What is disruptive innovation?
Disruptive innovation is about making products less expensive and more attainable by challenging the status quo with new ideas to quicken the pace of change. Most people credit Harvard Business School Professor Clayton Christensen with outlining the theory behind disruptive innovations.

In general, what is a good example of disruptive innovation?
Netflix

Why is disruptive innovation important to the clinical trial space?
Disruptive innovation is so important because it has the power to make drug development far less expensive so therapeutics can be more attainable.

(cont’d)
(The Buzz CONT’D)

How would you describe the DPharm conference?
DPharm is the definitive event for innovators in the clinical trial space. The entire conference introduces novel and bold approaches to help attendees think radically different about how we do clinical trials.

What do you see as some of the highlights for the 3rd annual event?
We have so many highlights, but to name a few, I am particularly excited about the opening presentation on designing a non-traditional clinical trial, followed by a case study on alternative clinical settings. We look forward to welcoming Dr Krishna Yeshwant from Google Ventures to give his perspective as a physician, programmer and entrepreneur on new approaches to disrupt drug development. Brand new to the program is a collaboration with MIT where they share the results of a Hackathon on barriers to clinical trials. We also have special guests from both Bloomberg Business Week and the Discovery Channel.

Who would you recommend attend the DPharm event?
The DPharm event is for anyone interested in innovative approaches to changing the pace of clinical trials. The event tends to draw a very senior-level crowd, but we know innovation can come from all levels of an organization.

A Look Ahead to the 2013 Highlights

How Not to Do a Traditional Clinical Trial with Genzyme

Innovation in Alternative Clinical Settings with Novartis & Walgreens

Disruptive Thinkers Interview Series with MedImmune, VA Boston Healthcare, Center for Connected Health, & Pfizer

The 2nd Annual Quick Fire Disruptive Technology Presentations in an “American Idol” Format

MIT Hackathon Results to Barriers in Clinical Trials

The Mobile Banking Revolution in Africa: What Can Drug Developers Learn from this Extraordinary Example of Disruption?

For more information and to register for the September 19-20, 2013 event, visit www.theconferenceforum.org. Use code DNEWS for 10% off.
Industry Views On Disruptive Innovation in Clinical Development
by Valerie Bowling, Executive Director, DPharm

Disruptive innovation is not a breakthrough innovation that makes good products better, but rather a specific type of innovation that is intended to make products more affordable and accessible. Disruptive innovation is not based on past data and reports (historical perspective), but something that can give us a way of looking at how to meet future needs with fresh thinking. I asked three R&D leaders: Dr Andreas Koester, VP, Clinical Trial Innovation & External Alliances; Janssen Pharmaceuticals, Dr Andrew Lee, SVP, Global Clinical Operations, Genzyme; and Dr John Orloff, SVP, Global Development & CMO, Novartis Pharma AG, to share their perspectives on disruptive innovation from within large pharmaceutical companies.

What is disruptive innovations and who should be responsible for it?

Dr Koester: Disruptive innovation is transformational. It is a game-changer: something that no one else has conceived or attempted, possibly a novel application (of a concept, process or system) from another industry. However, it must provoke discomfort and anxiety among stakeholders or it is simply incremental. Responsibility rests with anyone who has dissatisfaction with the status quo; it can be stakeholders, process owners and executers, and especially the customers.

Do disruptive innovations have to be big (a major change in the landscape) to have an impact on the advancement of clinical development?

Dr Koester: They need to be big, or novel, or they must change the very nature of how we do clinical development.

Who is responsible for coming up with disruptive ideas?

Dr Koester: Disruptive innovation, or any innovation, should come from all colleagues within a company. However, there should be no limits and no barriers that restrict disruptive innovation within a company. Some of the best ideas come from outside companies not necessarily in one’s own area of work. Sanofi R&D is encouraging "open innovation" through external collaborations with many groups (academic, technology etc). It is fun to work in such an open way. In my organization (Clinical Sciences and Operations) we have an innovation group and several innovation forums. We use "crowd sourcing" and social media tools to allow colleagues at all levels to put forward innovative ideas for consideration. Good ideas get supported through colleague endorsement (voting). The best ideas get brought to a governing group who look to enable the innovative ideas (resources, money, projects to use as pilots). The innovation group then manages the project conduct and deliverables. Colleagues feel their ideas are heard and they will get support if the innovation garners peer-level and management support. External innovations can also be brought in through the crowd-sourcing and social media (yammer) for evaluation.
How can R&D executives start thinking about disruption? What are some of the questions to ask?

**Dr Lee:** R&D executives are under immense pressure to improve R&D productivity. This has become a key issue as costs soar, the regulatory environment is increasingly more stringent and all of the easy disease targets have been tackled and overcome. Finding new ways to work is essential for survival. Elias Zerhouni at Sanofi has adopted an "open innovation" strategy that puts the very best minds in a collaborative ecosystem to innovate. His strategy is to focus on three key aspects: unmet medical needs, improving our science (fast to fail and improved translational medicine) and operational excellence. Everyone in the R&D organization knows the strategy and is encouraged to think differently. In the operational excellence space, many of the top pharma/biotech companies have supported a collaborative approach to solving common problems. This has resulted in the formation of "Transcelerate BioPharma Inc". While it is early days, initial reports show that the collaborative approach is working.

The types of questions to ask are simple. How can we do things smarter, quicker and at lower cost, without compromising quality? How can we find innovative ways and tools? How can we implement them? R&D heads should be creating internal and open ecosystems that challenge the status quo and supporting the best ideas.

**Dr Koester:** Start with the end in mind. Don’t start with the current state and plan how to make it better: visioning, “what-if” thinking, idea generation forums that focus on the ideal state in 2025...

R&D executives should be open-minded and hold back resistance/doubt when hearing unconventional ideas. They should create the environment to nurture the innovative ideas at their most fragile stage. They need to support the innovative ideas with the acknowledgement that not all innovative ideas will work out and innovations, especially disruptive innovations, are not going to be a smooth process (there are going to be ups and downs like a roller-coaster).

Who is responsible for driving disruptive innovation?

**Dr Orloff:** We all have a role to play if we want to hasten change. Disruptive innovation does not generally come from the top down and cannot be “mandated.” On the other hand, leadership should strive to create an environment and a culture conducive to innovative thinking that rewards rather than penalizes trying something new and different. Associates should be free to fail under protected circumstances that are de-risked from projects on the critical path. Interaction and cross-fertilization with colleagues from different sectors and industries can be a catalyst to disruptive thinking, but there must be organizational fortitude to test new ideas and models that will serve as the nidus for disruptive change.

For more information and to register for the **September 19-20, 2013** event, visit [www.theconferenceforum.org](http://www.theconferenceforum.org)

Use code **DNEWS** for 10% off.

Questions, Email Service@theconferenceforum.org
A Look at the 2012 Event

Live Illustrations of Disruptive Ideas

Our 2012 Co-Chairs open the program: (Right to Left) John Orloff, MD, Andreas Koester, MD, PhD, and Craig Lipset, MBA.

Audience Discussions

Networking Break

Patient Advocate Geri Burtchell Interviewed by Craig Lipset.

More 2012 Photos available on the Disruptive Innovations Conference Website at www.theconferenceforum.org
We are pleased to share the news that one of our DPharm sponsors, CRF Health, will be announcing several innovative enhancements to their TrialMax eCOA solutions. CRF Health, the leading electronic Clinical Outcome Assessment (eCOA) solutions provider, has added new usability and patient retention enhancements that improve the efficiency of collecting clinical outcome data directly from patients and sites.

Among the improved features:

- Patient and site user experience improvements through meticulous user interface design and extensive usability testing, further reducing patient and site burden
- Investigators have on-demand access to study specific training directly on the TrialMax Slate, improving site compliance by ensuring training is available when needed as a reference or for new staff supporting the trial
- Ability to send SMS and email reminders to patients across all TrialMax eCOA solutions to keep patients engaged
- The new TrialMax Slate study dashboard clearly displays the questionnaire status of all patient visits. This enhancement reduces site burden and increases the efficiency of the eCOA collection process by highlighting required and incomplete questionnaires

For more information on the enhancements to TrialMax eCOA solutions or on how CRF Health supports clinical trials by fitting into patients’ lives, visit their website or meet them at DPharm. www.crfhealth.com

**UPCOMING CONFERENCES**

**Global Clinical Trials**
Sept. 18, 2013
Boston

30 outstanding biopharma executives gather to share best practices in reducing complexities in global trials.

**Adaptive Trial Designs**
Sept. 18, 2013
Boston

Addressing how adaptive designs can improve critical decision-making by enabling pre-planned trial adaption in a way that maintains the validity and integrity of the trial.

**Chief Medical Officer Summit West**
Nov. 4-5, 2013
San Francisco

35 CMOs address the dual role of a CMO in directing all R&D functions with limited resources, while raising capital and strategizing for appropriate exits.

Use Discount Code DNEWS for 10% off on any of the above.

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