



TRANSPARENCY LIFE SCIENCES, LLC MEDIA REPORT

**Covering: FDA Clears IND For First Clinical Trial Protocol
Developed Using Crowdsourcing**

January 4, 2013

SELECTED INITIAL MEDIA COVERAGE OF *FDA Clears IND For First Clinical Trial Protocol Developed Using Crowdsourcing*

THE BURRILL REPORT

Wisdom of Crowds Applied to Clinical Trials Transparency Life Sciences applies digital technology to slash costs

By Daniel S. Levine
January 2013

Tomasz Sablinski has what he calls his “rule of eighties,” which says 80 percent of clinical trials are trials that nobody wants, cost 80 percent too much, and are being done with technology from the ‘80s.

Sablinski, a 30-year veteran of the drug development world with experience from Big Pharma to the virtual drug development arm of a private equity firm, co-founded Transparency Life Sciences with the intent of radically altering the costs of clinical trials.

Sablinski believes that by providing complete transparency on drug data, using crowdsourcing to shape clinical trials, and using digital tools wherever possible, Transparency will be able to produce better clinical data, faster, and with greater convenience to patients and others involved in the clinical trials process. In fact, his goal is to cut clinical trials expenses by as much as 80 percent.

No doubt there is room for savings. In fact, a study presented in June at the Drug Information Association’s annual meeting found as much as \$5 billion a year could be saved from the cost of clinical trials by eliminating unnecessary procedures. The study, conducted by researchers at the Center for the Study of Drug Development at Tufts University School of Medicine, found that clinical trial data gathered from as much as 25 percent of the procedures administered to patients may be unnecessary because they are not directly tied to the endpoints of clinical trial. Transparency thinks it can not only eliminate waste, but also improve efficiency through three elements critical to its approach to clinical trials. These include making available all of the information about a drug and sharing data; turning to the researchers, physicians, patients, and patient advocates among others to participate in providing ideas on clinical trial design through crowdsourcing on its website; and using digital tools to reduce the need to bring patients to clinics on a regular basis, minimizing transportation, waiting, and the use of healthcare workers.

Initially, Transparency is pursuing a portfolio of repurposed drugs to establish a proof of concept for its approach. Once it can demonstrate its approach passes regulatory muster and produces robust results and savings, it plans to in-license promising drugs in development that have stalled in the pipelines of pharma and biotech companies for a variety of reasons.

The company got a major boost in December when the U.S. Food and Drug Administration gave a go-ahead for a mid-stage trial of lisinopril as a treatment for multiple sclerosis. Lisinopril is an ACE inhibitor that has been used for years in millions of patients worldwide as a safe and effective treatment for hypertension. Multiple sclerosis is an autoimmune disorder in which the body’s immune system attacks the protective coating on nerve cells. Animal models of MS have suggested that ACE inhibitors modulate the immune response and could have benefit in MS

patients. Because the drug has a different mechanism of action than existing MS therapies, Transparency believes it could be used in combination with other drugs.

By reaching out to the 15,000 users on the Transparency website, which includes researchers, physicians, patients, and disease advocates, the company believes it will be able to focus the trial on matters that are important to patients.

MS trials have traditionally used what's known as the Expanded Disability Status Scale as their primary endpoint. Neurologists score eight functional systems, generally measuring the function of different parts of the brain on a scale to score patients. But Transparency's community instead argued the company should use the Multiple Sclerosis Functional Scale, saying that it is more important to patients and a better endpoint to use for the trial. That scale has generally been used as a secondary endpoint or not at all, says Sablinski. The scale measures leg function and the ability of the patient to walk, arm and hand function, and cognitive function.

Typically in MS trials, sponsors also perform costly MRI scans in mid-stage trials and advance compounds based on the results of radiological images of the brain, even though the MRI scans say nothing about function, which Sablinski notes is what patients care about.

"For internal decision making, pharmaceutical and biotech companies are using an end-point that, if you look at the correlation between it and clinical outcomes, is questionable to the point that FDA doesn't really care about it," he says, referring to the MRI scans. "We are trying to move to, pretty bluntly, something that matters to patients, and matters to physicians who treat them, and forget the MRI."

The use of digital technology to monitor patients during the trial rather than having them travel regularly to clinical trial sites to be examined by health workers will be a major source of savings. Transparency will ask patients to come to a clinic for the first visit at the start of the trial, and at the last visit, but everything else will be done digitally. To monitor patients, Transparency is working with the New York City-based telemedicine provider AMC Health, which will provide everything from two-way video monitoring to tools that use GPS-based devices to measure patient movements.

"We know first-hand how effective at-home patient monitoring can be, providing significantly improved care at a much lower cost," says John Holland, senior vice president for research and business development at AMC Health. FDA clearance of this lisinopril protocol, which primarily relies on telemonitoring-based patient assessments, is an encouraging breakthrough."

Sablinski says the initial goal is to perform clinical studies at 50 percent of current budget. The ultimate goal, though, is to get that down to 80 percent. Based on budgets the company has received from clinical research organizations for the lisinopril trial, he believes the savings will be closer to the 80 percent market.

Sablinski launched Transparency in part because of the barriers of implementing his model within Big Pharma, where he did try to implement parts of the approach he is now using, but came up against resistance. Among the objections, he says, were concerns about IP, disbelief that the crowd would come up with better ideas than the thought leaders and experts within the company, and insistence that regulators would never go along with it. "The common denominator," he says, "is protecting the system."

For that same reason, he decided it would be best for Transparency to pursue its own drugs rather than operate as a contract research organization, since in almost all cases, companies would want to dictate trial protocols and be very protective of the secrecy of their data.

“I realized my life is too short to try to change corporate culture,” he says. “It’s just too big of a task.”

FierceMobile Healthcare

FDA Approves First Remote Monitoring Drug Trial

By Greg Slabodkin
January 1, 2013

The U.S. Food & Drug Administration recently approved its first remote monitoring trial, a 12-month Phase 2a study by biopharmaceutical startup Transparency Life Sciences, according to an article posted by MedCity News. In the trial, multiple sclerosis patients will take the blood pressure drug lisinopril and wear vital sign monitors provided by New York-based telemonitoring company AMC Health.

The trial will include 180 subjects, and those with wearable vital sign monitors will transmit their data to investigators and also conduct secure video conferences with them. Researchers will collect data on blood pressure and heart rate, mobility, physical and mental function, symptoms, side effects, quality of life and medication adherence, directly from patients in their homes, eliminating the need for frequent visits to a study site.

As a result, AMC Health's remote monitoring technologies will dramatically reduce the cost of the study to just \$1.5 million. The trial is estimated to save \$3.5 million over a traditional Phase 2a study, which can cost upward of \$5 million AMC Senior Vice President for Research and Business Development John Holland tells MedCity News.

The study will help determine whether lisinopril is safe and has promise in the treatment of MS, and could lead to a follow-on Phase 3 efficacy trial. AMC Health also is providing telemonitoring services for a Phase 1 study of a new drug conducted by a major pharmaceutical company.

Last year, Danville, Pa.-based Geisinger Health Plan used a home telemonitoring program for patients with congestive heart failure that reduced their readmission rate by 44 percent, compared to a control group. The success of the telehealth program, which incorporated technology from AMC Health, has prompted Geisinger to expand those efforts to include patients with hypertension and diabetes.



Trial Designed With Crowd Input Gets FDA Signoff

By Marc Iskowitz
December 28, 2012

What's been called the first clinical study protocol developed using crowdsourcing methods received the FDA's imprimatur earlier this month. The agency approved Transparency Life Sciences' IND for a clinical trial designed to test a generic blood-pressure medication, ACE inhibitor lisinopril, in patients with relapsing remitting multiple sclerosis.

“We believe that we are the first clinical protocol cleared by the FDA that included input from patients as well as physicians and researchers,” Tomasz Sablinski, MD, PhD (pictured below), founder and CEO of Transparency Life Sciences, told MM&M in an e-mail.

Data will be collected directly from subjects in the yearlong, 150-180-patient placebo-controlled study with the help of remote-monitoring technology from another firm, Advanced Monitored Caregiving, making it a so-called virtual trial as well.

Sablinski said he hopes the firm's crowdsourced protocol design raises awareness of the trial among MS patients and physicians and facilitates recruitment and retention. If so, it could pave the way for what he sees as “a fresh approach” to making drug development more sustainable.

The high cost of running clinical trials, recruiting patients for them, and designing them in such a way as to yield the data required by regulators, payers and marketers are all challenges with which drug developers wrestle, as is the slow, some would say anemic, yield from drug pipelines (recent numbers suggest R&D productivity may be picking up).

Sablinski's firm wants to make the process more efficient. Its business model includes re-purposing generic drugs and testing them in clinical trials that derive their protocols from a global crowd's input, which TLS says can help ensure that the protocols have greater relevance to clinical practice and to patient needs.

For instance, TLS used a web-based tool to elicit insights from patients and healthcare experts, with the responses factoring into primary and secondary endpoints, inclusion/exclusion criteria and remote-monitoring strategies for its Phase IIa lisinopril protocol.

In addition, TLS says it practices full data transparency. “We plan to post all data (raw and final) on our website (with patient identifiers removed) for everyone to see and analyze,” added Sablinski.

Asked about the TLS study, an FDA spokesperson said the agency does not comment on ongoing clinical trials. “We are aware of studies that have tried to elicit data online, and even do informed consent online,” noted the spokesperson, Chris Kelly, in an e-mail. “There is tremendous interest in moving trials into healthcare settings and using patient records to seek potential participants, among other initiatives.”

However, trying to introduce such initiatives into clinical research has been a mixed bag. One such effort, Pfizer's 2011 Phase IV REMOTE trial involving overactive bladder drug Detrol LA, was said to be the first to recruit and communicate with patients entirely via web-based telemonitoring techniques. But the drugmaker halted the study earlier this year after it ran into problems attracting enough volunteers.

At the same time, the REMOTE trial proved that some new efficiencies could be worked into the trials process: online consent delivery and testing, in-home patient follow-up, expanded use of mobile, and at-home drug delivery. Pfizer's head of clinical innovation, Craig Lipset, said in a blog post that the drugmaker is working to integrate those tools into new trials.

To prevent similar roadblocks, TLS is collaborating with MS researchers at Stanford Medical School to conduct its trial and expects that their participation will facilitate patient recruitment, Sablinski said. That strategy, and remote monitoring of subjects, could also cut costs.

Sablinski said he wants to learn from previous efforts. If TLS's mid-stage trial confirms what preclinical testing has found, it could prove not only the value of lisinopril as a new therapeutic option for patients with MS, but also help the drug developer—and others—realize the promise of crowdsourcing and virtual trials to make R&D more viable.

Duke Translational Medicine Institute

FDA approves Phase 2 trial using remote monitoring, crowd sourcing

December 26, 2012

It looks like the U.S. Food and Drug Administration is feeling growing pressure to make clinical trial design more flexible. A newly approved Phase 2 clinical trial is the first to use both crowd sourcing and remote monitoring.

The regulator has granted New York-based biopharmaceutical startup Transparency Life Sciences a greenlight to study the effectiveness of a blood pressure drug lisinopril in multiple sclerosis patients, after clearing the company's Investigational New Drug application.

Telemonitoring company AMC Health will work with Transparency Life Science to do remote monitoring for the trial. For the 12-month study, data will be collected from the 180 participants' homes, using wearable monitors to collect vital signs. Secure video interaction between investigators and trial participants will facilitate communication between them.

In the runup to the FDA's clearance of the IND, Transparency Life Sciences had obtained insights from patients and healthcare professionals to strengthen the protocol for the Phase 2 trial, such as primary and secondary endpoints, inclusion and exclusion criteria and remote monitoring strategies.

To read the full article, click here ([MedCityNews](#)).



December 20, 2012

FDA-approved trial to use telemonitoring, crowdsourcing approaches

A Phase II clinical trial to examine the effectiveness of lisinopril in patients with multiple sclerosis by Transparency Life Sciences was approved by the FDA. The 12-month trial, which is the first to implement both remote monitoring and crowdsourcing techniques, will be performed by the biopharmaceutical startup with telehealth firm AMC Health.

(Links to [MedCityNews](#))

PharmaTimes

Lisinopril IND Is Crowdsourcing First, Says Transparency Life Sciences

By Peter Mansell
December 20, 2012

An Investigational New Drug (IND) application just approved by the US Food and Drug Administration is the first ever for a clinical trial protocol developed with the aid of crowdsourcing, its sponsor says.

The US application to assess lisinopril in a Phase II trial as an adjunctive therapy for multiple sclerosis (MS) also represents one of the first protocols to make intensive use of telemonitoring and other remote methods for patient-data collection, notes Transparency Life Sciences (TLS).

The US-based biopharmaceutical concern, which marked its official launch earlier this year as “the world’s first drug development company based on open innovation”, aims to demonstrate the value of its online Protocol Builder platform using repurposed off-patent compounds with extensive safety records.

The idea is to design clinical-trial protocols more in tune with the needs of patients, physicians, researchers and other stakeholders, enhancing the productivity of clinical development and the regulatory viability of resulting compounds while reducing timelines and costs.

Protocol Builder

A widely used antihypertensive that has shown potential efficacy against MS in animal studies, lisinopril was the first repurposed compound for which TLS opened up a clinical-trial protocol to collaborative input on its crowdsourced web platform.

According to Dr Tomasz Sablinski, founder and chief executive officer of TLS, the company has spent “much of this year” refining the Protocol Builder tool. The responses obtained from patients and healthcare experts were used to strengthen the lisinopril Phase II protocol.

These contributions included “valuable insights on primary and secondary endpoints, inclusion/exclusion criteria and remote monitoring strategies”, Sablinski commented, adding: “Going forward, we expect even more of the content of our protocols will be derived from curated crowd input”.

Telemonitoring solution

Another strand of the TLS strategy is to cut significantly the cost and inconvenience to patients of implementing clinical trials by replacing site visits with telemonitoring and other measurements taken in patients’ own homes.

To achieve its goal of a 50% or more reduction in the cost of clinical trials, TLS has partnered with Advanced Monitored Caregiving (AMC Health), a telehealth provider that offers a range of user-friendly in-home telemonitoring solutions.

In the proposed twelve-month lisinopril study, patients will visit clinical-trial staff in person only at the start and end of the protocol. All other study data will be collected at home.

Further input

TLS has posted the FDA-approved lisinopril protocol on its website and welcomes further input from patients, clinicians and researchers on details of the design, especially with respect to telemonitoring and statistical analysis.

The company is also seeking input to its Protocol Builders for low-dose naltrexone as a potential treatment for Crohn's disease and for the PPAR activator pioglitazone as a possible new therapy for Parkinson's disease.



FDA Clears Startup's Virtual Trial For Drug Against Multiple Sclerosis

Transparency Life Sciences picked up a win for its bet on open innovation in transforming drug development. The FDA cleared the developer's IND application to study a generic hypertension drug for a new potential use in patients with multiple sclerosis, after the startup tapped crowdsourced input from experts and patients on aspects of the clinical trial.

The study not only used New York-based Transparency's web-based Protocol Builder software to gather ideas on the design of the Phase II effort, but the trial will also be partially virtual. After patients' initial visits to trial sites, the planned 12-month study is expected to use telemonitoring technology from Advanced Monitored Caregiving and other partners to track participants until their final checkups, COO Marc Foster explained to FierceBiotechIT.

With these outside-the-box strategies, Transparency aims to drive down the cost of clinical trials by at least 50%. This is a big goal and one not easily achieved industry-wide, and at first blush, the startup's bold idea might draw some healthy skepticism. As published in a Nature Reviews Drug Discovery article in March, the number of FDA approvals per billion dollars in research money spent has been steadily declining over the past 60 years or so. The authors dubbed this "Eroom's Law," which is Moore's Law spelled backwards. Transparency's Foster believes there is hope for reversing the troubling trend.

"I think it's doable. It takes a fresh approach. It takes a bold approach," Foster said in a phone interview. "Just tinkering with the status quo is not working, and it's really resulted in an unsustainable clinical development model that has translated into escalating costs."

How does Transparency expect to drastically reduce the cost of clinical research? For starters, the company is crowdsourcing patients and healthcare experts to augment its reliance on internal thought leaders to design trial protocols. Its hope is to show that this is an efficient and effective approach to protocol design, which can take substantial time and money to complete

In the MS study, the company wants to trial a new use of a widely prescribed generic heart drug in the ACE inhibitor lisinopril, which has a well-established safety profile that allows the startup to begin its program with a midstage study. (A company co-founder documented the generic drug's benefits for MS in animal studies, resulting in a new method of use patent filing.) Foster also aims to get discounted supplies of the drug from generics companies. Overall, he sees an opportunity to pick up drugs that are ready for Phase II from around the industry, using the company's open innovation approach to reduce development costs of the molecules, with plans to license successful candidates to partners after midstage studies. The partners would foot the hefty bills for Phase III trials.

The company has found a lead investigator at Stanford who treats many MS patients, and Foster sees an opportunity to cut recruitment costs by enrolling all the estimated 150 to 180 study participants from the San Francisco Bay Area. Recruitment is notoriously expensive, and drawing from the investigator's large pool of patients for the study could significantly reduce that expense.

The next bucket of savings is expected to come from reduced clinical monitoring costs because participants will self-report their status from their homes with mobile devices for most of the study, reducing the cost of traveling to clinics with high costs of doing business, Foster says. Transparency is considering a GPS-enabled system to provide remote monitoring of MS patients' movements, as their neurological disorder causes progressive disability.

Transparency is taking a hybrid approach to virtual clinical development that might just work. We'll keep track of its progress.

BIO WORLD[®] TODAY

December 19, 2012

Transparency Life Sciences LLC, of New York, said the FDA cleared an investigational new drug application for lisinopril in multiple sclerosis. The protocol was crowdsourced, using telemonitoring for patient data collection, and Transparency said it was the first clinical trial protocol developed in such a way. The company is trying to reduce the cost of clinical trials by 50 percent or more, and is partnered with Advanced Monitored Caregiving, a telehealth provider, to that end. Study patients will have in person visits with the clinical trial staff at the beginning and end of the trial, and all other data will be collected at home.

FierceBiotech

THE BIOTECH INDUSTRY'S DAILY MONITOR

December 19, 2012

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Pfizer targets 600 primary-care sales jobs

It's the end of the year, and the end of the road for hundreds of Pfizer drug reps. The company is slashing its primary-care sales force by almost 20%, Bloomberg reports, taking its 3,000-strong army of reps down to around 2,400. That amounts to about 600 jobs, near the top end of the range predicted by sources earlier this month. The latest cuts come as Big Pharma moves away from the megablockbuster drugs--such as Pfizer's Lipitor--that required battalions of sales reps to call on primary-care doctors. [Read the story >>](#)



Tracy Staton

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Fda Clears Startup's Virtual Trial For Drug Against Multiple Sclerosis

By Ryan McBride
December 19, 2012

Transparency Life Sciences picked up a win for its bet on open innovation in transforming drug development. The FDA cleared the developer's IND application to study a generic hypertension drug for a new potential use in patients with multiple sclerosis, after the startup tapped crowdsourced input from experts and patients on aspects of the clinical trial.

The study not only used New York-based Transparency's web-based Protocol Builder software to gather ideas on the design of the Phase II effort, but the trial will also be partially virtual. After patients' initial visits to trial sites, the planned 12-month study is expected to use telemonitoring technology from Advanced Monitored Caregiving and other partners to track participants until their final checkups, COO Marc Foster explained to FierceBiotechIT.

With these outside-the-box strategies, Transparency aims to drive down the cost of clinical trials by at least 50%. This is a big goal and one not easily achieved industry-wide, and at first blush, the startup's bold idea might draw some healthy skepticism. As published in a Nature Reviews Drug Discovery article in March, the number of FDA approvals per billion dollars in research money spent has been steadily declining over the past 60 years or so. The authors dubbed this "Eroom's Law," which is Moore's Law spelled backwards. Transparency's Foster believes there is hope for reversing the troubling trend.

How does Transparency expect to drastically reduce the cost of clinical research? For starters, the company is crowdsourcing patients and healthcare experts to augment its reliance on internal thought leaders to design trial protocols. Its hope is to show that this is an efficient and effective approach to protocol design, which can take substantial time and money to complete.

In the MS study, the company wants to trial a new use of a widely prescribed generic heart drug in the ACE inhibitor lisinopril, which has a well-established safety profile that allows the startup to begin its program with a midstage study. (A company co-founder documented the generic drug's benefits for MS in animal studies, resulting in a new method of use patent filing.) Foster also aims to get discounted supplies of the drug from generics companies. Overall, he sees an opportunity to pick up drugs that are ready for Phase II from around the industry, using the company's open innovation approach to reduce development costs of the molecules, with plans to license successful candidates to partners after midstage studies. The partners would foot the hefty bills for Phase III trials.

The company has found a lead investigator at Stanford who treats many MS patients, and Foster sees an opportunity to cut recruitment costs by enrolling all the estimated 150 to 180 study participants from the San Francisco Bay Area. Recruitment is notoriously expensive, and drawing from the investigator's large pool of patients for the study could significantly reduce that expense.

The next bucket of savings is expected to come from reduced clinical monitoring costs because participants will self-report their status from their homes with mobile devices for most of the study, reducing the cost of traveling to clinics with high costs of doing business, Foster says. Transparency is considering a GPS-enabled system to provide remote monitoring of MS patients' movements, as their neurological disorder causes progressive disability.

Transparency is taking a hybrid approach to virtual clinical development that might just work. We'll keep track of its progress.



FDA Clears IND for First Study Protocol Developed Using Crowdsourcing

December 18, 2012

The FDA has cleared the Investigational New Drug Application (IND) for lisinopril to be assessed as an adjunctive therapy for multiple sclerosis (MS), according to Transparency Life Sciences (TLS), a drug development company based on open innovation.

The clearance is the first for a clinical trial protocol developed with the aid of crowdsourcing, and is among the first to make intensive use of telemonitoring and other remote methods for patient data collection.

"FDA clearance of our first crowdsourced protocol is a major milestone in our efforts to build a drug development company for the twenty-first century," said Tomasz Sablinski, MD, PhD, founder and CEO of TLS. "In response to widespread recognition that the existing development model is unsustainable, TLS is pioneering a fresh approach that leverages advances in technology and communications. We look forward to working with the FDA and a growing community of contributors and partners to implement the lisinopril phase II trial, as we also assess additional development candidates encompassing both new chemical entities (NCEs) and repurposed compounds."

A key element of TLS's approach is incorporating insights gathered from a global crowd into its clinical protocols using the company's Internet-based Protocol Builder, an online tool that elicits input from patients, physicians and researchers to help design clinical trials more efficiently and with greater relevance to clinical practice and patients' needs.

"We spent much of this year refining our Protocol Builder tool and were able to use the responses we obtained from patients and healthcare experts to strengthen the lisinopril phase II protocol," said Sablinski. "These included valuable insights on primary and secondary endpoints, inclusion/exclusion criteria and remote monitoring strategies. Going forward, we expect even more of the content of our protocols will be derived from curated crowd input."

A second TLS strategy is to dramatically reduce the cost and patient inconvenience of executing clinical trials by replacing patient site visits with telemonitoring and other measurements obtained from patients' homes. To achieve its goal of 50% or greater reduction in the cost of clinical trials, TLS is partnering with Advanced Monitored Caregiving (AMC Health), a comprehensive telehealth provider offering an array of easy-to-use in-home telemonitoring solutions. In the proposed 12-month lisinopril study, patients will visit in-person with clinical trial staff at the start and end of the trial, and all other study data will be collected at home.

"Based on our 10 years of successful operations, we know first-hand how effective at-home patient monitoring can be, providing significantly improved care at a much lower cost, said John Holland, senior vice president for research and business development, AMC Health. "FDA clearance of this lisinopril protocol, which primarily relies on telemonitoring-based patient assessments, is an encouraging breakthrough, and we look forward to working with TLS to ensure the success of this patient-centric approach to clinical research."

TLS has posted the FDA-cleared lisinopril protocol on its website and welcomes further input from patients, clinicians and researchers on details of the design, especially concerning the telemonitoring and statistical analysis aspects of the plan. TLS is also seeking input to its Protocol Builders for low-dose naltrexone as a potential treatment for Crohn's disease, and the PPAR activator pioglitazone as a possible new therapy for Parkinson's disease. In addition, the company's Indication Finder offers the opportunity to consider promising new indications for existing drug candidates.\



FDA Gives Go Ahead For Phase 2 Trial Using Remote Monitoring And Crowd Sourcing

By Stephanie Baum
December 18, 2012

It looks like the U.S. Food and Drug Administration is feeling growing pressure to make clinical trial design more flexible. A newly approved Phase 2 clinical trial is the first to use both crowdsourcing and remote monitoring

The regulator has granted New York-based biopharmaceutical startup Transparency Life Sciences a greenlight to study the effectiveness of a blood pressure drug lisinopril in multiple sclerosis patients, after clearing the company's Investigational New Drug application.

Telemonitoring company AMC Health will work with Transparency Life Science to do remote monitoring for the trial. For the 12-month study, data will be collected from the 180 participants' homes, using wearable monitors to collect vital signs. Secure video interaction between investigators and trial participants will facilitate communication between them.

In the runup to the FDA's clearance of the IND, Transparency Life Sciences had obtained insights from patients and healthcare professionals to strengthen the protocol for the Phase 2 trial, such as primary and secondary endpoints, inclusion and exclusion criteria and remote monitoring strategies.

It's a significant milestone for the FDA and for the pharmaceutical industry. The study is estimated to cost \$1.5 million. Using a more traditional clinical study model, with frequent site visits, the one year study could have cost as much as \$5 million, John Holland, senior vice president for research and business development for AMC Health told MedCity News in a phone interview. Another benefit is that it will reduce the geographical limitations of clinical trials.

AMC Health is also working with an unnamed pharmaceutical company in a Phase 1 study. The New York telemonitoring business has worked with pharmaceutical companies before, mostly on pilot studies evaluating the use of telemonitoring for clinical trials. It has also worked with Geisinger Center for Health Research in Danville, Pennsylvania to reduce readmissions by improving post discharge patient follow up.

"This will increase the quality and quantity of data, and reduce the burden on patients. Frequent data collection at home is also expected to increase patient safety, because if a side effect were to appear, researchers will know about it sooner," Holland said. "A lot of people are collecting

electronic patient-reported outcomes so that's not unique but I have not seen anyone else doing the biometric, medication adherence monitoring that we are doing."

Telemonitoring is not a perfect system either. Information provided by monitors tracking vital signs can generate false alarms. Scalability is also a problem when you are looking at a clinical trial of thousands of people.

Transparency Life Sciences has been a proponent of telemonitoring as an effective way to carry out clinical trials and ensure data is uniform. In an interview with MedCity News earlier this year, Marc Foster, Transparency's chief operating officer said: "One of the things you see a lot these days is researcher bias, where a doctor or clinician is taking data in a clinical setting their involvement can bias the results of a clinical trial. If people are at home in their most natural setting, the ability to take their data remotely we think would be more uniform."

Industry insiders from pharmaceutical companies to health IT companies to patient advocates have been pushing for the FDA to be more innovative in its approach to clinical trials. Pfizer's attempt to use social media to carry out the tricky job of patient recruitment, marked a critical step in how Big Pharma view alternative approaches to clinical trial design. Pharmaceutical companies have been conducting pilot studies for years to ascertain factors that could impact the accuracy of these studies. The evolution in the sophistication of devices that can monitor vital signs and transmit that data remotely without the patient keying it in makes this kind of clinical trial design more feasible. Proponents argue that they can better track participants' health than regular site visits.



Crowdsourcing, Telemonitoring To Cut Costs In Clinical Trials

By Marianne Hayes

New drug therapies have a long road from conception to commercial availability. According to drug development company Transparency Life Sciences (TLS), the current development model leaves much to be desired.

"From design through execution and analysis, today's clinical development process is loaded up with unnecessary costs, contributing to a \$50 billion pharmaceutical [research and development] price tag in the U.S. alone," said TLS co-founders Dr. Tomasz Sablinski and Marc Foster in a statement to Metro.

According to TLS, researchers estimate that the cost of developing an individual drug is currently more than \$1 billion.

"The implication is that lots of good drug candidates are never making it to patients because the cost barrier is too high," they added.

TLS is implementing a new drug development protocol called crowdsourcing, which integrates remote data collection methods like telemonitoring to cut trial costs. Crowdsourcing works by gathering key trial information from patients, physicians, researchers and experts and streaming it all through a web-based survey tool called Protocol Builder. Then TLS curates the responses and looks for overall trends, along with out-of-the-box ideas that might improve clinical trial design.

The crowdsourcing protocol will allow for the bulk of study data to be collected at home via telemonitoring. TLS hopes to achieve at least a 50 percent reduction in clinical trial costs as a result.

The company has received FDA approval to use the new protocol to test a multiple sclerosis therapy.

SELECTED NEW MEDIA COVERAGE OF *FDA Clears IND For First Clinical Trial Protocol Developed Using Crowdsourcing*

Digital Medicine

Crowdsourcing Virtual Clinical Trials

By Neelesh Bhandari
December 29, 2012

After a lot of theorizing and some abandoned efforts, a new Virtual Clinical Trial is now underway. Undertaken by Transparency Life Sciences' IND, this FDA approved clinical trial is designed to test a generic blood-pressure medication, ACE inhibitor lisinopril, in patients with relapsing remitting multiple sclerosis.

This crowd sourced trial is designed such that data will be collected directly from the subjects via remote web based monitoring. The company has billed this as a fully transparent virtual trial and plans to post all data (raw and final) on their website (with patient identifiers removed) for everyone to see and analyze.

Transparency Life Sciences is one of its kind, innovative drug development company which aims to use this collaborative and open approach to allow reduced cycle time, reduced error rates and decreased costs. But as previous efforts have shown us, their one big challenge is going to enrollment of patients as study subjects.

Read more about their Philosophy here.

Or Listen to this interview of Dr. Tomasz Sablinski, the Founder and CEO of Transparency Life Sciences.

http://soundcloud.com/blogbrevity/dr-tomasz-sablinski?utm_source=soundcloud&utm_campaign=share&utm_medium=raw&utm_content=http://soundcloud.com/blogbrevity/dr-tomasz-sablinski



FDA Clears Startup's Virtual Trial For Drug Against MS

December 19, 2012 11:44 PM

User: squiffy2

Transparency Life Sciences picked up a win for its bet on open innovation in transforming drug development. The FDA cleared the developer's IND application to study a generic hypertension drug for a new potential use in patients with multiple sclerosis, after the startup tapped crowdsourced input from experts and patients on aspects of the clinical trial.

The study not only used New York-based Transparency's web-based Protocol Builder software to gather ideas on the design of the Phase II effort, but the trial will also be partially virtual. After patients' initial visits to trial sites, the planned 12-month study is expected to use telemonitoring technology from Advanced Monitored Caregiving and other partners to track participants until their final checkups, COO Marc Foster explained to FierceBiotechIT.

With these outside-the-box strategies, Transparency aims to drive down the cost of clinical trials by at least 50%. This is a big goal and one not easily achieved industry-wide, and at first blush, the startup's bold idea might draw some healthy skepticism. As published in a Nature Reviews Drug Discovery article in March, the number of FDA approvals per billion dollars in research money spent has been steadily declining over the past 60 years or so. The authors dubbed this "Eroom's Law," which is Moore's Law spelled backwards. Transparency's Foster believes there is hope for reversing the troubling trend. ... Read More - [http://www.msnc.co.uk/index.cfm/fuseact ... ageid/3534](http://www.msnc.co.uk/index.cfm/fuseact...ageid/3534)

User: lyndacarol

A study of the ACE inhibitor lisinopril? Alert, alert, Anonymoose!!! You need to follow this.

Moderator: NHE

Both full papers are freely available.

Blocking angiotensin-converting enzyme induces potent regulatory T cells and modulates TH1- and TH17-mediated autoimmunity.
Proc Natl Acad Sci U S A. 2009 Sep 1;106(35):14948-53.

The renin-angiotensin-aldosterone system (RAAS) is a major regulator of blood pressure. The octapeptide angiotensin II (All) is proteolytically processed from the decapeptide AI by angiotensin-converting enzyme (ACE), and then acts via angiotensin type 1 and type 2 receptors (AT1R and AT2R). Inhibitors of ACE and antagonists of the AT1R are used in the treatment of hypertension, myocardial infarction, and stroke. We now show that the RAAS also plays a major role in autoimmunity, exemplified by multiple sclerosis (MS) and its animal model, experimental autoimmune encephalomyelitis (EAE). Using proteomics, we observed that RAAS is up-regulated in brain lesions of MS. AT1R was induced in myelin-specific CD4+ T cells and monocytes during autoimmune neuroinflammation. Blocking All production with ACE inhibitors or inhibiting All signaling with AT1R blockers suppressed autoreactive TH1 and TH17 cells and promoted antigen-specific CD4+FoxP3+ regulatory T cells (Treg cells) with inhibition of the canonical NF-kappaB1

transcription factor complex and activation of the alternative NF-kappaB2 pathway. Treatment with ACE inhibitors induces abundant CD4+FoxP3+ T cells with sufficient potency to reverse paralytic EAE. Modulation of the RAAS with inexpensive, safe pharmaceuticals used by millions worldwide is an attractive therapeutic strategy for application to human autoimmune diseases.

Angiotensin II sustains brain inflammation in mice via TGF-beta.
J Clin Invest. 2010 Aug;120(8):2782-94.

The renin-angiotensin-aldosterone system (RAAS) is a key hormonal system regulating blood pressure. However, expression of RAAS components has recently been detected in immune cells, and the RAAS has been implicated in several mouse models of autoimmune disease. Here, we have identified Ang II as a paracrine mediator, sustaining inflammation in the CNS in the EAE mouse model of MS via TGF-beta. Ang II type 1 receptors (AT1Rs) were found to be primarily expressed in CNS-resident cells during EAE. In vitro, astrocytes and microglia responded to Ang II treatment by inducing TGF-beta expression via a pathway involving the TGF-beta-activating protease thrombospondin-1 (TSP-1). TGF-beta upregulation in astrocytes and microglia during EAE was blocked with candesartan (CA), an inhibitor of AT1R. Treatment of EAE with CA ameliorated paralysis and blunted lymphocyte infiltration into the CNS, outcomes that were also seen with genetic ablation of AT1Ra and treatment with an inhibitor of TSP-1. These data suggest that AT1R antagonists, frequently prescribed as antihypertensives, may be useful to interrupt this proinflammatory, CNS-specific pathway in individuals with MS.

User: Anonymoose

I know! How cool is that?!

<http://www.thisisms.com/forum/general-discussion-f1/topic21374.html>

SELECTED OTHER COVERAGE OF AMC HEALTH'S *U.S. Food and Drug Administration Approves Remote Monitoring for Drug Trial*



AMC Health To Offer Telemonitoring Services For Lisinopril Trial

December 20, 2012

AMC Health will offer an array of telemonitoring services for clinical trial of lisinopril, which will be conducted by Transparency Life Sciences (TLS).

US FDA has granted Investigational New Drug (IND) status to Lisinopril, which allows TLS to conduct phase 2a study to know the effects of the drug, used to treat blood pressure in multiple sclerosis (MS) patients.

AMC Health, in partnership with TLS, will provide telemonitoring technologies, enabling researchers to collect data on blood pressure and heart rate, mobility, physical and mental

function, symptoms, side effects, quality of life and medication adherence, directly from patients in their homes avoiding the frequent physical presence at the study site.

AMC Health research and business development senior vice president John Holland said, "Pharmaceutical companies have been worried that the FDA would not accept telemonitoring in place of costly clinic visits."

"Frequent data collection at home is also expected to increase patient safety, because if a side effect were to appear, researchers will know about it sooner, without having to wait for the next study visit," Holland added.

TLS expects to bring down the 12-month trial costs to nearly \$1.5m, from an estimated costs between \$5-\$10m by using AMC Health's telemonitoring resources.

Patients will be required to be present in person only twice during the total trial period, according to AMC Health.



Clinical Trials Still Ripe For Mobile-Enabled Innovations

Jonah Comstock
December 27, 2012

Mobile technology presents a sorely-needed, long-awaited opportunity for innovating the clinical trial – making it cheaper, easier, and even more accurate. But there are a lot of pieces to a clinical trial, and, according to some, mobile technology has the capacity to influence almost every one. Different companies are experimenting with these different aspects: Only time will tell which of these pieces might fit together to create the clinical trial of the future.

Working with investigators

Clinical trials are typically conducted on behalf of pharmaceutical companies, but they're often conducted by third-party investigators – a broad group of care providers that include private practitioners, hospitals and universities.

Ideally, great care is taken to make sure investigators have good and consistent training in procedures for conducting a trial, not to mention great expense. Janssen R&D's Clinical Trial Innovation Unit, a division of Johnson & Johnson, is leveraging digital technology to streamline this process in two ways. The first is a shared online databank of all non-proprietary clinical information. This includes investigator training and capabilities and standard trial practices and procedures – nearly anything that isn't related to particular drugs.

"The idea was welcomed and embraced immediately, but then there are the technical and legal hurdles," Andreas Koester, head of the Clinical Trial Innovation unit, told MobiHealthNews. "Everyone we talked to said 'It's great that finally somebody is tackling it.'"

The second initiative is to create a standard online portal for investigators to communicate with pharmaceutical companies. The company is working on this initiative with TransCelerate BioPharma, an alliance of several large drug companies. Rather than having a different system and a different login username and password for each drug company an investigator works with,

the initiative would create a single sign-in that would give investigators access to all the drug companies they're working with. The data, including proprietary information on specific drugs, would still be firewalled and stored separately, but it would be accessed uniformly.

Reaching out to participants

Other companies are focusing on implementing mobile technology to enhance communication between participants and investigators. Omniscience Mobile has been working in that field for about three years, working with companies like Pfizer and Merck.

For recruitment, the company provides texting as a contact option for eligible participants, listing a text option in addition to the phone number and website on posters and billboards. When someone texts in, an automated system texts them back a series of eligibility questions about age, sex, and geographical location.

"What we find is if you give someone the option to call or text, the vast majority are going to text," said Omniscience CEO Jeff Lee. "You texted, you had this nice impersonal experience, and by seven or eight questions in, you're feeling very engaged."

If a person's answer determines that they are eligible for the trial, someone from Omniscience is alerted, either immediately if it's during business hours or the next day. The operator calls the potential participant back and finalizes the sign up.

When a patient joins a trial through Omniscience for the first time, they have to sign a lengthy informed consent form, and they're given a packet of trial information. The informed consent form can be daunting and the information packet is easily lost over the course of a multi-year trial. Janssen is working on digitizing their informed consent form.

"Of course, there's no value added if you just transfer the paper copy onto a screen," Koester said. "At the end of the process you can ask questions about key messages, risks, opportunity to withdraw without having an impact on care. We make sure the patient really understands what the trial is about."

Later this year, Omniscience is releasing an app that it can offer instead of the information packet. As well as having all the information in the welcome packet, the app will keep track of participants' appointments and store contact information and directions for the trial site. Lee said the app will be a "Trojan Horse" for other capabilities.

The company hopes to include a digital version of the diary that many clinical trial patients are expected to keep. These diaries, for keeping track of medication adherence, are often inaccurate because many participants forget about them and fill them out while they are in the parking lot right before their visit. An app could remind a participant to make entries or only allow them to fill it in within a certain time window.

At Janssen, Koester's team is working on a similar measure to ensure medication adherence during clinical trials: electronic blisters. Patients would be given their medication in "smart" packaging that would automatically send a text if the pill was opened at a different time than it was meant to be taken.

Remote monitoring

Telemedicine and remote monitoring are both increasingly well-established mobile health technologies, but their adoption in clinical trials is just beginning.

The FDA just approved its first remote monitoring trial, a 12-month Phase 2 trial by biopharma startup Transparency Life Sciences, MedCityNews reported. For the trial multiple sclerosis patients will take the blood pressure drug lisiniprol and wear vital sign monitors provided by AMC

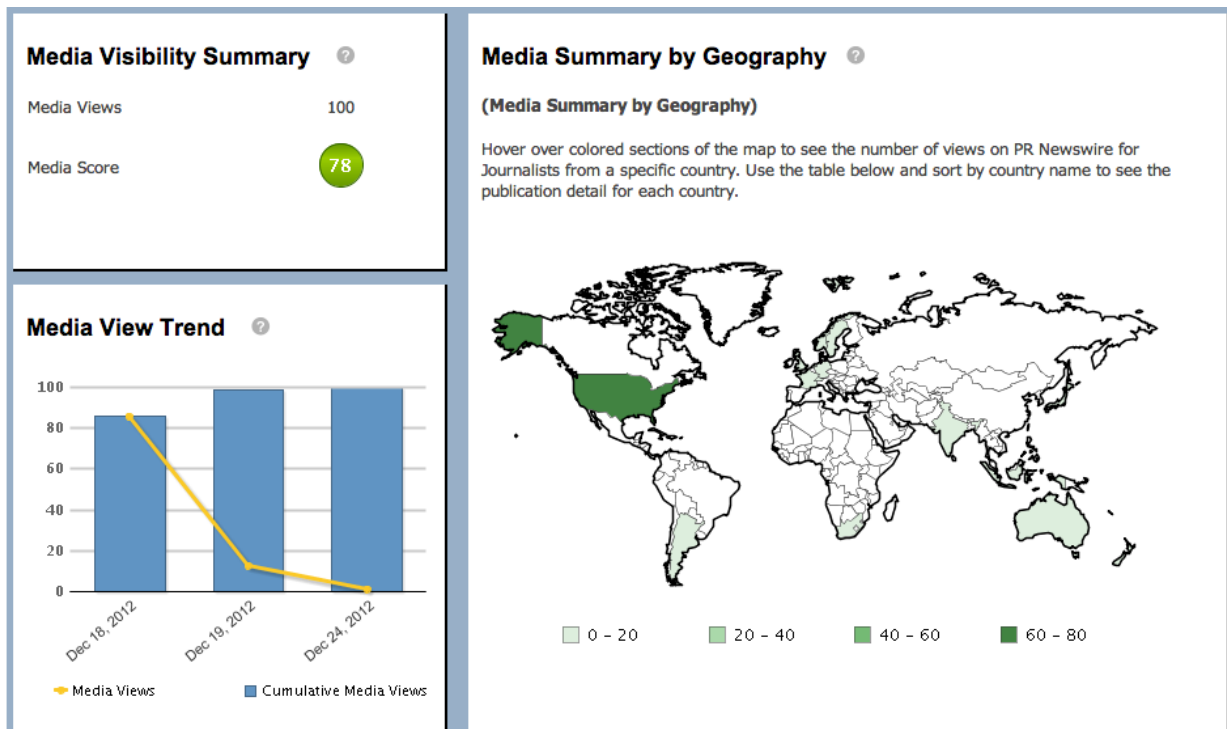
Health. The trial will include 180 subjects and those with wearable vital sign monitors will transmit their data to investigators and also conduct secure video conferences with them. The trial is estimated to save \$3.5 million over a traditional trial, AMC senior vice president for research and business development John Holland said, according to the report.

Lee said Omniscience is looking at pairing its offering with remote monitoring technologies, as well as employing passive monitoring of phone use, like what Ginger.io does, to keep tabs on mental health patients in clinical trials. During a recent webinar, Mark Brincat of mobile clinical trial company Exco InTouch said that mobile-enabled data collection could make clinical trials easier all around once the practice becomes accepted.

“One of the areas that we’re certainly looking [at], and we’re not the only company looking in this area is whether, by collecting realtime data from within clinical trials, we’re able to more effectively make decisions.” Brincat said. “Whether we’re able to start to think about having smaller trials, even, because you’re collecting more accurate data, and also, trying to improve adherence in clinical trials, which again ought to be able to drive down sample sizes and patient numbers in those trials.”

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