How might the pharmaceutical industry tackle the weighty issues of affordability and sustainability in the context of spiralling healthcare costs? *International Innovation* presents a selection of the most stimulating issues discussed at the two-day *Disruptive Innovation in Clinical Trials* conference held at the Park Plaza, London, on 4-5 March 2014.
THE COST OF drug development has spiralled in recent decades to an unsustainable degree. Along with this unprecedented financial burden comes an associated multiplied risk. Pharmaceutical companies are therefore left with the difficult balance of keeping efficacy, patient safety and ethics at the heart of their R&D, while having to generate a return on their investment in a workable timeframe.

Bringing a drug to market often takes a decade or more. In the context of today’s ageing population – as a result of which the healthcare service industry is under intense and increasing strain – there is now compelling evidence to suggest that the time is ripe for a sea change in drug development. So how might the time and cost of drug development be reduced? One pivotal game changer could be the role of technology in clinical trials: to disrupt the traditional model; to get life-saving drugs to patients in a shorter time; to reduce cost; and to lower risk.

WHAT IS DISRUPTIVE INNOVATION?

Clayton Christensen, Kim B Clark Professor of Business Administration at Harvard Business School and widely considered to be one of the most eminent academics in his field, describes disruptive innovation as a phenomenon in which relatively simple products enter the market, displacing the established – often more expensive or unnecessarily complex – competition to gain the market share. Key examples of disruptive innovation in recent decades are the mobile phone and the laptop computer. Disruptive innovation comes at a higher risk than incremental or radical innovation; however, the potential opportunities and financial rewards are far greater.

“Disruptive innovations enable a larger population of less skilled, less wealthy people to do things in a more convenient, lower-cost setting, which historically could only be done by specialists in less convenient settings”

Clayton Christensen

PHARMACEUTICAL INDUSTRY R&D SPENDING ON THE AVERAGE FDA APPROVED DRUG

1975
US $100 MILLION

1987
$300 MILLION

2005
$1.3 BILLION

Sources: Tufts Center for the Study of Drug Development; Forbes
WHAT LESSONS SHOULD BE LEARNED?

One emergent theme of the presentations and discussions at the conference is the lesson of disruptive innovation – that survivors within any sector must disrupt, or risk being disrupted themselves. For the clinical trials industry specifically, the old pharmaceutical/biotechnology development model is quickly becoming obsolete. In this rapidly changing landscape, nothing short of an innovation revolution is required, helping to maximise efficiency while adapting to a new paradigm driven not by the healthcare industry or even by medical clinicians, but with the patient positioned front and centre. Accordingly, there is an opportunity to include crowd sourcing in the design of protocols; risk-based monitoring and real-time informatics should then be harnessed to build improved quality into trial design.

THE PATIENT-CENTRIC REVOLUTION

The shift to patients as drivers, not subjects, of trials should be one example of a more general shift towards integrated community-based healthcare services and an increase in self-care. Technology affords unparalleled potential in addressing the many problems entrenched within the traditional model of clinical trial design and management: from more rapid enrolment of more relevant and representative participants to streamlining of logistics; faster acquisition and more intelligent use of data to better compliance rates; increased efficacy; and massively reduced time and cost. From a risk-averse model of limited success, a shakeup in clinical trials underpinned by disruptive innovation and easy-to-use technology in both their design and management could help to move towards pre-emptive, personalised medicine and intelligent healthcare.

HOW STUDY START-UP CAN BE IMPROVED

FIND AND RESOLVE BOTTLENECKS
ALIGN STUDY TEAMS AND SITES
SHARE DOCUMENTS AND COMMUNICATIONS
TRACK, MEASURE AND IMPROVE PAST PERFORMANCE

FROM CONFERENCE PRESENTATION:
The Pain of Study Start-up and the New Paradigm of Trusted Collaboration
JAE CHUNG,
Founder and Chief Executive Officer, goBalto
CONFERENCE HIGHLIGHTS, DAY 1

KEYNOTE:
The clinical trial environment of today and tomorrow: Innovation, partnerships and processes
IRA SPECTOR,
Senior Vice President, Global Development Operations, Allergan

PANEL DISCUSSION:
The future of clinical trials – what can we do as an industry to drive efficiency and revolutionise trials?
ELENA BOLANOS,
Senior Director of Clinical Operations, Lilly
JEFFREY KASHER,
VP, Clinical Trial: Materials, Implementation and Transformation, Lilly
JONATHAN SHEFFIELD,
Chief Executive, NIHR Clinical Research Network
IRA SPECTOR,
Senior Vice President, Global Development Operations, Allergan

CLINICAL RESEARCH CHALLENGES:
Why current clinical trial practice is not working
BEN GOLDAacre,
Writer, Broadcaster and Medical Doctor

PANEL DISCUSSION:
Industry response – why do clinical trials fail and what can we do about it?
PROFESSOR GEORGE SZMUkLER,
Associate Director, NIHR MHRN
BEN GOLDAcre,
Writer, Broadcaster and Medical Doctor
SIMON DENEgri,
Chair, INVOLVE, NIHR National Director for Public Participation and Engagement in Research, NIHR
DR KIRSTY WYDENBACH,
Medical Assessor Clinical Trials Unit, MHRA
CONFERENCE HIGHLIGHTS, DAY 2

DISRUPTIVE TECHNOLOGIES AND PROCESSES
Game changing mobile technologies with the potential to disrupt clinical trials
DAVID DOHERTY,
Business Development, 3G doctor

USING DISRUPTIVE MOBILE TECHNOLOGY TO VERIFY DRUG KIT DISPENSATION
JON SENDALL,
Senior IxRS Technical Consultant,
Worldwide Clinical Trials

A DISRUPTIVELY INNOVATIVE ENVIRONMENT FOR STATISTICAL ENGINEERING OF THE THERAPEUTIC ENTITIES
ATHULA HERATH, PHD,
Statistical Director, Research Statistics, Translational Science, MedImmune Biotech Unit of AstraZeneca
COMMON PROBLEMS CITED IN CLINICAL TRIAL MANAGEMENT AND HOW DISRUPTIVE INNOVATION CAN ADDRESS THEM...

INEFFICIENCY OF COST AND TIME
Average cost of $1.5-4 billion and many years to gain market approval is suggestive of a wasteful and risk-averse industry following a 35-year-old paradigm – a rarely disrupted but outdated model.

Intelligent use of integrated technology and effective design and management of trials could signify huge time and cost savings.

DATA MINING
If data are not suitably streamlined to suit intelligent trial design, there is a risk of collecting ‘noise’; currently 50 per cent of data collected is never used.

Trials should be adaptive, driven by a crowd-sourcing approach that ensures only the most relevant data are collected.

COMPETITION
Proprietary data collection and publication can lead to duplication, secrecy, reduced trust and ultimately unmet patient needs.

The push towards transparency of data and open innovation should lead to the convergence of good ideas.

COMPLEXITY
Trials are often designed with >50 inclusion/exclusion criteria, followed by extremely complex design and management.

Increased protocol efficiency is guaranteed by simplification to a few interactive questions.

LOGISTICS
Working with multiple partners and across many sites with no centralised communication can slow down progress.

Better technological frameworks around process, people, systems and integration will streamline and speed up trials, reducing bottlenecks and minimising opportunity for error.

ELIGIBILITY CRITERIA
Over-restrictive criteria results in trials often being performed on healthy participants representing 5 per cent of the population, leaving 95 per cent unrepresented.

The impact of opening up trials to a more representative sample and no longer being risk-averse will benefit patients.

HIGH FAILURE RATE
There is a propensity not to publish so-called ‘negative’ results; indeed, half of trials today have gone on not to be published. 85 per cent of prescriptions in the UK are for drugs that went onto the market more than 10 years ago.

Initiatives such as the Open Trials Database will help to derive secondary analyses of ‘missing’ and unpublished data.

ENROLMENT AND RETENTION RATES
When trials are complicated, inconvenient and unappealing to participate in (for example requiring a lot of time and/or travel), enrolment rates will be lower, take longer and compliance cannot be ensured.

Electronic patient data could be harnessed in the future to improve enrolment (assuming prior approval from ethics committees); for example, helping to engineer automatic enrolments for treatments by clinicians, allowing for head-to-head trials of widely prescribed treatments. Compliance reporting will be as standard in mobile-driven trials.

POOR TRIAL DESIGN
Trials consume more than half resources in rework.

A dynamic learning approach to trial development would help to build quality into the design. Trials should be adaptive to ongoing dialogue between regulators, patients and the pharmaceutical industry.

THE INVISIBLE PATIENT
Patients are often not consulted or engaged until phase III of clinical trials, rather than being engaged as advocates and collaborators from the beginning of the process.

The patient community is set to become the dominant force, empowered by portable and easy-to-use technology for self-assessment and care.

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