

Provocative Dialogue. Insightful Education. Purposeful Collaboration.

PARTNERSHIPSTM

IN CLINICAL TRIALS

The largest gathering of CLINICAL OUTSOURCING and DEVELOPMENT EXECUTIVES in the world. An ALL NEW EXPERIENCE designed to embrace change and transform an industry.

EXECUTIVE SUMMARY

March 4-7, 2012 • Orlando, FL



www.clinicaltrialpartnerships.com

PARTNERSHIPS™

IN CLINICAL TRIALS

Dear Colleague,

Now that the 21st Annual Partnerships in Clinical Trials conference has concluded, we can appreciate how far we've come and how much we have to look forward to in 2013.

This year's event brought together a variety of thought leaders and top experts from the clinical trial sector who addressed transformative business models in the pharmaceutical industry and profound shifts in the outsourcing landscape.

The net is that these changes demand innovation, improved operational processes, new, more effective long-term strategies and more integrated, intuitive approaches for relationship building and partnering with CROs — and this year's event helped position our constituents for success on all fronts!

Each year we expand the scope of Partnerships to reflect the changing business and scientific environment in which we live. This year was particularly important because we made a number of exciting changes based on your input. Notably, we introduced:

- Six brand new summits — Virtual Clinical Trials, Innovative Patient Recruitment and Retention Strategies, Clinical Trials in China, Outsourcing Strategies for Small-Midsize Pharma and Biotech, Clinical Drug Safety, and Disruptive Drug Development
- Three new tracks focusing on the management of global trials, best practices for medical device trials, and future trends in clinical research
- A first-ever Women's Clinical Leadership Forum, and much more!

As a whole and individually, these summits, tracks, forums and sessions covered fresh topics, key challenges and emerging opportunities. And the response to the new and improved Partnerships in Clinical Trials has been phenomenal!

We would like to thank Emily Schaller, a special keynote speaker who lives with cystic fibrosis and who not only provided an insightful view of the clinical trial experience from a patient's perspective, but who also reminded and inspired us to implement more patient-centered approaches to trial management.

Thanks also to Dr. Peter Mueller, CSO & EVP, Global Research & Development of Vertex, who related how the drug development and partnership strategy of Kalydeco was implemented and enabled cystic fibrosis patients like Emily to finally have access to a treatment for the disease.

But while exceptional keynote speakers and practical case study content are an integral part of the Partnerships experience, it's the audience that makes this *the* event to attend each year.

We are proud and grateful to state without hesitation that Partnerships in Clinical Trials consistently draws the industry's best, brightest and most engaged professionals from sponsors and CROs alike. Collectively, our audience represents current and future clinical trial leaders.

Next year we meet back in Orlando for the 22nd Annual Partnerships in Clinical Trials, and we look forward to experiencing it with you.

Until then, on behalf of the Partnerships team, we are pleased to present this recap and overview of Partnerships in Clinical Trials 2012. Thank you to everyone who made this year such a memorable success!

All the best,



Danya Burakoff
Program Director
Partnerships in Clinical Trials
IIR



Megan Antonelli
Managing Director
Biopharmaceutical & Healthcare Division
IIR



FEEDBACK

“ This was my first ‘Partnerships’ conference and I enjoyed it. The cutting edge content – like Craig Lipset’s ‘virtual clinical trials’ presentation and Craig Venter’s talk – was terrific! ” – John Lamattina, Independent Consultant (Former President, Global R&D, Pfizer)

EVENT HIGHLIGHTS

FEEDBACK

“ The fact that post-market safety discussions were included in a Clinical Trial event is an indicator of the thought-leading and thought-provoking agenda that was offered. The event itself was one of the best in terms of the overall non-stressful nature of the networking events. I am extremely thankful to have participated in this conference and hope to be there again. ” – Daniel Jacob, MD, Medical Director, Global Pharmacovigilance, Baxter Healthcare Corporation



New Beginnings: Partnerships 2012 Reinvigorates, Restores & Resets



By Marc Dresner, Sr. Editor & Special Communications Lead, IIR USA

The Partnerships in Clinical Trials 2012 conference could perhaps best be summed in two words: new beginnings.

As my colleagues, Megan Antonelli and Danya Burakoff, noted in their opening letter, we made a number of significant additions and changes to this year’s program designed to inform, inspire and provoke in new ways.

But the real ‘new beginnings’ to which I refer relate much more to the industry as it moves forward with renewed confidence, clarity and direction in uncertain times.

Sponsors and CROs, alike, emerged from Partnerships 2012 with the tools, information and solutions to begin anew, reset strategy and navigate the seismic changes occurring across the industry.

For your convenience, we’ve consolidated highlights from the event into four thematic sections, including session summaries and exclusive one-on-one interviews conducted at the conference, as well as a special feature covering the hugely successful Women’s Clinical Leadership and invitation-only Disruptive Innovation Leaders’ Forums, respectively.

Lastly, we’ve added “value boxes” encapsulating the tangible deliverables the audience took away with them. Of course, you had to be there to get the goods, but this recap should provide some sense of the return one can expect from investing in the Partnerships in Clinical Trials experience...

The Collective Perspective — Wall Street • Private Equity • Investment Banking • CRO



VALUE BOX

Candid, clear, comprehensive... The audience received an insider's map to guide strategic planning based on sector trends and underlying drivers from industry analysts and the investment community.

Headline-making CRO consolidation is done; M&A activity will be limited to small specialty providers



Moderated by:
Ian Lauf
Global Sourcing Manager,
Medical & Clinical Trial
Central Services
Boehringer Ingelheim

This exceptional mix of financial perspectives specializing in the clinical research industry converged on the Partnerships stage for a powerhouse panel led by a sponsor-side moderator.

It happened in a packed ballroom, thick with anticipation and crackling with energy at a pivotal time in the industry's history when more than anything, people want reliable answers to burning questions.

With more than a decade in strategic sourcing, budgeting and contracting, and clinical trial finance experience at several sponsors, Lauf asked the tough questions and also added his own insight with regard to thoughts and concerns sponsors have when they see CRO purchasing movement.

The panelists delivered surprisingly frank answers. In fact, the group at points drew audible gasps from the crowd.

Above all, one point really set the room abuzz: Headline-making CRO consolidation is done; M&A activity moving forward will be limited to small specialty providers.

In aggregate, the panel offered a cautiously optimistic outlook for the clinical research industry.

PERSPECTIVES ON PARADE

Wall Street: Eric Coldwell,
Robert Baird & Co.



An incisive, relatively bullish take: Backlogs up, revenue projected up 10%. Still, volatility reigns. "It feels like we've been walking in an earthquake for the last four years."

Wall Street: David Windley,
Jeffries & Co.



Decades focused on the CRO sector, he assumed a skeptical posture compared to Coldwell. "The revenue looks positive... The shortcoming of the CRO industry's performance has been and remains profitability."

Private Equity: Jonathan Leff,
Warburg Pincus



In the hot seat via Lauf: "Why is PE so interested in the CRO industry?" A: "We're lemmings." It started with Quintiles, but persists because the industry has many of the attributes that attract PE investors, notably *stable* and *predictable* cash flow. (PE is betting on backlogs.)

Investment Banking: Michael
Martorelli, Fairmount Partners



An M&A specialist, the deal-maker notes: "Due diligence is more detailed, more extensive and more outsourced than ever. If it's a due diligence firm that may not specialize in the CRO sector, you could be at a disadvantage because these deals move fast and you need to be prepared to answer any questions buyers may have."

CRO: Jeffrey McMullen, CEO,
PharmaNet/i3



McMullen has piloted PharmaNet through a series of ownership models, going from private to public to private again via last year's acquisition by PE-backed InVentiv Health.

Key insight: "There are more similarities than differences between public and private ownership configurations. The differences have to do mostly with the timing, execution strategy and the reporting requirements," said McMullen.



Financial Panel Highlights

2012 will be another year of fits and starts for CROs, with revenue growth estimates ranging from flat to as much as 15% depending on the source.

The disparity between the current backlog build up (2012 est. up 15-20%) and performance shortfall has experts scratching their heads and waiting for the rubber to meet the road.

RFP values and volume appear on a slight upswing, but pharma R&D budgets look flat at best.

The percentage of R&D budgets dedicated to outsourcing in the past year increased approx. 9% to the high 30s and is likely to climb at least into the low 40s in 2012.

CRO industry profitability remains depressed, due in part to headcount increases, and IT and facility investments based on anticipated project volume that hasn't yet materialized.

Bigger = Better. Private equity interest in CROs will likely continue based on perceived market share stability and opportunities for margin growth among the leading CROs. (Note: PE may look to combine smaller specialist players into new entities to compete with top five CROs.)



CRO Dollars & Financial Sense

Over 100 industry stakeholders tuned in to a webinar hosted earlier in the year by Partnerships in Clinical Trials featuring **Ian Lauf** and **Garen Sarafian**, Vice President, Healthcare Technology & Distribution for Citigroup Investment.

Interactive would be an understatement; the audience logged more than 60 questions in an hour!



What's keeping the industry up at night?

(Verbatim from the chat log)

- Pharma expects a lot from CROs, but doesn't always seem prepared to pay for it. How do we move the industry away from focusing on the bottom line price during negotiations and toward outsourcing cost effectiveness and added value?
- Why have backlog burn rates been so slow? If it's because of more backlog from strategic deals, why are these so slow to convert to revenue? Is there some tipping point where this burn rate will suddenly improve?
- You mentioned that "you can't survive as a regional CRO," yet only \$6bn of the \$14bn currently outsourced is covered by the top tier CROs! Please explain.
- There may be more revenue opportunity based upon the increasing complexity of clinical trials; however, my experience is that margins have decreased 10-15% in the past 15 years.
- We've seen point-of-care diagnostics applied during a recent trial. Do you see the application of this technology being used in the future for clinical trial testing?
- You will see monitoring decreasing over the next three years with the new FDA guidance on risk-based monitoring, with significant impact for CROs.



Audience Poll: Industry Disagrees with Wall Street?

Our finance panelists agreed pre-clinical and early stage R&D investment is out, but look at what sponsors and CROs polled in our webinar had to say:

R&D activity in the next 12-18 months?

Pre-Clinical Lead ID/Optimization

34% said increase
4% said decrease

Phase 1 Clinical

72% said increase
8% said decrease

Phase 2 Clinical

74% said increase
14% said decrease



Macro Trends Mostly Bode Well for CROs

- + End markets going through structural change, creating opportunities for CROs
- + Client demands favor larger CROs disproportionately
- + Nature of drug trials becoming more complex, increasing CROs' revenue potential
- + Proprietary Citi Survey & ongoing checks suggest R&D spend to increase, pricing stable
- R&D trial growth remains uncertain based on analysis of NIH data

Source: Garen Sarafian, Citigroup Investment

II. Partnering Changes Innovation Equation

Game-Changer: Innovation a “Team Sport”



VALUE BOX

The audience was armed with concrete direction and a practical blueprint for executing innovation.

Most companies do not have the capacity to focus on more than four products if they want to be innovation leaders



Professor, Fortune 500 consultant and author of the game-changing text, “The Game-Changer,”

Ram Charan captivated the crowd with his Rx for innovation success.

He took to the floor, weaving his way through the enthusiastic audience and occasionally punctuating points old school style with the aid of an overhead projector. (Ironically, the innovation expert isn't a PowerPoint fan.)

Charan stressed that focus is critical to innovation, and said most companies do not have the capacity to concentrate on more than four products if they want to be innovation leaders.

At first blush, this assertion appeared at odds with the direction the pharmaceutical industry is taking. I.e., the shift from the \$14 billion single blockbuster to a portfolio of \$400 million specialty drugs tailored to smaller patient populations.

But upon further consideration, Charan's advice and the industry's trajectory are not incompatible in the least. In fact, companies moving into personalized medicine tend to be highly focused on a specific therapeutic area.

Charan's Rx for Innovation Success

- Small teams are more effective, and diversity of perspective and expertise are key.
- Forget consensus. Understanding and capitalizing upon the variety of assets and viewpoints the CRO and sponsor bring to the table, respectively, is as important from an innovation standpoint as cultural compatibility is to successful partnering.
- To make partnerships work, there needs to be an “integrator” — a mediating role that can bring the right mix of disciplines together synergistically. Organizations need to invest in developing formal training programs for this role and in finding the right people to fill it. ➤

ASK THE EXPERTS INTERVIEW



Guest:
Donna Jarlenski
Senior Director, Clinical Development Operations
Momenta Pharmaceuticals

Innovation Imperatives, Orphan Drugs and Oncology

Q What can we learn from current activity in orphan drugs and personalized medicine with regard to drug development and clinical research in the future?

The strategies and tactics necessary to develop orphan drugs are emblematic of the direction in which the drug development industry is moving because the cost of new drug development is becoming decreasingly sustainable. Also, the shift to personalized medicine as more is learned about disease processes at the genetic level will cause drug development to target smaller, more exclusive patient populations.

Additionally, the importance of biomarker development and need for increased precision in adaptive trial design are no longer nice-to-haves. Increasingly specific ways to ethically and directly target potential patient populations are becoming mandatory and techniques to assess costs of goods are developing in specificity.


“The importance of biomarker development and need for increased precision in adaptive trial design are no longer nice-to-haves”

continued on page 7 >

Panel Explores the Expanding and Blurring Role of CRO, R&D

A subsequent panel of top execs from Abbott, TEVA, PPD and RPS led by Charan caught the audience by surprise when the conversation took a provocative turn...

Scientific progress of all stripes is increasingly falling to smart CROs who can innovate more effectively, less expensively and faster, leaving traditional sponsors — who often have to fight internally to greenlight research — to focus on successfully getting the product to market at the right price point for reimbursement.

 **BOTTOM LINE:** Ability to bring scientific (i.e., R&D) innovation and solutions to the table will likely be a key CRO differentiator in an increasingly commoditized market dominated by Big Five players offering almost indistinguishable capabilities. ➤

PERSPECTIVES ON PARADE



Bill Sharbaugh, COO, PPD: Traditional sponsor-CRO roles have blurred, and in cases are reversing as Big Pharma increasingly outsources R&D. (Example: PPD has a group in its lab services business that is testing a variety of technologies related to discovery of monoclonal antibodies and shopping the technology to potential pharma clients.)



Meryl Wiernik, Senior Director of Strategic Outsourcing, TEVA: The generics giant is moving toward a fully outsourced model on multiple fronts, so role reversal is serious business because TEVA's project managers must now be retrained to manage external partners — an entirely different skill set.



Rene Sluijter, Global Outsourcing Head, Abbott Labs: Observed that the difficulty of the integration aspect of partnering is exacerbated by the fact that sponsors, themselves, tend to be highly siloed — structurally and culturally.



Dan Perlman, Chairman & CEO, RPS: The pharmaceutical industry has been financially fat and happy for too long. As a result, until recently, there wasn't any pressure to innovate. Sponsors, he said, aren't accustomed to scrutinizing potential partners to the extent required and to avoid duplication or waste, while CROs are trying to adapt to an emerging outsourcing model that requires them to bring additional value to the table under difficult economic circumstances. ➤

◀ Jarlenski interview, continued from page 6

Q How has/will the partnering landscape change as a result?

Recently, some of the largest pharmas have published sweeping organizational changes empowering smaller groups to become their own development organizations while maintaining shared resources with partners in an attempt to meet some of these challenges. According to some sources, niche provider organizations have increased 60% over the last eight years. The traditional CRO industry is also offering more compartmentalized, stand-alone services and partnering with niche providers with increase alacrity.

Q Can you point to a specific therapeutic area that organizations should consider, directionally, as they think about drug development in light of the shifts taking place?

Oncology drug development has led the way in personalized medicine, due in large part to breakthroughs in understanding the mechanism of cancers. This arena seems an appropriate model to study as the drug development process shifts.

Q What steps should CROs and other providers take to better accommodate sponsors?

CRO and other niche providers must have more highly skilled technical resources to partner with sponsors. Collaborations between multiple sources of funding — private, academic, corporate partnerships — are increasingly necessary. Also, this field has led the way in consolidated and systematic data collection techniques and processes, making it able to compare the utility and side effects of drugs across a class or a patient population. Adaptive study design is perhaps the best developed in this research and the need for skilled medical judgment at the level of the investigational site is the most acute in this area. ➤

ASK THE EXPERTS INTERVIEW

“Oncology drug development has led the way in personalized medicine, due in large part to breakthroughs in understanding the mechanism of cancers. This arena seems an appropriate model to study as the drug development process shifts”

III. Sponsor/CRO Relationships Messy But Promising

Survey Says Strategic Partnerships Work Despite Fail Rate



VALUE BOX

The audience received the latest intelligence on the state of strategic partnering from both sponsor and CRO perspectives, what's working and where improvement opportunities lie that may be used to inform partnering strategies moving forward.

AVOCA Group's 2012 survey showed an alarmingly high strategic partnership fail rate, primarily due to perceived quality/performance shortfalls



Patricia Leuchten
President and Founder
The Avoca Group

In a special session, Partnerships in Clinical Trials attendees were the first to access new 2012 data from an annual survey by The AVOCA Group, a research and consulting firm specializing in sponsor/CRO relationship management.

While satisfaction with strategic partnerships among both sponsors and CROs runs reasonably high, the picture isn't as pretty as one might expect.

In fact, members of the audience were shocked when AVOCA reported an alarmingly high fail rate in industry strategic partnerships, primarily due to perceived quality/performance shortfalls. (see below)

The results raised questions and eyebrows, and reinforced the urgent need for standardized quality management best practices and metrics for monitoring them.

The good news, according to AVOCA Group CEO Patty Leuchten, is that the concept of strategic alliances is sound, and her firm's research indicates that relationships improve over time.

"The challenge is not in intention; it's in implementation," said Leuchten. "Those partnerships that succeed set up clear expectations and have a good handle on governance from the outset."

Leuchten also noted that risk-sharing, process alignment and bringing CRO partners in early and establishing consultative relationships with them are critical, but frequently overlooked factors for success. ➤

AVOCA Group 2012 Survey Highlights

- More than 22% of pharmaceutical industry clinical outsourcing executives surveyed have discontinued a strategic partnership with a CRO; 88% cited poor quality/performance issues as the reason for the break-up.
- Satisfaction with existing strategic partnerships runs high, although interestingly sponsors (63%) issued significantly higher scores than did CROs (54%) on their collaborations overall.
- Clearly, some partnerships are set up for success from the start. Among those in place for >3 years, sponsors reported it took about one year for the relationship to begin to bear fruit on key goals!
 - **Reduced costs:** A little more than half of the respondents achieved cost savings in one year or less; however, *almost a quarter of the respondents reported never achieving cost savings.*
 - **Improved quality:** 54% of respondents indicated improved quality within one year; however, *21% reported never achieving improved quality.*
 - **Improved efficiency:** Less than half the respondents felt that efficiency and the reduction in effort for oversight was achieved within one year; *28% said it was never achieved.*
 - **Operational expertise:** 75% of respondents reported receiving the expected operational expertise within one year; *only 8% said that this was never achieved.*
 - **Process improvement:** Only 36% saw process improvement within one year; however, 40% reported that their expectations with respect to process improvement were met between one and two years. *Almost one quarter reported that their expectations in this area were never met.* ➤

Technological Tricks to Shrink Timelines, Improve Quality



VALUE BOX

The audience learned specifically how appropriate selection and integration of clinical development technologies can improve quality and shrink timelines by 10-15% (i.e., about 30-60 days on an average two-year trial).

Speakers:



Johann Proeve
Head of Global Data Management
Bayer



Nagaraja Srivatsan
SVP
Cognizant

A standout in the Partnerships in Clinical Trials **eClinical Technology & Data Management** track, Dr. Johann Proeve and Nagaraja Srivatsan contemporized the streamlining of clinical development via technology.



BOTTOM LINE: Faster protocol development, good site selection and site training can accelerate FPFV by 10-15%. Reporting & Analysis and CSR can be achieved 5-10% faster post DB Lock by adoption of standards, integrated edit checks for CDM and Biostats, and early availability of patient data for testing of TLGs and CSR prior to DB Lock.

The session featured an overview of the clinical development process from protocol development to reporting and analysis and the factors in between that influence and frequently impede timelines, followed by a solution scheme for each respective step in the process covering the challenge, prescribed “intervention” and potential impact.

Proeve homed in on EDC and xEDC checks and reviewed emerging best practices based on data available (see below) and offered a detailed description and analysis of several complex programs to improve data quality:

1. Local lab data conversion to conventional common units
2. SAEs not reported as such (IME list)
3. Potential DILI (drug induced liver injury) case identification ➤

Data Available to Improve Study Quality

- Coded data
- Audit trail data in EDC
 - Site performance
 - Monitor performance
 - Data management performance
- Comparisons of data across sites
- Comparisons of data across countries

Points of Interest: Data Integration, Governance & Triage

- Align CDM and KPIs to suit business objectives
- Focus on underlying information structure (source it, report it, view it)
- We have all the tools available but more integration is more important ➤

ASK THE EXPERTS INTERVIEW

Managing Quality



Guest:
Jorge Guerra
SVP, Global Clinical Operations
Biogen Idec

Q Like many other sponsors in the industry, Biogen Idec has become increasingly focused on quality management. Why?

Compliance...We need to develop a proactive approach to monitoring, especially as we expand globally. We cannot continue to build quality through inspection.

Q What does quality management entail from your perspective?

It starts with protocols, avoiding amendments, getting it right the first time — minimizing variability and probability of errors — and then standardizing how we work with sites across therapeutic areas. Reporting is also key.

Q How much progress have you made toward achieving your partnering goals with regard to quality?

We're relatively early in the process, just getting started. We have a risk management methodology in place and we just rolled out a new clinical trial management system. We're also looking closely at EDC.

IV. Partnering With Patients (Centricity Revised)

Can A Crowd of Patients Outperform the Smartest KOL?



VALUE BOX



James Surowiecki offered a compelling argument and examples of how collective intelligence

(i.e., crowdsourcing) may be leveraged in a clinical trial context to improve the patient experience and research results.

Your top KOL may not necessarily provide the best opinion in the room, depending on whether or not the room is crowded with patients...

New Yorker columnist **James Surowiecki**, author of the seminal text “The Wisdom of Crowds” and one of the original architects behind the crowdsourcing movement suggested that there may be a potentially less expensive, but equally if not more insightful solution to relying exclusively on KOLs — with the added benefit of engaging the patient population!

“Under the ‘right’ conditions, groups of people can be remarkably intelligent — often smarter than the smartest person in the group,” said Surowiecki.

“When you think about drug development, if you can figure out ways to tap into the collective knowledge of employees, partners and patients, you can dramatically improve your ability to make decisions, solve problems and — this is especially important to the pharma industry today — even do a better job of forecasting the future,” Surowiecki told the mesmerized crowd.

Eli Lilly used prediction markets to forecast clinical trial outcomes; the market did an exceptional job of separating successful candidates from failures and did so remarkably quickly

Surowiecki followed with a flurry of examples of wise crowds in action, illustrating that as the problems become more complex, collective intelligence becomes, if anything, more impressive. ➤

Tapping Into the Wisdom of Your Crowd: Three Key Conditions

1 Find a way to aggregate lots of pieces of knowledge to produce an uninhibited, collective judgment — not a suggestion box

➤ Big organizations, bureaucracies and hierarchies are designed to facilitate the flow of information, but the top-down model upon which they’re built inherently sets up obstacles to getting information from where it lives to the decision makers who need it due to silos, hoarding and fear of telling the unpleasant truth.

2 Cognitive Diversity — the more the better, not to be confused with conventional HR diversity models (although the two are not mutually exclusive); it’s fundamental to problem-solving because it expands the range of information and insight available

➤ The collective intelligence of a group increases proportionate to the randomness of IQ/expertise/background/perspective in the mix; what outsiders bring is different — they use different heuristics, frame problems differently... This is why participatory medicine shows such promise. It’s important to integrate patient perspectives because they’re highly likely to be different from those found in the organizations with which they interact and whose stated purpose is to serve them. Surowiecki: “The more homogeneous groups talk to each other the dumber they become.”

3 Encourage independent thinking

➤ Easier in theory than practice because human beings by nature tend to imitate. We like to work with people who we think are like us and who agree with us, but the best group decisions do not emerge by consensus; they emerge out of healthy conflict. If you really want to innovate, you need people who are ready and willing to respectfully argue with one another, to “fight the good fight.” “When you build a team, recognize that dissenting is not the same as dissention,” said Surowiecki. ➤

“The more homogeneous groups talk to each other the dumber they become”

FEEDBACK

““ This was a great event for sharing innovative ideas, meeting people across the industry and building new relationships. A well-organized and informative meeting with high-quality speakers. ””

– Miguel Orri, Senior Director, Clinical Sciences, Pfizer

Pfizer on the Virtual Verge of Patient Centricity



VALUE BOX

A detailed update on Pfizer's two-year-old "REMOTE" initiative to move clinical trials into the virtual realm included frank commentary on the pilot's highly publicized recruitment setback. But more importantly, the audience walked away with an indisputable benchmark for state-of-the-art in clinical trials.

"It didn't work," **Pfizer Senior Director of Clinical Sciences Miguel Orri** said in reference to the patient recruitment shortfall that delayed deployment of a highly anticipated industry first — a virtual clinical trial.

Orri acknowledged the implicit irony of the setback: A controversial approach to conducting clinical trials designed to make the experience more patient friendly gets a green light from regulators and a raspberry

from patients because, according to Orri, the project team paid too much attention to regulatory considerations and failed to fully understand and appreciate the patient's point of view.

Editor's note: Pfizer has since reportedly taken steps to revise the model by soliciting patient feedback, and expects to quickly exceed original recruit goals in the U.S. and move forward with a European iteration. ➤

Pfizer's "REMOTE": The New Patient Centricity Model

Dubbed "REMOTE" (Research on Electronic Monitoring of OAB Treatment Experience), the IND pilot for Pfizer's overactive bladder extended release treatment breaks ground by using a combination of smartphone, desktop Web and call centers to collect clinical data without requiring trial subjects to visit terrestrial clinical sites.

Theoretical advantages:

- Overcome long-standing recruitment and retention issues by eliminating barriers to access (i.e., patient proximity to facilities), thereby broadening the potential participant pool
- Improve retention and compliance by making it easier for patients to participate (no travel required — flexibility/convenience/no appointment necessary); and medicines are promptly delivered to the home, potentially decreasing withdrawal incidence and associated complications
- Cut costs and cycle times (faster, more efficient and less labor-intensive data collection modality)
- Transparency and support: Participants access a private, Web-based community of trial peers and administrators

Potential hurdles:

- **Limited application:** Sources estimate the virtual model in its current state may be effectively applied to roughly 20% of trials today — nothing to sneeze at, but obviously not a silver bullet. To wit: The at-home model implicitly excludes certain injectibles and delivery technologies that require professional administration, special storage conditions, etc.
- **The human vs. technology factor:** Trust and comfort are critical to recruitment and retention. Reliance primarily on a technological interface may inhibit participation among certain demographics and populations (indeed, Pfizer's recruitment shortfall confirmed this to be the case)
 - **Solution:** Pfizer is exploring "flying" investigators — a subset of traditional site investigators specialty trained to visit patients in the home (Orri noted that this program could be extremely effective if costs could be reimbursed by payers)
 - **Solution:** The REMOTE approach may prove most effective when applied in under-developed markets where infrastructure favors cellular technology over access to physical sites and for diseases that tend to concentrate around younger populations who are presumably more comfortable with and proficient using technology



Technovelties Come of Age



VALUE BOX

Technologies that have been considered highly experimental for years are now being quite successfully deployed among select populations. ROI for those who attended included an in-depth look at emerging competitive-edge techniques and access to the individuals leading the charge.

Time is a funny thing. Last year, people were curious about mobile apps, QR codes were an oddity, and both were ruled out when it came to clinical recruitment and research. Consensus was that targets hadn't a clue about how these technologies work and had no interest in them; this stuff didn't apply.

A series of case studies and real world applications in action enthralled — and sometimes jarred — the **Patient Recruitment & Retention Summit** audience. People in their 50s and

60s — let alone 30s and 40s, rural and urban alike — are more savvy than their cohorts designing trial protocols suspected. And incidences of chronic conditions like diabetes that were historically most common among middle-aged adults and seniors are dramatically increasing in younger populations.

Little wonder then that the most popular sessions in this year's Patient Recruitment & Retention track focused on technovelties like mobile apps and QR codes. ➤

Technology for Patient Recruitment and Retention: Pros & Cons



Contributor:
Nariman Nassar, Director,
UCSF Participant
Recruitment Service



Text Messaging

- Many patients prefer to inquire via text message. When presented with a phone number to call, or a text message option, 65-70% will inquire via text message
 - Patients are highly engaged via text message
 - 90+% response rate is common for each screening question received by the respondent
 - Abandonment rate is quite low, including screeners with nine questions
 - Previous deployments have generated significant ROI
 - A recent study ran patient recruitment advertising for three months without text messaging, and then for three months with text messaging
- Results:
- :: Cost per Response decreased 15%
 - :: Cost per Referral decreased 32%
 - :: ROI calculated at >650%



Mobile Apps

- **Limited Reach** — Downloaded software apps are limited to smartphones, which are used by only 36% of mobile subscribers in the US, and 14% of mobile subscribers around the world
- **Expensive** — To reach the full smartphone audience, the software app needs to support all major smartphone platforms: iOS, Android, Windows, RIM, Nokia. This creates a significant cost multiplier for development and maintenance of the app
- **Highly Inefficient as a Direct Response Option** — For study promotional materials driving potential patients to an app, there are too many steps required:
 1. Go to your phone's app store
 2. Find our app
 3. Download it
 4. Figure out where the app is on your phone
 5. Click on the app to learn more about this study



QR Codes

- Inexpensive
- Only work for smartphone users
- Relatively few have incorporated QR scanning into behavior
- Execution is tricky
 - You can't remember a QR code and 'text' it later
 - Challenging for outdoor advertising

FEEDBACK

“ I was impressed by the ‘Disruptive Drug Development Forum’ — the participants were extremely open with respect to their position and the issues we encounter in the industry. ”

– Johann Proeve, Head of Global Data Management, Bayer HealthCare

Exclusive Leadership Forums



1st Annual Women's Clinical Leadership Forum Sets Execs For Success!



By all accounts, the 1st Annual **Women's Clinical Leadership Forum** on March 4 was a huge hit!

As its name suggests, this unique professional development program was open exclusively to women specializing in clinical trial outsourcing

"The Women's Clinical Leadership Forum was an opportunity to learn and to teach, to synthesize our collective experience and intellectual capital, and to produce concrete, practical takeaways" - Shantal Feltham, Stiris Research

and operations for the pharmaceutical, biotech and medical device industries and their CRO partners.

The Forum focused on business success strategies, and the caliber of speakers, information, experience and expertise shared made it a high point of the conference according to those who attended.

In addition to a prestigious list of top exes from biopharma and CROs, the Forum featured **Moira Forbes**, President of ForbesWoman — a recognized authority on women's business and leadership issues — and FDA Assistant Commissioner for Women's Health **Marsha Henderson**, whose office co-sponsored the Forum.

"The Women's Clinical Leadership Forum was an opportunity to learn and to teach, to synthesize our collective experience and intellectual capital, and to produce concrete, practical takeaways that will enable all of us — regardless of what stage you're at in your career path — to do business

better," said Stiris Research President and CEO **Shantal Feltham**.

While the Forum wasn't about gender politics in business, there were certainly inspiring stories shared and advice dispensed that uniquely applied to women executives.

"Women tend to be reluctant to accept credit for — let alone publicize — their accomplishments as individuals," said Millennium Pharmaceuticals Senior Director of Clinical Outsourcing **Francis Grote**.

"We often frame success in terms of 'we' and teams, and while this is an admirable and often very effective trait, it also does a disservice because in business you need to be able to promote yourself if you want to succeed. Men don't generally have an issue with it; women do," Grote said.

"As leaders, we need to do a better job of demonstrating behaviors that junior executives — women and men — can model for success." ➤

Disruptive Development Dominates Clinical Leaders' Forum

Editor's note: By invitation only, this exclusive group of senior clinical decision makers and R&D leadership met to tackle key challenges facing clinical development and R&D.



Contributor:
Dr. Mitchell Katz
Executive Director, Medical Research Operations
Purdue Pharma

Key themes:

- 1 Assessing the Impact of Massive Industry Consolidation
- 2 The Increasing Globalization of Clinical Trials/Drug Development
- 3 The New Reimbursement Paradigm and Its Impact on the Clinical Trials Program
- 4 Industry Changes Required to Maintain Long Term Viability

Takeaways

■ Organizations must change the way they conduct Clinical Development. We cannot continue to do things the way we always have. Internal organizations must be more flexible and adapt to continuous change. Changing internal culture is key!

■ The regulatory landscape is getting more challenging to navigate as there are more requirements to conduct trials globally, so developing close working relationships with regulators in each respective country is critical.

■ Global competition for qualified Principal Investigators, patients and vendors is intense.

■ CROs/Vendors are an extension of our internal development teams. We must develop a different type of relationship based on trust, collaboration and expertise. We must balance the level of oversight and not micro-manage.

■ There is a bigger commitment from many organizations to license out research and development because internal investment requirements have increased significantly and budgets have decreased significantly. This is partly because success rates are down.

One of the more defining, ah-ha moments occurred when we all realized that in order for the industry to get back on track, we — the collective we — needed to work together to make a difference, with one voice to influence regulators. An example that I gave was the quality consortium in which many pharma companies are participating to create quality management standards. Ultimately the goal is to leverage best practices from all of our companies to develop one industry-wide set of quality standards and metrics to present to the FDA. ➤

Partnerships in Clinical Trials Awards & Community

The 2nd Annual Partnerships in Clinical Trials Awards were presented in a special ceremony on Tuesday, March 6. Congratulations to all of our winners!



Biopharmaceutical Leadership: This award honors an executive member from a biotech or pharmaceutical company who has excelled in leadership of a company initiative in 2011 -2012.
Winner: **Deidre BeVard**, Vice President, Development Operations, **Endo Pharmaceuticals**



Clinical Trial Innovation: This award honors a person who has embraced trial innovation, applied innovative tools or techniques for clinical trial strategy, and/or implemented novel partnering strategies to improve trials and fast forward projects from candidate drug to marketed product.
Winner: **Craig Lipset**, Head of Clinical Innovation, **Pfizer, Inc.**



Novel Application of Technology for Clinical Trials: Technology has the power to improve the way the world works and lives. This award recognizes a person and/or company for their innovative vision and use of technology to improve clinical trials.
Winner: **Peter S. Benton**, Executive Vice President, eClinical Solutions, **Bioclinica**

Clinical Trial Business Women of the Year: This award recognizes a woman who has exemplified strong & innovative leadership and has set an example to other women in the clinical trials industry on a global scale.
Winner: **Gena Reed**, CEO, **Paragon Biomedical**

Special Recognition: Winners: **Jae Chung**, Founder & CEO, **goBalto** and **Covance, Inc.**



This year, Partnerships in Clinical Trials' special networking platform, **myPartnerships**, enrolled 1326 members and facilitated nearly 100 private meetings between attendees!

Trial sponsors increased 15%!

More than 1500 clinical operations and outsourcing executives attended PCT 2012!

BY INDUSTRY



- **55%** Pharmaceutical, Biotech and Medical Device
- **40%** CROs and Other Service Providers
- **5%** Sites

BY FUNCTION



- **24%** Strategic Sourcing
- **24%** Clinical Operations
- **12%** Clinical Research
- **35%** Business Development/Sales/Marketing
- **5%** Principal Investigator or Medical Director

BY SENIORITY



- **35%** Director
- **35%** Vice President & Senior Vice President
- **15%** C-level
- **15%** Manager

BY COUNTRY

USA	Denmark
Belgium	Sweden
Mexico	Norway
Germany	Israel
United Kingdom	Jordan
France	Argentina
China	Switzerland
Canada	Latvia
Japan	Colombia
Netherlands	Portugal
Singapore	India
Malaysia	Italy
Australia	South Africa
Brazil	Czech Republic
Russian Fed.	Taiwan
Ireland	

Sponsors & Exhibitors

Partnerships in Clinical Trials 2012 sponsors and exhibitors increased 9% over the year prior — a promising indicator of the industry's health. Of total sponsors and exhibitors, 35% were new and 13% were international companies, suggesting the clinical trial industry continues to enjoy robust growth. We're delighted that they chose to invest their marketing resources in Partnerships in Clinical Trials 2012!

MARQUEE SPONSOR



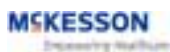
PLATINUM SPONSORS



GOLD SPONSOR



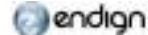
ASSOCIATE SPONSORS



SUPPORTING SPONSORS



EXHIBITORS



continued on page 16 >

Sponsors & Exhibitors

EXHIBITORS



FORTITUDE CLINICAL



Harrison Clinical Research
Harrison



FEEDBACK

“ Partnerships in Clinical Trials is an excellent opportunity to get a lot of business done in a small window. It was great to have all the vendors in one place — current and potential partners. I met people who already work with my company for the first time in person and reconnected with peers. ”

- Mark Travers, Vice President, Global Head of CSU and CSU Networks, Sanofi



Upcoming Content & Ongoing Connections

Although the Partnerships in Clinical Trials 2012 U.S. conference is over, our job has just begun. The Partnerships in Clinical Trials team is committed to keeping the clinical research community smart and up to speed throughout the year...

Stay tuned for Partnerships TV 2012! This streaming video series features in-depth interviews and presentations from experts and leaders at the forefront of clinical trials and drug development. Visit <http://bit.ly/PCTKnowledgeVault>



About the Host/Interviewer

Marc Dresner is IIR USA's sr. editor and special communication projects lead. He is the former executive editor of *Pharma Market Research Report*, a confidential newsletter for market research professionals specializing in the pharmaceutical, biotech and healthcare industries. He may be reached at mdresner@iirusa.com. Follow him @mdrezz

Partnerships TV 2012

- ▶ Bernard Munoz, Chief Apostle, Breakthrough Innovation, InnoThink Center for Research in Biomedical Innovation (former Corporate Strategy Advisor, Eli Lilly)
TOPIC: Tackling the Innovation Crisis
- ▶ Susan Gould, Sr. Director Clinical and Medical Affairs, Baxter Healthcare
TOPIC: Medical Devices: Unmet Needs and Opportunities in Clinical Trials
- ▶ Jorge Guerra, SVP, Global Clinical Operations, Biogen Idec
TOPIC: Managing Quality and Risk in Partnerships
- ▶ James Garner, VP, General Mgr, Global R&D Center (Asia), Takeda
TOPIC: Asia: Unpeeling the Clinical Trials Onion
- ▶ Rehbar Tayyabkhan, Executive Director, Global Clinical Development, Bristol-Myers Squibb
TOPIC: Sponsor-CRO Relations: The New Model
- ▶ Mark Travers, VP, Global Head of CSU and CSU Networks, Sanofi
TOPIC: Transactional vs. Strategic Partnerships: Pros, Cons, Perils and Pitfalls
- ▶ Donna Jarlenski, Senior Director, Clinical Development Operations, Momenta Pharmaceuticals
TOPIC: Clinical Trials and Drug Development Models: Orphan Drugs & Oncology

Get connected to
Your Partnerships
Community TODAY!



@PartnershipCROs



Partnerships with CROs Group



www.clinicaltrialpartnershipsblog.com



Partnerships in Clinical Trials Fan Page

SAVE THE DATE

23rd Annual **PARTNERSHIPS**TM

IN CLINICAL TRIALS

April 22-24, 2013 • Orlando World Center Marriott • Orlando, FL

www.clinicaltrialpartnerships.com

CONTACTS

Speaking Opportunities

Danya Burakoff

Program Director

T: +1.646.895.7337

E: dburakoff@iirusa.com

Marketing/Media Partnerships

Allison Rigels Nilsen

Sr. Marketing Manager

T: +1.646.895.7327

E: arigels@iirusa.com

Sponsorship Sales Opportunities

Andrew Sinetar

Manager Global Sales Strategy

T: +1.646.895.7484

E: asinetar@iirusa.com

Exhibition Opportunities & Exhibit Hall Sessions

Richard Dexter

Exhibit Sales Representative

T: +1.646.895.7452

E: rdexter@iirusa.com

PARTNERSHIPS INTERNATIONAL



4th Annual

Partnerships in Clinical Trials Asia

September 12-14, 2012

Shanghai, China

www.clinicalpartnershipsasia.com



3rd Annual

Partnerships in Clinical Trials Latin America

August 13-15, 2012

American Chamber Sao Paulo, Brazil

www.pctla.com



15th Annual

Partnerships in Clinical Trials Europe

November 2012 • Hamburg, Germany

www.ct-partnerships.com



Premier

Partnerships in Clinical Trials Northern Africa & the Middle East

TBD



Premier

Partnerships in Clinical Trials Eastern Europe

TBD

