

Clinical Open Innovation

Reinventing Invention through an *Open Clinical Intelligence Network*

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The Lilly logo is a stylized, red, cursive script of the word "Lilly". It is positioned in the bottom right corner of the page.

A Call to Action

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In November of 2010, John Lechleiter, CEO and President of Eli Lilly Company, issued this challenge: *"The innovation engine is broken, but we know we can fix it, and we must -- not as a matter of blind faith, but of vision."*

The pharmaceutical industry is ripe with innovation opportunities. To find it, all the industry has to do is look outside its own walls. In recent years, a dramatic shift in the availability and use of information has occurred. People everywhere have become empowered by digital knowledge and are collaborating to utilize information in innovative ways. Much of this shift, however, hasn't been applied to the invention processes in life sciences, especially in contrast to other industries. The opportunity and our vision for Clinical Open Innovation are found here.

There is ample evidence that this opportunity is ripe for the picking. First, there has been a massive growth in publicly-available data along with clear work models and technologies to link data across domains. Second, advanced technologies exist to find and then visualize information for new insights and rapid decision-making. Third, the two-way capabilities of the internet have enabled a massive crowd of users to engage in the information like never before, bringing their own insights and ideas to the table. Last, and perhaps most important of all, there is a great untapped reserve of motivated talent eager to help us advance the mission of fighting disease.

The opportunity in front of us is the establishment of open, collaborative environments where these disruptive forces are tapped and channeled into a wider, more participative model of work. The Lilly Clinical Open Innovation Team is working to realize this opportunity by establishing what we call an *Open Clinical Intelligence Network (OCIN)*.



"Innovation means invention implemented and taken to the market. And beyond innovation lies disruptive innovation, which actually changes social practices."

- Henry Chesborough, Open Innovation

What is an Open Clinical Intelligence Network?

Let's answer this question by first exploring what we believe the network will produce and then explore the model we use to guide its construction. There are three basic products: *knowledge*, *utilities*, and *participation*.

Knowledge

The internet produces *knowledge* because it runs on a simple currency – the hyperlink. With this simple construct, massive webs of information continuously link together producing a supply of open knowledge that traditional, closed systems cannot begin to match. The internet is a generative knowledge system because by its very nature it is driven to connect the dots.

Wikipedia is a testament to the internet's generative powers. Today, it houses more than 3.5 million hyperlinked articles which have been edited more than 450 million times. Millions of users from all corners of the globe and walks of life have freely donated their knowledge and time to build the wiki. No other traditional, closed-system encyclopedia even comes close to Wikipedia's size, usage, diversity, and transparency.

This same sort of power can be unleashed for all things clinical. The Open Clinical Intelligence Network we envision will be a first-class internet system. Like Wikipedia, it will fully leverage the internet's inherent ability to generate new knowledge by enabling the citizens of the world to connect the clinical dots.

Utilities

The internet is about more than knowledge, however. It also offers a wealth of practical *utilities*. This is made possible by a familiar tool called a web-browser. This ubiquitous piece of software can be found on most computers, mobile phones and increasingly on everyday items including our automobiles, appliances, and TVs. Modern web-browsers are practical because not only do they make text clickable, they also support highly visual, interactive web apps.

Tools like Google's search engine make it easy for anyone with a web-browser to locate information. The utility of the internet in recent years has advanced well

beyond search. Domain-specific applications of every sort are only a click away and most cost little to nothing. With modern internet applications you can manage projects, explore stock markets, track the latest news, visualize the solar system, shop the world, manage your health, or be a citizen scientist. And this can all be done from practically anywhere with any number of devices.

The potential for clinical internet applications is high and largely untapped. We envision an Open Clinical Intelligence Network filled with intelligent, browser-based applications ranging from search tools that understand clinical semantics, to interactive visualizers, to situational apps that mash-up public data. The OCIN will be a rich repository of interconnected knowledge with an open app store that makes clinical knowledge consumable and actionable.

Participation

Finally, the internet is a system of *participation*. Its ethos goes beyond knowledge generation and practical utilities to the users themselves. The internet is a massive interconnected crowd of people. Its real power lies with its ability to allow much of the world's population to quickly self-organize and then work and play together. The internet works because it invites participation.

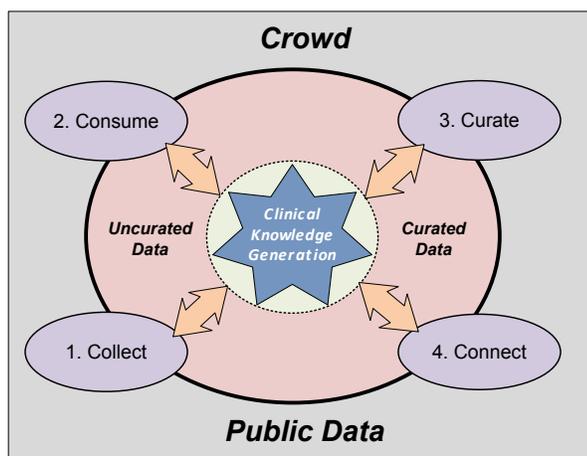
As evidence, witness the popularity of Facebook. This social site is popular because it helps people self-organize into communities with shared interests and a disposition to participate. It's key to know that Facebook does more than build communities. It is also generative. For example, each time a Facebook user likes a post or tags faces in a photo, new information is connected into the network. This knowledge is then leveraged by a multitude of Facebook apps to bring real utility to the community.

The OCIN is fully open for participation. We believe its success hinges on an engaged, self-organizing, well-connected clinical crowd. Like Facebook, it will blend knowledge generation into an ecosystem filled with practical apps all available on the fabric of a people-centric social environment.

The 4C Model

The Open Clinical Intelligence Network is a social, knowledge-generation system filled with useful apps. With this understanding, we can derive a simple model to guide its construction.

Our model, which we call the 4C Model, mixes the basic tenets of the internet, including openness, knowledge, and the crowd, with four specific activities that interact to produce a generative system. These activities are: *collect*, *consume*, *curate*, and *connect*.



OCIN 4C Model

Collect

This activity is concerned with the “webification” of data. Today, a lot of clinical data is public and available on the internet. Unfortunately, this data is often encoded in a variety of digital formats which often limit its usefulness. These range from digital scans of paper FDA documents to formal databases of trials, drugs, and investigators. The *collect* activity is concerned with making this data much more consumable on the internet. We are focusing our efforts on converting public clinical data into standardized formats with improved interfaces, links, and semantics. We will also synchronize the data into open, crowd-friendly environments such as a wiki. Our first target is clinical trial data from the NIH Clinical Trial Registry.

Consume

Once data has been collected and webified, it is important to seed the OCIN with web applications that give it utility. To bootstrap this activity, we have built an internet app (mash-up) that will allow the clinical

crowd to explore clinical trial data. This includes interactive timelines and geographic visualizations for collections of trials selected by the user with a multi-faceted filtering capability. By way of comparison, imagine being able to explore the more than 100,000 trials in the registry as easily as you can shop in Amazon’s web store. Our goal is to inspire others to build more apps using the webified data collected into the OCIN.

Curate

This activity gets to the heart of knowledge generation. Museum curators are responsible for acquiring, categorizing and organizing artifacts into exhibits. In this same manner we will enable the clinical crowd to create their own clinical exhibits. They will organize things like trials into collections that then get tagged with semantics such as NIH Medical Subject Headings (MeSH terms). This tagging process will generate new knowledge. As the OCIN grows, we intend to link the clinical collection data into a Wiki which the crowd can use to improve the data by adding annotations, correcting mistakes and providing missing information. All knowledge contributed to the OCIN will be open. Creative Commons public domain licensing (CC0) will be used throughout.

Connect

The final activity in the 4C model is about connecting people and enabling crowd participation. It will connect the clinical knowledge collected and curated in the OCIN with the vast array of existing tools for sharing and social networking. To initiate this process, we will implement online forums that give a voice to the users of the network. Our goal from the start is to engage the crowd, listen carefully to their needs, and respond quickly with new data, apps, and features.

In summary, the 4C Model combines proven tenets of the internet, including crowd participation and openness, with four specific activities: *collect*, *consume*, *curate* and *connect*. We believe that the resulting network will bring the generative powers of the internet to the world of clinical development and advance our strategy of “reinventing invention.”

The Value of an Open Clinical Intelligence Network

With a model to guide bringing an OCIN to life, we can turn our attention to its effects. With any Open Innovation effort, it is important to know that transformations often emerge in ways that no one predicts. That said, we do fully expect that the application of open models of work to clinical development will cause value to emerge in several known categories. These include *productivity*, *diversity*, and *knowledge*.

Productivity

The first and most obvious value of an OCIN is making it simpler and faster to find answers. Participants will have open access to a gallery of clinical utilities, including faceted search tools, interactive visualizations, and hyperlinked data - all presented in humanized social tools and networks. This will give them the ability to quickly answer common, but often difficult clinical questions, including: What are the comparative trials? Where are the Investigators located? Who is in the marketplace?

It is important to point out that our goal is to empower OCIN participants to continuously grow and improve the utility of the network. The OCIN technical platform is being architected in a way that allows participants with technical skills to easily extend the utility of the network. We will insist on standard, open interfaces to clinical data, and then encourage developers to create and share situational apps (mash-ups) that meet particular needs. As a result, we expect a virtuous cycle of productivity improvement. We believe the utility of the network will grow and improve over time.

Diversity

A healthy open network grows and thrives because it brings value to a wider variety of participants. While the OCIN will clearly be valuable to traditional researchers and clinicians, it's our belief that an even bigger value will come from opening the network to new participants.

We predict that new non-traditional communities will emerge and self-organize around clinical research

intelligence. Patients for example, could use the network to build, curate and discuss personalized collections of clinical information relevant to their health condition. Patient communities could organize and run their own observational trials. OCIN participants could even express unmet medical needs or voice their unique perspectives on trial designs.

Diversity is valuable. It produces more ideas. It fosters intellectual cross-pollination. It breaks down traditional boundaries. We believe that a clinical intelligence network that is fully open will increase diversity and with this increase bring valuable new insights, approaches and perspectives to clinical research.

Knowledge

As we explained in the 4C model, a fundamental effect of open networks is the generation of new knowledge. We believe the OCIN should make it easy and natural for anyone to participate in knowledge-generation activities, such as linking trials to regulatory documents, tagging and rating items, assembling clinical collections, and connecting disease targets to trials. OCIN will leverage the scale, speed and knowledge of the crowd to directly enrich the information in ways traditional, closed methods cannot.

"The more a piece of knowledge becomes available, the more valuable it potentially becomes, because of the wider array of possible uses for it."

-James Surowiecki, *Wisdom of Crowds*

As people in the OCIN interact with information and with each other, another type of knowledge will emerge: insight into the network itself. Modern information technology has the ability to semantically graph information networks. This enables deep insights into the network. These include the strength of

relationships, heuristics, and patterns of behavior and usage. For example analysis of the network can reveal which trials or targets are referenced the most, who in the network is leading the innovation ideas, and what's trending in the network. The ultimate value of a network results from observing it.

In summary, we believe that knowledge access, diversity and participation will breed important innovation and productivity for clinical development. We cannot predict the growth pattern, the specific communities, or the exact information that will emerge. However, we are certain that the value of the network will grow the more knowledge becomes available.

Conclusion

The Lilly Clinical Open Innovation Team is committed to transforming clinical development – for science, for innovation, and for those suffering from disease. Our vision is to shape open information, generative systems, and the crowd into a valuable Open Clinical Intelligence Network. This bold plan can reshape how clinical development gets done.

We have the necessary ingredients. The methods, data, tools, environment and ultimately our strong motivation are ready. We welcome your participation in this open innovation. *Let's go!*

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