients. The patient was encouraged to call the investigative site to learn more about the study and be screened for inclusion. Often, UBC would use its centralized clinical coordinating call center for this type of outreach effort, but because of the small number of sites, we directed patients directly to the sites.

Additionally, while customers were in the pharmacies to fill their prescription, the pharmacist provided the study recruitment pamphlet to the customer and the pharmacist encouraged that person to call the investigative site about the study. Each pharmacist was provided with a supply of 50 additional pamphlets for hand-out in the pharmacy.



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Unlike chain pharmacists, independent pharmacists are the owners of their stores and are financially motivated to get involved with health-related initiatives such as this one. Leveraging pharmacists was a good recruitment solution to a challenging protocol. An important goal is to continually look to refine this process and learn more about the best ways to work through pharmacists to reach physicians and patients for important strategic and scientific programs.

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Earlier this year, UBC formed a strategic partnership with the National Community Pharmacists Association (NCPA). This relationship creates new opportunities to implement patient-based product research and other development programs in conjunction with pharmacists across the country.

This partnership provides access to pharmacists, physicians and patients for programs such as:

- Patient-reported outcomes research and surveys
- Clinical trials and registries, including patient recruitment
- Medication therapy management and adherence programs
- Disease management programs / patient education
- Pharmacy-branded direct-to-consumer communications
- Medicare Part D initiatives

“We have found great value working with the NCPA network of community-based pharmacists to deploy patient-based studies and other scientific research across the United States,” said UBC co-founder and CEO Ethan Leder. “This partnership allows us to deliver additional value to our clients and provides a unique opportunity to integrate pharmacists and their customers into our clients’ evidence-based product development programs.”

A key resource offered by NCPA is *Pharmacist e-Link*, an Internet-based communication link to nearly 60,000 pharmacists nationwide. *Pharmacist eLink* features daily news and information, continuing education, practice resources, and patient care opportunities. Community pharmacists turn to *eLink* for patient care opportunities such as flu immunization programs, blood pressure, cholesterol and HbA1c screening initiatives, health management and more.

Additionally, the NCPA recently launched Community Medications Therapy Management, Inc. (CMTM). CMTM is a Pharmacy Solutions Provider, deploying technical solutions that enhance the pharmacist-patient relationship. This summer, CMTM successfully launched an industry-wide platform enabling pharmacists to deliver rules-based, direct-to-patient programming. This platform is currently being utilized by over fifteen thousand pharmacies (independent and chain) for Medication Therapy Management programs. Later this year, CMTM will launch Adherence, Trial Recruitment, and Patient Education solutions.

#### **About NCPA**

The National Community Pharmacists Association represents more than 60,000 pharmacists practicing in the nation’s 24,000 independent pharmacies. Independent pharmacies represent 42 percent of the drugstores in the U.S. This network represents the largest virtual chain pharmacy in the world, touching over 120 million consumers on an average of 3.7 times each month. The retail pharmacy is the most frequently visited health care venue in the world.

Unlike chain pharmacists, independent pharmacists are the owners of their stores and are financially motivated to get involved with health initiatives — from disease management and patient compliance to market research and clinical trial recruitment.

Because independent pharmacies cater to the senior population, they have very strong and influential relationships with their customer base of ~ 5,000 patients per pharmacy.

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# International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 9

OCTOBER 28 - 31, 2006 — COPENHAGEN, DENMARK

## Pre-Meeting Short Course

Saturday, October 28, 2006, 1:00 PM - 5:00 PM

### Instrument Development & Evaluation for Patient-Reported Outcomes Assessment

**Faculty:** **Andrew Lloyd, M. Phil**, Research Scientist and Deputy Director, United BioSource Corporation, London, UK; **Patricia van Hanswijck de Jonge, PhD, MSc**, Senior Research Associate, United BioSource Corporation, London, UK

#### PODIUM PRESENTATIONS

##### ES4: Systematic Review of Budget Impact Analyses

**Muszbek N, Hutton J.** United BioSource Corporation, London, UK

##### CV1: Cost-Effectiveness of Eptifibatide in Patients Undergoing Percutaneous Coronary Intervention in Germany

**Dewilde S<sup>1</sup>**, Bruggenjurgen B<sup>2</sup>, Welte R<sup>3</sup>, Willich SN<sup>4</sup>.  
<sup>1</sup>United BioSource Corporation, Brussels, Belgium, <sup>2</sup>Alpha Care, Celle, Germany, <sup>3</sup>GlaxoSmithKline, Munich, Germany, <sup>4</sup>Charite University Medical Center, Berlin, Germany

##### ES8: Treatment Costs of Different Phases in Breast Cancer (BC) in Hungary

**Muszbek N<sup>1</sup>, Benedict A<sup>2</sup>** <sup>1</sup>United Biosource Corporation, London, UK. <sup>2</sup>United BioSource Corporation, Budapest, Hungary

##### MC7: Translation and Validation of New Language Versions of the Ankylosing Spondylitis Quality of Life (ASQOL) Questionnaire

Doward LC<sup>1</sup>, McKenna SP<sup>1</sup>, Meads DM<sup>1</sup>, Twiss J<sup>1</sup>, **Revicki D<sup>2</sup>**, Wong R<sup>3</sup>, Luo MP<sup>4</sup>. <sup>1</sup>Galen Research, Manchester, UK, <sup>2</sup>United BioSource Corporation, Bethesda, MD, USA, <sup>3</sup>Abbott, Parsippany, NJ, USA

#### Visit Us at Booth #27

to learn more about our expanded services  
and meet our Scientific Staff.

Join us for lunch in the  
Exhibit Hall on Monday, October 30.

#### POSTER PRESENTATIONS

##### PND15: Relapsing-Remitting Multiple Sclerosis (RR-MS) Patients' Valuation of MS Treatment Benefits

**Narewska J<sup>1</sup>, Lloyd A<sup>1</sup>, Dewilde S<sup>2</sup>**, Hass SL<sup>3</sup>, Miller DW<sup>3</sup>.  
<sup>1</sup>United BioSource Corporation, London, UK, <sup>2</sup>United BioSource Corporation, Brussels, Belgium, <sup>3</sup>Elan Pharmaceuticals Inc, San Diego, CA, USA

##### PUK1: Factors Associated with Overactive Bladder in Men and Women: Results from the Epic Study

Irwin DE<sup>1</sup>, Milsom I<sup>2</sup>, Reilly K<sup>3</sup>, Hunskaar S<sup>4</sup>, Kopp Z<sup>3</sup>, Herschorn S<sup>5</sup>, **Coyne KS<sup>6</sup>**, Kelleher C<sup>7</sup>, Artibani W<sup>8</sup>, Hampel C<sup>9</sup>, Abrams P<sup>10</sup>. <sup>1</sup>University of North Carolina, North Carolina, NC, USA, <sup>2</sup>Sahlgrenska Academy at Goteborg University, Göteborg, Sweden, <sup>3</sup>Pfizer, Inc, New York, NY, USA, <sup>4</sup>University of Bergen, Bergen, Norway, <sup>5</sup>University of Toronto, Toronto, ON, Canada, <sup>6</sup>United BioSource Corporation, Bethesda, MD, USA, <sup>7</sup>St. Thomas' Hospital, London, England, UK, <sup>8</sup>University of Padova, Padova, Padova, Italy, <sup>9</sup>Johannes-Gutenberg-Universität, Mainz, Germany, <sup>10</sup>Southmead Hospital, Bristol Urological Institute, Bristol, UK

##### PUK23: Impact of Overactive Bladder on Frequency of Sexual Activity and Sexual Satisfaction in Women: Results from the Epic Study

Irwin DE<sup>1</sup>, Milsom I<sup>2</sup>, Reilly K<sup>3</sup>, Hunskaar S<sup>4</sup>, Kopp Z<sup>3</sup>, Herschorn S<sup>5</sup>, **Coyne KS<sup>6</sup>**, Kelleher C<sup>7</sup>, Artibani W<sup>8</sup>, Hampel C<sup>9</sup>, Abrams P<sup>10</sup>. <sup>1</sup>University of North Carolina, North Carolina, NC, USA, <sup>2</sup>Sahlgrenska Academy at Goteborg University, Göteborg, Sweden, <sup>3</sup>Pfizer, Inc, New York, NY, USA, <sup>4</sup>University of Bergen, Bergen, Norway, <sup>5</sup>University of Toronto, Toronto, ON, Canada, <sup>6</sup>United BioSource Corporation, Bethesda, MD, USA, <sup>7</sup>St. Thomas' Hospital, London, UK, <sup>8</sup>University of Padova, Padova, Italy, <sup>9</sup>Johannes-Gutenberg-Universität, Mainz, Germany, <sup>10</sup>Southmead Hospital, Bristol Urological Institute, Bristol, UK

##### PUK24: Linguistic Validation of the Overactive Bladder Questionnaire (OAB-Q), Overactive Bladder Short Form Questionnaire (OAB-Q SF), and OAB Assessment Tool (OAB- V8) In 4 Languages

McKown S<sup>1</sup>, Gawlicki M<sup>2</sup>, Reilly K<sup>3</sup>, **Coyne KS<sup>4</sup>**. <sup>1</sup>Corporate Translations, Inc, Chicago, IL, USA, <sup>2</sup>Corporate Translations, Inc, East Hartford, CT, USA, <sup>3</sup>Pfizer, Inc, New York, NY, USA, <sup>4</sup>United BioSource Corporation, Bethesda, MD, USA

##### PUK25: Linguistic Validation of the Patient Perception of Bladder Condition Questionnaire (PPBC) In 10 Languages

McKown S<sup>1</sup>, Gawlicki M<sup>2</sup>, Reilly K<sup>3</sup>, **Coyne KS<sup>4</sup>**. <sup>1</sup>Corporate Translations, Inc, Chicago, IL, USA, <sup>2</sup>Corporate Translations, Inc, East Hartford, CT, USA, <sup>3</sup>Pfizer, Inc, New York, NY, USA, <sup>4</sup>United BioSource Corporation, Bethesda, MD, USA

## 11th Annual European Congress

### MARK

#### PAR10: The Cost-Utility of Adalimumab (Humira®) in Patients with Rheumatoid Arthritis (RA) in Denmark

Aagren M<sup>1</sup>, Davies A<sup>2</sup>, Pang F<sup>3</sup>, Winding B<sup>4</sup>. <sup>1</sup>MUUS-MANN Research & Consulting, Copenhagen, Denmark, <sup>2</sup>United BioSource Corporation, London, UK, <sup>3</sup>Abbott Laboratories Ltd, Maidenhead, Berks, UK, <sup>4</sup>Abbott Laboratories, Gentofte, Denmark

#### PDB44: Exploring Differences in Patient Versus Public Preferences in Health Utilities: A Qualitative Study

Lloyd A<sup>1</sup>, Nafees B<sup>1</sup>, Rousculp M<sup>2</sup>, Girach A<sup>3</sup>, Ahmad A<sup>4</sup>. <sup>1</sup>United Biosource Corporation, London, UK, <sup>2</sup>Eli Lilly and Company, Indianapolis, IN, USA, <sup>3</sup>Eli Lilly and Company, Surrey, UK, <sup>4</sup>Royal Liverpool University Hospital, Liverpool, UK

#### PIH4: The Cost-Effectiveness of IVF In Italy: Implications of the New Law

Dale PL, United BioSource Corporation, London, UK

#### PIN15: Chronic Hepatitis B (CHB) Management Costs in Sweden

De Cock E<sup>1</sup>, Dale P<sup>1</sup>, Cerri KH<sup>2</sup>, Zammit D<sup>2</sup>, Flamholz L<sup>3</sup>. <sup>1</sup>United Biosource Corporation, London, UK, <sup>2</sup>Bristol-Myers Squibb, Braine l'Alleud, Wallonie, Belgium, <sup>3</sup>Dept of Infectious Diseases, Malmö, Sweden

#### PSU4: Ventral, Umbilical, and Inguinal Hernia: Review of the Current Literature

De Jonge P<sup>1</sup>, Lloyd A<sup>1</sup>, Tan R<sup>2</sup>, Narewska J<sup>1</sup>, Doyle S<sup>1</sup>, Nafees B<sup>1</sup>. <sup>1</sup>United BioSource Corporation, London, UK, <sup>2</sup>Ethicon, Livingston, UK

#### PRS3: Cost-Effectiveness of Roflumilast in the UK: A 1-Year Study in Patients with Severe to Very Severe COPD

van Nooten F<sup>1,2</sup>, Rutten-van Molken M<sup>1</sup>, Lindemann M<sup>3</sup>, Sandtmann R<sup>3</sup>. <sup>1</sup>Erasmus MC, Rotterdam, The Netherlands, <sup>2</sup>United BioSource Corporation, Brussels, Belgium, <sup>3</sup>ALTANA Pharma AG, Konstanz, Germany

#### PCN69: Health Utilities in the UK for Second Line Advanced Non-Small Cell Lung Cancer (NSCLC) Following Prior Chemotherapy

Nafees B<sup>1</sup>, Stafford M<sup>1</sup>, Bhalla S<sup>2</sup>, Watkins J<sup>2</sup>. <sup>1</sup>United BioSource Corporation, London, UK, <sup>2</sup>Eli Lilly UK

## Is Pharma Ready for Consumer-directed Health Care?

By Lael Cragin, MPH

In today's increasingly cost-constrained health care environment, industry is accustomed to stakeholders such as clinicians, health care facilities, and third-party payers demanding evidence of value for money. However, the health care market landscape is changing as costs are increasingly being shifted to consumers and as they become even more cost-conscious purchasers of health care rather than sole recipients of care. This poses real challenges for industry and must be carefully addressed to ensure commercial success.

In the past five years, health insurance premiums have increased nearly five times faster than the overall rate of inflation—from an average of \$2,424 in 2000 for a single beneficiary to \$4,024 in 2005—leading to debate about ways to reduce the growing cost of health care coverage. In the 1990s, employers responded to cost pressures by using managed care companies to pressure providers to reduce their prices and use of expensive services. A so-called managed care “backlash” on the part of patients and providers ensued, forcing insurers to lift restrictive policies and employers to shift costs to employees by increasing employees' out-of-pocket payments for their insurance as well as the health care services they receive, or by ceasing to offer health care benefits altogether.

One way employers have shifted costs to employees is through a relatively new type of health insurance product known as consumer-directed health plans (CDHPs). CDHPs combine a high-deductible health plan (minimum deductible of \$1,050 for a single beneficiary and \$2,100 for a family in 2006) with a tax-advantaged health reimbursement account (HRA) or health savings account (HSA) that enrollees can use to pay for a portion of their health expenses. Whereas HRAs are employer-owned and funded, HSAs are employee-owned and may be funded by both the employer and employee. More importantly, unlike HRAs, HSAs are fully portable to a new employer. Since enrollees bear a greater share of the initial cost of care, the average annual premium for a CDHP, which was \$2,700 in 2005, is typically 20-30% lower than the average annual premium for all employer-sponsored plans.<sup>1</sup>

Proponents of CDHPs believe that they can help restrain the growth in health care costs. The theory is that by more closely aligning receipt and payment of health care services, enrollees will become more cost-conscious purchasers of health care services. Since account funds are rolled over from one year to the next, enrollees have an incentive to seek lower-cost health care services and limit their discretionary spending on health care by obtaining care only when necessary. Furthermore, CDHPs enable enrollees to gain greater

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## Is Pharma Ready?

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control over their health care purchasing decisions and accumulate tax-advantaged savings for medical expenses, similar to tax-advantaged savings for retirement via an IRA or 401K.

Some increasingly common but by no means required components of CDHPs are patient-education and decision-support tools that provide information to enrollees on the cost and quality of health care services, including information about prescription drugs. It is through the use of pricing and quality information that enrollees are expected to seek better value for their health care dollars. Already, demand has increased for new comparative prescription drug pricing tools that compare alternative therapies, offer pricing information, and calculate out-of-pocket payments and savings for patients on an annualized basis. Although not directly

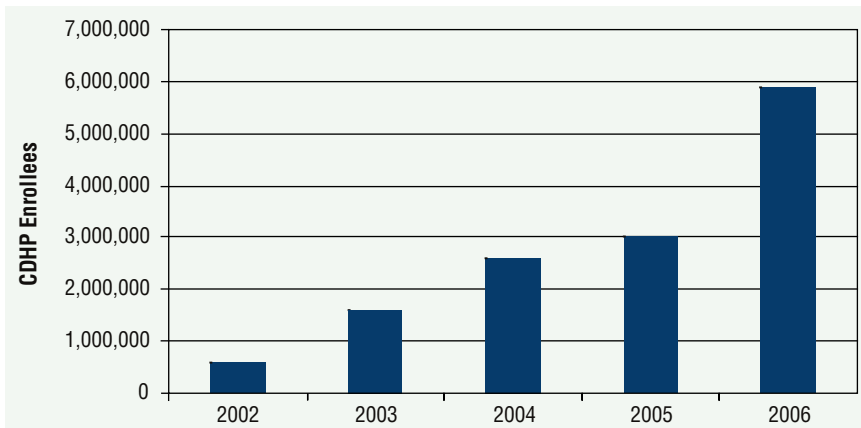
associated with a CDHP, Consumer Reports Best Buy Drugs ([www.bestbuydrugs.org](http://www.bestbuydrugs.org)), for example, produces drug reports that combine an expert review of the scientific evidence on prescription drugs with drug price and cost data to produce an independent and unbiased resource on the comparative efficacy, safety, and value of prescription drugs. Nevertheless, initial reports indicate decision-support tools, overall, do not provide sufficiently detailed measures of cost and quality to enable enrollees to identify higher value treatment options.

Still in its infancy, it is too soon to determine the impact CDHPs will have on health care access, quality, utilization, and cost. But one thing is certain: CDHPs are growing in popularity. The number of firms offering CDHPs to employees is doubling annually, and by 2010 CDHPs are expected to cover between 20 million and 30 million lives (Figure 1). Although CDHPs constitute a small portion of the health insurance market, employers are increasingly offering plans with CDHP-like features, specifically high deductibles (Figure 2). Even the

Centers for Medicare & Medicaid Services (CMS) has taken note of the potential for CDHPs to restrain growth in health care costs. As part of a demonstration project, it will provide beneficiaries with access to coverage through CDHPs in the Medicare Advantage programs in 2007. (Historically, the increasingly popular HSA-type plans have not been available to Medicare beneficiaries.) Moreover, Medicare's CDHP demonstration program will require insurers to provide enrollees with pricing and quality information.

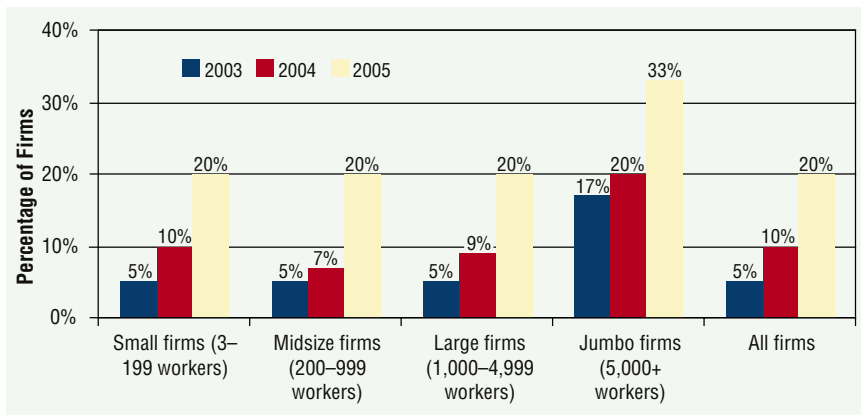
In today's increasingly cost-constrained health care environment, industry is accustomed to stakeholders such as clinicians, health care facilities, and third-party payers demanding evidence of value for money. As health care costs are increasingly being shifted to consumers and as they become even more cost-conscious purchasers of health care rather than sole recipients of care, pharmaceutical companies will need to develop strategies for building and communicating evidence of value that can be readily understood by consumers and their families in addition to providers and third-party payers. Since the FDA regulates communication about drugs, there are legal and regulatory issues to be addressed as well. All will pose continuing challenges for industry and must be carefully addressed to ensure commercial success.

**Figure 1. Estimated Number of Lives Covered by CDHPs**



Source: Business Insurance; US Government Accountability Office (GAO)

**Figure 2. Among Firms Offering Health Benefits, Percentage Offering a High-deductible Health Plan, by Firm Size**



Source: Kaiser/HRET Employer Health Benefits Surveys, 2000-2005. Note: a high-deductible is defined here as a plan with an annual deductible of at least \$1,000 for single coverage and \$2,000 for family coverage; the percentages shown above are for all plans with a high-deductible, regardless of whether they are offered with an HRA or HSA.

For more information, please contact Lael.Cragin@unitedbiosource.com.

<sup>1</sup>Kaiser/HRET Employer Health Benefits Surveys, 2000-2005.

## Recent Presentations

### Annual Meeting of the Slovak Society of Cardiology

October 5–7, 2006, Bratislava, Slovak Republic

“The Role of Pharmacoeconomics in Hungary in Decision-Making Using the Example of Plavix.” **Noemi Muszbek, MSc**, Research Associate, United BioSource Corp., London, UK

### 31st ESMO Congress

September 29 – October 3, 2006, Istanbul, Turkey

“Cost of Managing Recurrent Human Epidermal Growth Factor Receptor 2 (HER2) Positive Breast Cancer in Women Previously Treated for Early Stage Disease in the UK.” Brazil L<sup>1</sup>, **Remak E<sup>2</sup>**, Poole C<sup>3</sup>, **Muszbeck N<sup>2</sup>**, Cohen C<sup>4</sup>, Geary U<sup>4</sup>, Walker M<sup>4</sup>; <sup>1</sup>Guys and St Thomas’ Hospital, London, UK; <sup>2</sup>United BioSource Corp., London, UK; <sup>3</sup>City Hospital, Birmingham, UK; <sup>4</sup>Roche Products Ltd, Welwyn Garden City, UK

### Elicitation of UK Health Utilities in Primary, Recurrent and Metastatic Breast Cancer

van Hanswijck de Jonge P<sup>1</sup>, Doyle S<sup>1</sup>, Farina C<sup>2</sup>, Walker M<sup>2</sup>. <sup>1</sup>United BioSource Corp., London, UK; <sup>2</sup>Roche Products Ltd.

### 2006 Alliance Health Pharmaceutical Conference: Creating and Maintaining an Informed and Compliant Patient

September 22, 2006, Princeton, NJ, USA

KEYNOTE SPEAKER: **Laurie Hughes, MBA**, Executive Director, Center for Pricing and Reimbursement, United BioSource Corp., Arlington, VA, USA

### 5th Annual Off-Label Usage Conference: A Practical Guide to Managing Risks and Meeting Business Objectives

September 20–21, 2006, Philadelphia, PA, USA

“Pediatric Off-label Use of Pharmaceuticals: Difficulties in obtaining sufficient evidence to support pediatric drug labeling Review of the current initiatives which are trying to address the problem of pediatric off-label drug use.” **Matthew Reynolds, PhD**, Senior Director, Epidemiology & Risk Management, United BioSource Corp., Medford, MA, USA

### NCI-NIH Patient-Reported Outcomes in Clinical Trials: Evaluating and Enhancing the Payoff to Decision Making

September 20–21, 2006, Bethesda, MD, USA

“Industry and U.S. Food and Drug Administration Perspectives on Patient-Reported Outcomes in Cancer Trial.” CHAIR: **Dennis Revicki, PhD**, Senior Vice President and Director, Center for Health Outcomes Research, United BioSource Corp., Bethesda, MD, USA

### Phase IV Clinical Trials

September 18–19, 2006, Philadelphia, PA, USA

“The Importance of Phase IV Studies in Risk Minimization Action Plans (Risk MAPs).” **Annette Stemhagen, DrPH, FISPE**, Vice President, Epidemiology & Risk Management, United BioSource Corp., Ambler, PA, USA

### 2006 Annual EuroQol Group Plenary Meeting

September 14–16, 2006, Barcelona, Spain

“Impact of Cancer on Health Related Quality of Life: Evidence using the EQ-5D.” Pickard AS<sup>1,2</sup>, Wilke C<sup>1,2</sup>, Lin HW<sup>1,2</sup>, **Lloyd A<sup>3</sup>**; <sup>1</sup>College of Pharmacy, Univ. of Illinois at Chicago, Chicago, IL, USA; <sup>2</sup>Dept. of Pharmacy Administration, College of Pharmacy; <sup>3</sup>United BioSource Corp., London, UK

### ACCC's 23rd National Oncology Economics Conference

September 13–16, 2006, St. Louis, MO, USA

“Medicare Rule Changes, The Practical Translation/Solution” **Sandy Robinson, MPA**, Executive Director, Center for Pricing and Reimbursement, United BioSource Corp., Arlington, VA, USA

### 2006 BASL Annual Meeting

September 7–8, 2006, Dublin, Ireland

“Economic Evaluation of Individualised versus Standard Treatment Approach for Patients with Chronic Hepatitis C Virus Genotype-1 (G1) Low Viral Load (LVL) Using Peginterferon Alpha-2b Plus Ribavirin in the United Kingdom.” Naoumov N<sup>1</sup>, Zeuzem S<sup>2</sup>, Tatman N<sup>1</sup>, **Cragin L<sup>3</sup>**, **Sorensen S<sup>3</sup>**; <sup>1</sup>UCL Institute of Hepatology, Univ. College London, London, UK; <sup>2</sup>Saarland Univ. Hospital, Homburg/Saar, Germany; <sup>3</sup>United BioSource Corp., Bethesda, MD, USA

### Kessler Medical Rehabilitation Research & Education Corp.

September 6, 2006, UMDNJ-NJ Medical School, NJ, USA

“Evidence-based Medicine.” **Susan Ross, MD, FRCPC**, Vice President, Medical Affairs, United BioSource Corp., Medford, MA, USA

### 16th European Respiratory Society Annual (ERS) Congress

September 2 – 6, 2006, Munich, Germany

“Agreement Between a Self-report Screener for Nasal Congestion and Nasal Examination.” Krouse J<sup>1</sup>, Meltzer EO<sup>2</sup>, **Stull D<sup>3</sup>**, Naclerio R<sup>4</sup>, Long A<sup>5</sup>, Lund V<sup>6</sup>, **Frank L<sup>3</sup>**, Kim S<sup>7</sup>; <sup>1</sup>Wayne State Univ., Detroit, MI, USA; <sup>2</sup>Univ. of California at San Diego and Asthma Medical Group and Research Center, San Diego, CA, USA; <sup>3</sup>United BioSource Corp., Bethesda, MD, USA; <sup>4</sup>Univ. of Chicago, Chicago, IL, USA; <sup>5</sup>Allergy Associates, Massachusetts General Hospital, Boston, MA, USA; <sup>6</sup>Institute of Laryngology and Otolaryngology, Univ. College London, London, UK; <sup>7</sup>Schering-Plough, Kenilworth, NJ, USA

“Development of the Congestion Quantifier: a Self-report Screener for Nasal Congestion.” **Stull D<sup>1</sup>**, Krouse J<sup>2</sup>, Naclerio R<sup>3</sup>, Meltzer EO<sup>4</sup>, Long A<sup>5</sup>, Lund V<sup>6</sup>, **Frank L<sup>1</sup>**, Kim S<sup>7</sup>; <sup>1</sup>United BioSource Corp., Bethesda, MD, USA; <sup>2</sup>Wayne State Univ., Detroit, MI, USA; <sup>3</sup>Univ. of Chicago, Chicago, IL, USA; <sup>4</sup>Univ. of California at San Diego and Asthma Medical Group and Research Center, San Diego, CA, USA; <sup>5</sup>Allergy Associates, Massachusetts General Hospital, Boston, MA, USA; <sup>6</sup>Institute of Laryngology and Otolaryngology, Univ. College London, London, UK; <sup>7</sup>Schering-Plough, Kenilworth, NJ, USA

“Cost-effectiveness of Omalizumab in Swedish Asthma Patients.” **Dewilde S<sup>1</sup>**, **Dale P<sup>2</sup>**, Turk F<sup>3</sup>; <sup>1</sup>United BioSource Corp., Brussels, Belgium; <sup>2</sup>United BioSource Corp., London, UK; <sup>3</sup>Novartis Pharmaceutical Corp., Basel, Switzerland

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## Recent Presentations *continued*

"How Does Patients' Quality of Life Guide their Preferences Regarding Asthma Therapy?" Kaptein A<sup>1</sup>, **Lloyd A<sup>2</sup>**, McIntosh E<sup>3</sup>, Rabe K<sup>1</sup>, Williams A<sup>4</sup>. <sup>1</sup>Leiden Univ. Medical Centre, Leiden, Netherlands; <sup>2</sup>United BioSource Corp., London, UK; <sup>3</sup>Univ. of Oxford, London, UK; <sup>4</sup>GlaxoSmithKline, UK

### 6th European Conference on Health Economics

July 6–9, 2006, Budapest, Hungary

"Hungarian Cost-Utility Analysis of Anastrozole vs Tamoxifen in Postmenopausal Women with Early Breast Cancer." **Benedict A<sup>1</sup>**, **Muszbeek N<sup>1</sup>**, Jones DM<sup>2</sup>; <sup>1</sup>United BioSource Corp., London, UK; <sup>2</sup>AstraZeneca, UK

### AcademyHealth 2006 Annual Research Meeting

June 25–27, 2006, Seattle, WA, USA

"Bayesian Methods." **Bryan R. Luce, PhD, MBA**, Senior Vice President, Science Policy, United BioSource Corp., Bethesda, MD, USA; **Christopher S. Hollenbeak, PhD**, Surgery and Health Evaluation Sciences, Penn State College of Medicine, Hershey, PA, USA and Visiting Scientist, United BioSource Corp., Bethesda, MD, USA; David Vanness, PhD, Asst. Professor of Population Health Sciences, Univ. of Wisconsin Medical School, Madison, WI, USA

### The European League Against Rheumatism (EULAR) 2006

June 21–24, 2006, Amsterdam, The Netherlands

"Impact of Systemic Lupus Erythematosus on Health-Related Quality of Life." **Howard K<sup>1</sup>**, **Petrillo J<sup>1</sup>**, Laouri M<sup>2</sup>, Kalunian KC<sup>3</sup>, Garg J<sup>4</sup>, Shikier R<sup>1</sup>. <sup>1</sup>United BioSource Corp., USA; <sup>2</sup>Genentech, South San Francisco, CA, USA; <sup>3</sup>Rheumatology, Univ. of California San Diego, San Diego, CA, USA; <sup>4</sup>Genentech, South San Francisco, CA, USA

"Validation of LUP-QOL: A Lupus-specific Measure of Health-Related Quality of Life." **Shikier R<sup>1</sup>**, **Howard K<sup>1</sup>**, Yu EB<sup>2</sup>, Kalunian KC<sup>3</sup>, **Petrillo J<sup>1</sup>**, **Thompson C<sup>1</sup>**, Brunetta P<sup>2</sup>, Laouri M<sup>2</sup>; <sup>1</sup>United BioSource Corp., Bethesda, MD, USA; <sup>2</sup>Genentech, South San Francisco, CA, USA; <sup>3</sup>University of California San Diego, San Diego, CA, USA

"Cost-Effectiveness of the 3 TNF Antagonists vs Abatacept in the Treatment of Moderate to Severe Rheumatoid Arthritis (RA)." **Davies A<sup>1</sup>**, Cifaldi MA<sup>2</sup>, Weisman MH<sup>3</sup>, Segurado OG<sup>4</sup>; <sup>1</sup>United BioSource Corp., London, UK; <sup>2</sup>Abbott Laboratories, Abbott Park, USA; <sup>3</sup>Cedars Sinai Medical Center, LA, USA; <sup>4</sup>Abbott Laboratories, Abbott Park, USA

### 42nd DIA Annual Meeting

June 18–22, 2006, Philadelphia, PA, USA

"Evidence-based Medicine Throughout the Clinical Drug Development and Product Life Cycle." **Matthew W. Reynolds, PhD**, Sr. Director, Risk Management & Safety Services, **Isabella Sledge, MD, MPH**, Assoc. Medical Director, United BioSource Corp., Medford, MA, USA

"Evaluation of Risk Management Programs Using Existing Databases." **Annette Stemhagen, DrPH, FISPE**, Vice President, Epidemiology & Risk Management, United BioSource Corp., Ambler, PA, USA

"Clinical Supply Chain Management: Integrated Solutions/Drug Accountability." **Kimberly Sierk**, Product Manager, United BioSource Corp., San Francisco, CA, USA

"Use of Patient and Drug Registries for Safety Monitoring and Assessment/ Establishing Efficient and Effective Processes in a Safety Surveillance Registry/ Developing Registries for Postmarketing Risk Assessment: Successes and Challenges." **Gerald Faich, MD, MPH, FISPE**, Senior Vice President, Epidemiology & Risk Management; **Annette Stemhagen, DrPH, FISPE**, Vice President, Epidemiology & Risk Management, United BioSource Corp., Ambler, PA, USA

"Policy, Business, and Statistical Issues Related to Bayesian Approaches for Late Phase Practical Clinical Trials." **Bryan Luce, PhD, MBA**, Senior Vice President, Science Policy, United BioSource Corp., Bethesda, MD, USA; **Christopher Hollenbeak, PhD**, Visiting Scientist, United BioSource Corp., Bethesda, MD, USA

"Automated Tools for the Electronic Management of Complex Inventory in Global Studies." **Scott Hamilton, PhD, MS**, Senior Statistician, United BioSource Corp., San Francisco, CA, USA

"Addressing Challenges Associated with Clinician Rated Scales." **Catherine Spear**, Group President, Training and Education Group, United BioSource Corp., Wayne, PA, USA

### 4th Annual Forum on Anonymous Patient-Level Data and Analysis

June 12–13, 2006, Philadelphia, PA, USA

CHAIR: **Matthew W. Reynolds, PhD**

"Case Studies: Leverage Multiple APLD Databases to Examine Critical Research Questions—Advantages, Pitfalls and Determining the Best Strategy." **Matthew W. Reynolds, PhD**, Sr. Director, Risk Management & Safety Services, United BioSource Corp., Medford, MA, USA.

### Society for Medical Decision Making 10th Biennial European Conference

June 11–13, 2006, Birmingham, UK

"Patient and Societal Values and Utilities for Cancer Related Fatigue—Whose Preferences Should Count?" **Lloyd A, van Hanswijck de Jonge P**, United BioSource Corp., London, UK

### American Hernia Society: 3rd International Hernia Congress

June 7–9, 2006, Boston, MA, USA

"The Measurement of Chronic Pain and HRQoL Following Inguinal Hernia Repair: A Review of the Literature." **van Hanswijck de Jonge P<sup>1</sup>**, **Lloyd A<sup>1</sup>**, Tan R<sup>2</sup>. <sup>1</sup>United BioSource Corp., London, UK; <sup>2</sup>Ethicon Endo Surgery, Johnson & Johnson, UK

### 42nd ASCO Annual Meeting

June 2–6, 2006, Atlanta, GA, USA

"Prevalence of Pre-Existing Conditions and Incidence of New Medical Conditions after Diagnosis of Non-Small-Cell Lung Cancer." Koo L<sup>1</sup>, **de Lissovoy G<sup>2</sup>**; <sup>1</sup>AstraZeneca, Wilmington, DE, USA; <sup>2</sup>United BioSource Corp., Bethesda, MD, USA

"Estimating Costs of Care for Patients with Newly Diagnosed Metastatic Colorectal Cancer (mCRC)." **Knopf K<sup>1</sup>**, **Paramore C<sup>2</sup>**; <sup>1</sup>Visiting Scientist, United BioSource Corp., Bethesda, MD, USA; <sup>2</sup>United BioSource Corp., Bethesda, MD, USA

## Training for an International Audience *continued from page 7*

training and assessment curriculum as well as in the scoring methodology. For example, culturally neutral training and assessment materials will be consistent throughout the entire program, exclude references to language-specific idioms and patient stereotypes, reflect protocol-specific conventions, and leverage a grading and assessment methodology that accounts for cultural differences.

**Neutralizing Cultural Biases.** Beyond obvious language differences, potential inter-cultural factors, medical practices and training differences, as well as assessment biases, can broaden the variance between countries and adversely affect study outcomes. It is vital to look closely at these potential discrepancies and factor them into international training programs in order to minimize such variances.

One very effective approach is to employ **Language Specific Break-Out Sessions** that incorporate translated videos and supporting training materials. These sessions are led by Multi-lingual Expert Trainers who have participated in rigorous preparation and certification sessions that guarantee inter-trainer reliability. This approach promotes much higher inter-rater agreement, independent of language or country. Access to a certified network of **National Language Champions (NLCs)** to assist with global training and assessment programs in all languages, including document translation, is critical. These multi-lingual clinicians possess therapeutic expertise and extensive experience with clinical research.

**Minimizing Logistical Complexities.** Trying to manage the logistics of a complex global multi-site, multi-country study can be challenging. Thus, in addition to developing a culturally neutral curriculum, simplification of meeting logistics wherever possible is advantageous. For example, many development programs often involve multiple protocols. In these situations, a series of country-specific meetings that encompass multiple protocols can serve to streamline the training process, thus making certification much more effective while simultaneously minimizing logistical complexities and budgets.

In conclusion, a valid challenge exists in standardizing the data collected from multi-centre clinical trials across various countries, and this challenge must be addressed to ensure that all significant treatment effects emerge in these trials. The proper training of investigators and subjects is one crucial factor in helping to alleviate potential issues associated with multi-national trials and could also equate to the need for smaller sample sizes in each location.

For more information, please contact Alan.Kott@unitedbiosource.com.

## Upcoming Presentations

### The Infectious Disease Society of America 44th Annual Meeting

October 12–15, 2006, Toronto, Canada

“HIV Patient Insight into the Impact of Medication Attributes on Adherence: A Qualitative Analysis.” **Flood RM<sup>1</sup>**, Davis A<sup>2</sup>, **Howard K<sup>1</sup>**, Jordan J<sup>2</sup>, Beusterien K<sup>1</sup>. <sup>1</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>2</sup>GlaxoSmithKline, Research Triangle Park, NC, USA

### 57th Annual Meeting of the American Association for the Study of Liver Diseases

October 27–31, 2006, Boston, MA, USA

“Economic Evaluation of Individualized versus Standard Treatment Approach for Patients with Chronic Hepatitis C Virus Genotype-1 (G1) Low Viral Load (LVL) Using Peginterferon Alpha-2b Plus Ribavirin in the United Kingdom.” Zeuzem S<sup>1</sup>, Naoumov N<sup>2</sup>, Tatman N<sup>2</sup>, **Cragin L<sup>3</sup>**, **Sorensen S<sup>3</sup>**; <sup>1</sup>Saarland University Hospital, Homburg/Saar, Germany; <sup>2</sup>UCL Institute of Hepatology, University College London, London, UK; <sup>3</sup>Center for Health Economics & Policy, United BioSource Corporation, Bethesda, MD, USA

### 2006 Annual Meeting of American College of Allergy, Asthma & Immunology

November 9–15, 2006, Philadelphia, PA, USA

“Impact of Congestion Associated with Allergic Rhinitis on Sleep, Daytime Somnolence and Fatigue, and Work and School Productivity.” **Stull DE<sup>1</sup>**, **Roberts L<sup>1</sup>**, **Frank L<sup>1</sup>**, Heithoff K<sup>2</sup>; <sup>1</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>2</sup>Schering-Plough, Kenilworth, NJ, USA

“Development and Validation of the Congestion Quantifier 5-Item (CQ5): A Screening Tool for Nasal Congestion.” **Stull DE<sup>1</sup>**, Krouse J<sup>2</sup>, Naclerio R<sup>3</sup>, Meltzer EO<sup>4</sup>, Long A<sup>5</sup>, Lund V<sup>6</sup>, Kim S<sup>7</sup>; <sup>1</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>2</sup>Department of Otolaryngology/Head and Neck Surgery, Wayne State University, Detroit, MI, USA; <sup>3</sup>Department of Surgery, Section of Otolaryngology, Head and Neck Surgery, University of Chicago, Chicago, IL, USA; <sup>4</sup>University of California at San Diego and Asthma Medical Group and Research Center, San Diego, CA, USA; <sup>5</sup>Allergy Associates, Massachusetts General Hospital, Boston, MA, USA; <sup>6</sup>Institute of Laryngology and Otolaryngology, University College London, London, UK; <sup>7</sup>Schering-Plough, Kenilworth, NJ, USA

### 59th Annual Meeting of the Gerontological Society of America

November 16–20, 2006, Dallas, TX, USA

“Evaluating the Relationship Between Self-Rated Health and Depression Using an Accelerated Growth Curve Model.” Kercher K<sup>1</sup>, Kosloski K<sup>1</sup>, **Stull D<sup>2</sup>**, van Dussen D<sup>3</sup>; <sup>1</sup>University of Nebraska at Omaha, Omaha, NE, USA; <sup>2</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>3</sup>University of Maryland, College Park, MD, USA

### 5th Annual LifeScience Alley Conference & Expo

December 6, 2006, St. Paul, MN, USA

“Planning Double-Duty Outcomes: Supporting FDA Approval & CMS Reimbursement.” **Diane Simison, PhD**, Executive Director, United BioSource Corporation, Center for Pricing and Reimbursement, Arlington, VA, USA

# 13th Annual Conference of the International Society for Quality of Life Research (ISOQOL)

OCTOBER 10-14 2006 LISBON, PORTUGAL

## Patient-Reported Outcomes and the Global Regulatory Environment: The ISOQOL Workshop on Measures and Methods

October 10, 2006, Lisbon, Portugal

OPENING PLENARY SESSION: 8:30-10:30 AM

"EMA and FDA Regulatory Perspectives on PROs and New Product Development and Labeling". SPEAKERS: Olivier Chassany, Mira Pavlovic, and Edwin Rock; MODERATORS: **Dennis Revicki**, William Lenderking

PLENARY SESSION 2: 11:00-11:45 AM

"Conceptual Framework and Guidance on Statements about PRO Findings in Product Labels and Promotional Materials." SPEAKERS: **Dennis Revicki**, David Cella, Neil Aaronson, William Lenderking; RESPONDENT: Edwin Rock

PLENARY SESSION 5: 2:30-3:15 PM

"Statistical Analysis Issues for PROs: Missing Data, Multiplicity, and Longitudinal Data Structure." SPEAKERS: Diane Fairclough, Jeff Sloan, Peter Fayers, **Dennis Revicki**; RESPONDENT: Donna Lamping

PLENARY SESSION 6: 3:30-4:15 PM

"Interpreting PRO Results: Methods for Determining Responsiveness and MID." SPEAKERS: Ron Hays, David Cella, **Dennis Revicki**, Jeff Sloan; RESPONDENT: Albert Wu

PLENARY SESSION 7: 4:15-4:45 PM

"Commentary and Closing Session: PROs and You: Where Do We Go From Here?" MODERATORS: William Lenderking, **Dennis Revicki**

## WORKSHOP

### Advanced Psychometric Methods: Application in PRO Instrument Development and Evaluation

**Dennis Revicki, PhD, Donald Stull, PhD**, Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA

## ORAL PRESENTATIONS

### Psychometric Validation of the Overactive Bladder Satisfaction with Treatment Questionnaire

**Margolis MK<sup>1</sup>**, Cerulli A<sup>2</sup>, Arieli R<sup>2</sup>, Kahler KH<sup>2</sup>, Fox KM<sup>3</sup>, **Hsieh R<sup>1</sup>, Coyne K<sup>1</sup>**. <sup>1</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>2</sup>US CD&MA / Health Economics & Outcomes Research, Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; <sup>3</sup>Strategic Healthcare Solutions, LLC, Monkscon, MD, USA

### Responsiveness of the Adult ADHD Quality of Life Questionnaire

**Matza LS<sup>1</sup>**, Johnston JA<sup>2</sup>, Faries DE<sup>3</sup>, Malley KG<sup>4</sup>, **Coyne KS<sup>1</sup>**. <sup>1</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>2</sup>US Outcomes Research, Eli Lilly and Company, Indianapolis, IN, USA; <sup>3</sup>Outcomes Research, Eli Lilly, Indianapolis, IN, USA; <sup>4</sup>Rockville, MD, USA

### Validation of the Revised Patient Perception of Migraine Questionnaire for Use in Clinical Trials: Measuring Satisfaction with Acute Migraine Treatment

**Revicki DA<sup>1</sup>, Kimel M<sup>1</sup>, Chen WH<sup>1</sup>, McCormack J<sup>1</sup>**, Burch SP<sup>2</sup>. <sup>1</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>2</sup>Global Health Outcomes, GlaxoSmithKline, Research Triangle Park, NC, USA

### Initial Validation of the Ask-20 Survey Assessing Barriers to Medication Adherence

Yu-Isenberg KS<sup>1</sup>, **Matza LS<sup>2</sup>, Coyne KS<sup>2</sup>**, Psujek J<sup>3</sup>, **Stoeckl M<sup>2</sup>**, Skinner B<sup>1</sup>, Quillian-Wolever R<sup>5</sup>. <sup>1</sup>Medical Affairs Commercial Operations, GlaxoSmithKline, RTP, NC, USA; <sup>2</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>3</sup>Center for Integrative Medicine, Duke University Medical Center, Durham, NC, USA; <sup>4</sup>Center for Integrative Medicine, Duke University Medical Center, Durham, NC, USA

## POSTER PRESENTATIONS

### Validation of a Total Gastrointestinal Symptom Rating Scale (GSRs) Score for Use in a Renal Transplant Population

Kilburg A<sup>1</sup>, **Kleinman L<sup>2</sup>, Chen WH<sup>3</sup>, Revicki D<sup>3</sup>**, Ganasakthy A<sup>4</sup>. <sup>1</sup>HE & OR Transplant, Novartis Pharma AG, Basel, Switzerland; <sup>2</sup>Center for Health Outcomes Research, United BioSource Corporation, Seattle, WA, USA; <sup>3</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>4</sup>Health Economics and Outcomes Research, Novartis Pharmaceuticals, East Hanover, NJ, USA

### Responsiveness and Minimal Important Differences of the GSRs Total Score in Renal Transplant Patients

**Kleinman L<sup>1</sup>, Chen WH<sup>2</sup>, Revicki D<sup>2</sup>**, Kilburg A, Gnanasakthy A<sup>4</sup>. <sup>1</sup>Center for Health Outcomes Research, United BioSource Corporation, Seattle, WA, USA; <sup>2</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>3</sup>HE & OR Transplant, Novartis Pharma AG, Basel, Switzerland; <sup>4</sup>Health Economics and Outcomes Research, Novartis Pharmaceuticals, East Hanover, NJ, USA

### Evaluating Methods for Linking Pain Items from Two Studies Using Item Response Theory Analysis

**Chen WH<sup>1</sup>**, Lai JS<sup>2</sup>, Cook K<sup>3</sup>, Amtmann D<sup>4</sup>, **Revicki D<sup>1</sup>**. <sup>1</sup>Center for Health Outcomes Research, United Biosource Corporation, Bethesda, MD, USA; <sup>2</sup>CORE, Northwestern University, Evanston, IL, USA; <sup>3</sup>University of Washington, Seattle, WA, USA; <sup>4</sup>University of Washington, Seattle, WA, USA

### Psychometric Evaluation of a Most Troubling Symptom Scale for Generalized Anxiety Disorder Clinical Trials

Gharabawi G<sup>1</sup>, Pandina G<sup>1</sup>, **Revicki D<sup>2</sup>, Kleinman L<sup>2</sup>**,Turkoz I<sup>3</sup>, Engelhart L<sup>3</sup>. <sup>1</sup>Medical Affairs, Janssen Pharmaceutica, Inc., Titusville, NJ,USA; <sup>2</sup>Center for Health Outcomes Research, United Biosource Corporation, Bethesda, MD,USA; <sup>3</sup>Ortho-McNeil Janssen Scientific Affairs, L.L.C., Titusville, NJ, USA

### Validation of the Overactive Bladder Family Impact Measure

**Matza M<sup>1</sup>, Coyne KS<sup>1</sup>, Brewster-Jordan J<sup>1</sup>**, Goldfischer E<sup>2</sup>. <sup>1</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>2</sup>Research, Hudson Valley Urology, P.C., Poughkeepsie, NY, USA

### Evaluating the Placebo Effect when Treating Overactive Bladder

**Coyne KS<sup>1</sup>, Thompson C<sup>1</sup>, Stull D<sup>1</sup>**, Jumadilova Z<sup>2</sup>. <sup>1</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>2</sup>Outcomes Research, Pfizer, Inc, New York, NY, USA

### Testing a Conceptual Model of Health-Related Quality of Life in Overactive Bladder

**Coyne KS<sup>1</sup>, Thompson C<sup>1</sup>, Stull D<sup>1</sup>**, Jumadilova Z<sup>2</sup>. <sup>1</sup>Center for Health Outcomes Research, United BioSource Corporation, Bethesda, MD, USA; <sup>2</sup>Outcomes Research, Pfizer, Inc, New York, NY, USA

## Information Explosion/Overload

By Laurie A. Smith, MLIS

The advent of technology has resulted in an increase in the amount of information and problems associated with information overload. It is now estimated that seven million pages of information are added to the World Wide Web every day.<sup>1</sup> Through technology, information is more accessible, but the easy identification and retrieval of relevant and quality information remains an obstacle. The result is information overload wherein the amount of information received becomes a burden.

### Retrieving Quality Information

Is it possible to keep up with the growth of information and still find only that which is relevant? It is estimated that an internal medicine physician would need to read 17 articles daily in order to keep up with the literature.<sup>2</sup> “Biomedical science, a field in which more than two million journal articles are published annually, is far too broad a discipline for individuals to be able to cover more than a small fraction of current content, let alone keep up with developments outside their own specialties.”<sup>3</sup> One cannot read everything, so there needs to be a mechanism to find the best information that can realistically be read.

The National Library of Medicine (NLM) on the campus of the National Institutes of Health (NIH) in Bethesda, Maryland is the world’s largest medical library. The indexing of journal articles at NLM was initiated with the Index-Catalogue of the Library of the Surgeon-General’s Office. This index contains materials dated from the fifteenth century through 1950.<sup>4</sup> The IndexCat is a digitized version of the printed Index-Catalogue and contains 2.5 million journal articles and 16,000 journal titles.<sup>5</sup>

Following the Index-Catalogue, and overlapping some years, is the Index Medicus, which serves as an index to articles in biomedical journals worldwide. Part of Index Medicus was digitized into OLDMEDLINE, an NLM database of 1,760,000 citations from 1950 through 1965.<sup>6</sup> The third index created was “MEDLINE (Medical Literature Analysis and Retrieval System Online), the NLM’s premier bibliographic database. Begun in 1966 with 150,000 articles, it now contains approximately 13 million references to journal articles in life sciences with a concentration on biomedicine.” MEDLINE covers publications in 40 languages from 70 countries, and between 1500 and 3500 references are added each day.<sup>7</sup>

EMBASE, another important bibliographic database not associated with NLM, has nine million citations with between 6,000 and 8,000 citations added weekly since 1974.<sup>8</sup>

The numbers of medical and scientific research articles published annually are estimated to be from 1.4 million to 6 million. “MEDLINE-indexed journals represent an increasingly smaller portion of the broader universe of medical information.

NLM currently estimates that about 14,000 biomedical journals are published but that it selects only about one-quarter of new submissions for indexing based on quality and relevance to biomedical topics.”<sup>9</sup> Clearly, even indexing does not address the challenge of finding all the relevant information.

### The Problems Inherent in Searching through Vast Amounts of Information

The identification of relevant documents from large databases such as MEDLINE and EMBASE is a challenge, and searches tend to produce long lists of varying quality. Searching problems arise for three reasons.

First, there are inherent limitations of indexing. Search filters in PubMed, EMBASE, and other databases assist users in finding relevant articles, but these are not perfect.

Studies were conducted to determine how various filters fared in the retrieval process. In this context, “sensitivity” is the ability of a search to retrieve relevant articles and “specificity” is the ability of the search to exclude irrelevant items. Text-word searching is more successful than subject searching in locating relevant papers but was found to have low specificity. It also requires

... “sensitivity” is the ability of a search to retrieve relevant articles and “specificity” is the ability of the search to exclude irrelevant items.

users to determine a large number of terms to account for both the relevant variables as well as the differences in terminology utilized by different authors. The use of index terms in a search was found to result in more precise searching but with a cost of lower sensitivity. Each search strategy using text words or index terms provides some unique hits.<sup>10</sup> Those looking for all articles on a topic and those conducting systematic reviews will be best served by the most sensitive search. Those with little time who are looking for a few good articles will likely be best served by the most specific strategies. Many search strategies have low precision, meaning searchers will continue to spend time discarding irrelevant retrievals.<sup>5</sup>

Ultimately there is no one perfect search that will yield exactly what is needed. Sifting through abstracts of irrelevant articles will remain a part of the process.

“Pre-filtered” sources such as reviews, clinical guidelines, meta-analysis, randomized controlled trials, and systematic reviews are becoming increasingly indispensable for clinicians and researchers seeking to synthesize the literature.

These are good ways to filter, but one must be aware of the downside to only searching one or several of these sources.

*continued on page 20*

## SPOTLIGHT ON SCIENCE

## Recent Publications

- **Boscoe A, Paramore C, Verbalis JG.** "Cost of Illness of Hyponatremia in the United States." *Cost Eff Resour Alloc* 2006;4(1):10.
- **Brubaker L, Chapple C, Coyne KS, and Kopp Z.** "Patient-Reported Outcomes in Overactive Bladder: Importance for Determining Clinical Effectiveness of Treatment." *Urology* 2006; 68(Suppl.2A):3-8.
- **Coyne K, Tubaro A, Brubaker L, Bavendam T.** "Development and Validation of Patient-Reported Outcomes Measures for Overactive Bladder: A Review of Concepts." *Urology* 2006; 68 (Suppl.2A):9-16.
- **Coyne KS, Matza LS, Thompson C, Jumadilova Z, Bavendam T.** "The Responsiveness of the OAB-q among OAB Patient Subgroups." *Neurourology and Urodynamics*; In Press.
- **de Lissovoy G, Matza LS, Green H, Werner M, Edgar T.** "Cost-effectiveness of Intrathecal Baclofen Therapy for Treatment of Severe Spasticity Associated with Cerebral Palsy." *J of Child Neurology*; In Press.
- **Dewilde S, Turk F, Tambour M, Sandström T.** "The Economic Value of anti-IgE in Severe Persistent, IgE-mediated (allergic) Asthma Patients: Adaptation of INNOVATE to Sweden." *Current Medical Research and Opinion* 2006; 22(9):1765-1776.
- **Fleurence RL, Dixon JM, Milanova T, Beusterien K.** "Review of the Economic and Quality of Life Burden of Cervical Human Papillomavirus (HPV) Disease." *American Journal of Obstetrics and Gynecology* 2006; In Press.
- **Fleurence RL, Hollenbeak C.** "Rates and Probabilities in Economic Modeling: Transformation, Translation, and Appropriate Application." *Pharmacoeconomics*; In Press.
- **Fleurence RL, Dixon J, Revicki DA.** "Economics of Atypical Antipsychotics in Bipolar Disorder: A Review of the Literature." *CNS Drugs* 2006; 20(7):591-9.
- **Fahrbach K, Sledge I, Cella C, Linz H, Ross SD.** "A Comparison of the Accuracy of Two Minimally Invasive Breast Biopsy Methods: A Systematic Literature Review and Meta-Analysis." *Archives of Gynecology & Obstetrics*, Apr. 2006; 1-11.
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- **Kleinman L, Revicki DA, Flood E.** "Validation Issues in Questionnaires for Diagnosis and Monitoring of Gastroesophageal Reflux Disease in Children." *Current Gastroenterology Reports* 2006; 8(3):230-6.
- **Leidy NK.** "Evolving Concepts in the Measurement of Treatment Effects." *Proc Am Thorac Soc* 2006; 3(3):212-7.
- **Bevans M, Marden S, Leidy NK, Soeken K, Cusack G, Rivera P, Mayberry H, Bishop M, Childs R, Barrett J.** "Health-Related Quality of Life in Patients Receiving Reduced-Intensity Conditioning Allogeneic Hematopoietic Stem Cell Transplantation." *Bone Marrow Transplant* 2006; 38(2):101-9.
- **Leidy NK.** "Evolving Concepts in the Measurement of Treatment Effects." *Proc Am Thorac Soc* 2006; 3(3):212-7.
- **Miller-Davis C, Marden S, Leidy NK.** "The New York Heart Association Classes and Functional Status: What Are We Really Measuring?" *Heart & Lung* July/August 2006; 35(4):217.
- **Powers A, Marden S, McConnell R, Leidy NK, Campbell C, Soeken K, Barker C, Davey R, Dybul M.** "Effect of Long-Cycle Structured Intermittent Versus Continuous HAART on Quality of Life in Patients with Chronic HIV Infection." *AIDS* 2006; 20(6):837-845.
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- **Matza LS, Stoeckl M, Shorr JM, Johnston JA.** "The Impact of Atomoxetine on Health-Related Quality of Life and Functional Status among Patients with ADHD." *Expert Rev Pharmacoeconomics Outcomes Res.* 2006; 6(4):379-390.
- **Matza LS, Buchanan RW, Purdon S, Brewster-Jordan J, Zhao Y, Revicki DA.** "Measuring Changes in Functional Status Among Patients with Schizophrenia: The Link with Cognitive Impairment." *Schizophr Bull.* 2006; In Press.
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## NEWS BRIEFS

## Sandy Robinson Promoted to Executive Director

As of October 1, Sandy W. Robinson, MPA, has been promoted to Executive Director of UBC's Center for Pricing & Reimbursement (CPR). In this role, Ms. Robinson leads the reimbursement team at CPR and provides comprehensive strategic solutions in the areas of reimbursement and product economics. Ms. Robinson brings clients over 15 years of experience in both the payer and reimbursement consulting arenas. She has extensive expertise in coverage and reimbursement for third-party payers, payer access teams, strategic market analyses, technology assessment, program design and communications which crosses most therapeutic areas, patient populations and treatment settings. Ms. Robinson has managed projects for pharmaceutical companies, biotech firms and health alliances.

Prior to joining UBC's Center for Pricing & Reimbursement, Ms. Robinson was Vice President of PharmAnalysis Group, Inc. (acquired by United BioSource Corporation in August

2004). Previous experience includes being founder and president of SWR Consulting, a private health care research and consulting firm (1995-1999) and Associate Director in the Health Care Division at State and Federal Associates (S&FA) from 1992-1995. She began her career in health care at Hawaii Medical Service Association (HMSA) (Blue Cross/Blue Shield of Hawaii), where she served, in her last assignment, as Supervisor in the Institutional Adjudication Unit, Claims Administration Department. Prior to that, Ms. Robinson conducted technology assessment and served on the medical policy development committee for the plan.

Ms. Robinson received her Master's degree in Public Administration/Public Policy from Western Kentucky University and her undergraduate degree in Biology/Chemistry from Catawba College.

For more information, please contact  
Sandy.Robinson@unitedbiosource.com

## UBC Welcomes New Visiting Scientist

John A. Rizzo, PhD has joined United BioSource Corporation as a Visiting Scientist. Dr. Rizzo is a Professor of Economics, Cardiology and Preventive Medicine and the Director, Center for Health Services and Outcomes Research at Stony Brook University in New York.

Professor Rizzo is a health economist whose research interests include applied microeconomic studies of physician and pharmaceutical markets, the application of econometric methods to clinical outcomes research, and pharmacoeconomic evaluations of medical treatments and technologies. He has conducted research on the economic value of hospital admitting privileges to physicians, the determinants of physician earnings, and the impact of advertising on competition in the physician and pharmaceutical industries.

Dr. Rizzo's work in pharmacoeconomics and outcomes research has demonstrated appropriate statistical techniques for risk factor assessment and includes economic evaluations of alternative treatments in geriatrics, psychiatry, and cardiovascular medicine. His work has appeared in leading economics, health services, and medical journals, including *the Journal of Political Economy*, *the Journal of Law & Economics*, *the Journal of Human Resources*, *the Review of Economics & Statistics*, *the Journal of Economic Behavior & Organization*, *Medical Care*, *the Journal of the American Medical Association*, *Pharmacoeconomics*, and *the Journal of Thoracic and*

*Cardiovascular Surgery*. Dr. Rizzo placed 15th in world rankings for most pages published in the field of health economics during the period 1991-2000, and was one of 30 health economists to place on top 50 lists for both numbers of articles published and pages published in the field of health economics from 1991-2000 (as cited in the May 2003 issue of *Health Economics*).

"John's expertise in the area of health economics and his knowledge of the pharmaceutical industry will be an excellent resource for the UBC scientific team and our clients," acknowledges Dr. Lynn Okamoto, Director of UBC's Center for Health Economics & Policy. "We have already had the opportunity to consult with Dr. Rizzo on a number of research projects with very positive results and look forward to leveraging his expertise on future projects."

Professor Rizzo has consulted for leading health care and government organizations, and has testified as an economics expert in antitrust cases involving the pharmaceutical industry. He received his PhD in economics from Brown University. Prior to joining Stony Brook, Dr. Rizzo taught at Yale University, Ohio State, and Cornell University.

"I am impressed by the high level of research activity at UBC and look forward to productive research collaborations," says Rizzo.

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## Information Explosion/Overload

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Disadvantages inherent in pre-filtered sources include significant publication time lags, questionable research integrity, and the possibility of missing other relevant articles.

Some clinicians use pre-filtered, evidence-based medicine resources such as ACP Journal Club, Evidence-Based Medicine, and the Cochrane Library. This is a good way for clinicians to read quality materials, but it is not a comprehensive enough view of literature for researchers.

A second searching problem arises from the scatter principle of relevant articles. Core journals in a discipline consist of a small number of critical journals that publish most papers in a field. "High citation rates, impact factors, and circulation rates, and low manuscript acceptance rates and indexing on Brandon/Hill Library List appear to be predictive of higher methodological quality scores for journal articles."<sup>11</sup> The difficulty for the searcher is that although the best articles on a topic tend to be concentrated in a few strong journals, good articles are scattered among many different journals.

A third problem is the user's limited search skills. Because of the enormous size of these databases, searching requires a thorough knowledge of how the database is structured and articles are indexed. One must understand how to do field searching using subject headings (MeSH or Emtree), text word searching, exploding, subheadings, logical (Boolean) operators, and other limits such as dates, language, and publication types.

### What To Do

It is impossible for an interested individual to keep up with the amount of available information. Dong suggests that the practitioner or researcher should strive to manage information by developing three basic skills: finding potentially relevant information, filtering out the best from the much larger volume of less credible information, and judging whether to believe the information that remains. Most articles are not relevant or appropriate for making decisions because they may be scientifically weak, report laboratory research not yet ready for clinical application, or are only intended to share ideas without supplying data to support them. The challenge is to find the few pivotal articles among the much larger number of useful ones.<sup>12</sup>

One way to handle information overload is to rely on the services of an information professional. The role of the professional should be to create catalogs of resources, to subscribe to the best resources for their organization, and to provide advice for focused searching. It is not only the role of the information professional to identify and access all relevant information but also to protect users from information overload.<sup>13</sup>

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