Optimized Clinical Trial Patient Recruitment
Powered by Patients and Their Data

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Executive Summary

After decades of drug development research and billion of dollars of investment, the pharmaceutical industry in the US has built a megawarehouse of data on their clinical trial patients. This data is siloed, fractured, and never shared in fear of losing any market advantage. Because of this, fewer drugs make it to market, and more lives are lost. But clinical trial patients, as rightful owners of the data, have access to their own clinical trial data, and we believe, we can empower patients to not only access, but share their information so to bring greater transparency to this murky market and inspire cross-collaboration among pharma.

In an answer to this, our team has created Clinico, a web platform where patients can upload, manage and share their medical and clinical trial data with researchers and pharmaceutical companies. Clinico is the only platform that incentivizes cross-collaboration among pharmaceutical companies to bring more drugs to market cheaper and faster, while also giving data ownership and its benefits back to patients.
# Table of Contents

- **Executive Summary** 2
- **Problem Statement** 4
- **Proposed Solution** 5
- **User Research** 7
  - User Interviews and Key Findings 7
    - Participants / Patients 7
    - Contract Research Organizations (CRO) 8
    - Pharmaceutical Companies 8
    - Biostatisticians 9
  - Personas 11
    - Patient Persona: Kathy 11
    - Researcher Persona: Jeremy 12
- **Solution Details** 13
  - User Flow 13
    - Patient Side 13
    - Researcher Side 16
  - Business Model 19
  - Revenue Model 21
    - Grow, Keep, Get Customer Strategy 22
    - Demand Generation Map 23
    - Competitive Landscape 24
    - Key Partners 25
  - Solution Architecture 26
    - Data Architecture 26
- **Conclusion** 29
- **Future Considerations** 29
- **Appendix** 31
Problem Statement

Traditional clinical trials are extremely expensive, proprietary and siloed. Pharmaceutical companies spend $240 billion each year recruiting patients and conducting clinical trials to bring new drugs to market, and despite the high levels of spending, only 17% of all research studies are ever published for the public to read. The lack of transparency among pharmaceutical companies has introduced redundancy in clinical trial studies, slowed process improvement in trial design and management, and contributed to the high average cost of individual trials. Because the companies hold the data of the patients and clinical trials proprietarily, the patients themselves and other researchers lose out on any future benefits from being able to share and access that data even though it is rightfully their data.

Additionally, of the 17% of studies that are published, rarely are negative or inconclusive findings (or the study protocols or participant-level data) ever published or shared publicly. And if negative outcomes are published, its published several years later and often published on company websites where it is extremely hard to locate. Negative outcomes though are equally important as positive outcomes for target validation or invalidation purposes as quoted in Hayes and Hunter’s paper, "Why is publication of negative clinical trial data important?" (2012):

“This is important because, for key targets, many companies will be working on the same target in parallel, but without sharing all their knowledge in the hope of retaining important commercial advantage. This gives rise to the potential waste of vast sums of money on compounds for which the molecular target has essentially been invalidated, but the data are not publicly available. This becomes even more important if data that has been published to validate these targets pre-clinically is not always reproducible (Prinz et al., 2011). Because most compounds do fail at phase IIa (Arrowsmith, 2011b), spending large sums of money on compounds doomed to fail is to the commercial disadvantage of everyone; therefore, we strongly believe that all clinical trial data should be made publicly available in a timely manner."

Pharmaceutical companies do not want to tarnish their reputation in any way or lose a market advantage among their competitors, so they refuse to collaborate at all costs. Research has shown

1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3514755/
though, that an increase in collaborative efforts between companies for novel targets or mechanisms might be more cost-effective and time-efficient. Pharmaceutical companies’ productivity is at an all-time low and collaboration may be key to bring down the cost and reduce time to market for drug research and development.

An examination of GSK’s published pipeline in 2007 versus that in 2011, and Pfizer’s pipeline in 2008 versus 2011 reveals that over 90% of compounds that were in phase II in 2007 and 2008, respectively, were no longer in the pipeline of 2011. This may be because of some toxicity or other strategic reasons, but a significant proportion of attrition (51%) seems to be due to lack of efficacy. This “failure of efficacy” information is of course valuable to further efficient and cost-effective drug development between pharmaceutical companies but is either unavailable or extremely hard to find.

This is a critical failure of the pharmaceutical industry in the United States - billions of dollars are wasted, research is stalled, drugs are not making it to the market, lives are lost - all because pharmaceutical companies do not want to pose any risk of losing any slight competitive advantage among their peers. It’s time that patients come first.

**Proposed Solution**

The previous section outlined the current competitive landscape in the pharmaceutical industry and public’s clear need for data sharing and collaboration. To break this barrier, we envision building Clinico, a web platform where patients can upload, manage and share their medical and clinical trial data with researchers and pharmaceutical companies.

Right now, because negative clinical trial outcomes are not often made known, patients have access to a very powerful set of data that is rightfully theirs to access and share. We believe that by creating a marketplace with Clinico, patients can then upload and be paid for access to their clinical trial data and outcomes (medical notes, scans, blood tests, etc, acquired while on a trial). This scenario is ripe to disrupt the industry because honestly, pharmaceutical companies may be frustrated but also interested as paying customers. They may not prefer that their data be shared publicly, but may choose to partake.

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in the marketplace anyway to purchase insights into their competitors. We believe this tension is where there is room for innovation and reshaping the dynamics in the industry.

**High level overview of Clinico**

With this data sharing platform, Clinico aims to benefit both the patient and researchers community. It encourages the patient to be more data aware, empowers them to share their data to contribute to the medical research, and provides them with financial rewards if their data is used. To researchers and pharmaceutical companies, Clinico opens up access to previously highly guarded aggregate and patient level trial data. Companies can leverage this newly available data to improve their trial design, mitigate known risks/mistakes, and save on drug development cost.

**Key Solution Benefits**

- Empowered patient data ownership
- Cost savings by eliminating duplicative efforts
- New discoveries through improved access to data
- More drugs to market with decreased overhead
User Research

User Interviews and Key Findings

As part of the process to understand the existing challenges in the clinical trial space and validate our proposed solution, we were able to connect and interview with over 15 people over the past few months. Interviewees include but are not limited to participants of clinical trials, trial managers on site, and researchers and managers in pharmaceutical companies. The key findings from the most relevant ones are summarized below.

Participants / Patients

We conducted one-hour long phone interviews with 4 ex-clinical trial patients about their trial experiences. Some of them are now active patient advocates, who publicly share their experiences to raise awareness and drive improvements in clinical trial operations.

Key Findings

- Patients participate in clinical trials for two main reasons: improvement of their own conditions, and contributing to treatment development that will help other patients in the future.
- Patients experience common frustrations during the end-to-end process:
  - Discovery: Finding the right trial is challenging as patients have to navigate through the jungle of clinicaltrials.gov.
  - Enrollment: There is a long waiting period (4 - 5 weeks) between enrollment and trial start due to slow contracting process. As a result potential treatment urgently needed by patients is delayed.
  - In trial: Process is often opaque. Patients receive little to no feedback about their performances during the trial, and have limited insights into their conditions or next steps. Sometimes patients would get dropped from a trial because their biomarkers fall out of range, but they are not given any explanations on why they are dropped.
- Patient data exists but is hard to access. Patients need to be proactive and take the initiative themselves, and the process is not straightforward.
• Data collection and reporting is incomprehensive: some qualitative data are not collected during doctor’s visit, and patients feel concerned about reporting side effects.
• Level of expertise varies across sites. Personalized care and knowledgeable personnel at the trial site are important for patient overall experience and retention.

Contract Research Organizations (CRO)

We interviewed 2 trial managers who manage the setup and oversee the day-to-day operations of clinical trials on the CRO side.

Key Findings
• When a pharmaceutical sponsor put out a bid for a clinical trial, different CROs will respond with their offerings with cost estimations. Whether a trial has monitoring, data management, or payments coordinated by CROs is totally dictated by the bidding process. Every trial is different.
• Clinical trial setup can be a lengthy process with back and forth budget negotiations.
• Delays in trial operations are most usually related to the specific trial sites due to contracts drafting and budget negotiations.
• Pharmaceutical sponsors often prefer to use well known institutions for trial sites. Even though smaller facilities can have quicker turnaround time and lower overhead cost, they favor the more recognizable institutions in case the trial gets published.

Pharmaceutical Companies

We interviewed 5 people from different pharmaceutical companies. They work on clinical trial design and monitoring, and their roles range from clinical research associate, medical director, to clinical trial process improvement specialist.

Key Findings
• One key issue in trial design is to decide what data should be collected, as there is no easy way to capture all insights and detect all deviations that happen during a trial.
• The value of data from previous clinical trials comes at the cohort level. Individual patient data is harder to generalize and less useful.
• Patient retention is critical to the success of trial operation. It is currently a reactive process, and some people have been devising ways to better engage patients.

• As different aspects of a trial might be outsourced to different vendors, there lacks a centralized database for all patient data. Different logins to separate systems are needed, and aggregate data analysis is usually done in Excel by bio-statisticians.

• There is an inherent tension between CRO and pharmaceutical sponsors - sponsors have to rely heavily on the reports from CROs, and yet CROs are reluctant to be held responsible for (say if their payment is dependent on) the trial performance.

• Clinical trial data from other companies can potentially be useful, but is almost impossible to get as companies are very protective of their data. Companies leverage competitive intelligence teams to research and stay informed about their competitors.

• Even when there might be opportunity for collaboration, the division of responsibilities between companies gets tricky so people don't do it.

Biostatisticians

Biostatisticians apply statistical methods to study questions relating to the health of people - as individuals or members of population. In the context of clinical trials, biostatisticians perform analysis on clinical trial data to generate insights and provides statistical support to the studies. We interviewed 2 biostatisticians who have worked on clinical trial data.

Key Findings

• Clinical trial data has standards, but its format is highly dependent on the protocol of the trial. Data is usually collected at the patient level.

• The participants don’t usually have access to their own data, at least not during the trial.

• Pharmaceutical companies buy prescription data from IMS for market research, and electronic health record data for clinical decision making and R&D uses. The raw data and results from clinical trials are tightly guarded by the company and not shared publicly.
Personas

Based on our interviews, we created 2 personas to summarize our findings and guide solution design.

Patient Persona: Kathy

Background

Kathy is a business development manager at software company. She has a family with 2 kids, and they live in Greenville, South Carolina.

Kathy was diagnosed with Type I diabetes when she was a kid. Over the years she has learned to manage her conditions without letting them affect other parts of her life. Because of her long history with the disease, she is knowledgeable and knows where/how to look for signs of concern. Besides her day job, she actively participates in online patients community to share her experiences and look for latest medical researches on the disease.

Goals & Motivations

Living a busy life, Kathy wants an easy way to stay informed about the latest treatment and medication options, and help people whom she met on the online community to improve or control their conditions.

Frustrations

Kathy was enrolled in a phase III clinical trial a few years ago. She felt that the onsite coordinator wasn’t very knowledgeable or experienced, and the process was less than transparent. It was a big commitment in terms of time and effort, and yet she did not feel appreciated for her participation. After the trial, when she wanted to access her own data to understand her progress, she had to call up different people, and the data was raw and hard to understand. There was no portal for her to access or analyze that data.
Researcher Persona: Jeremy

Jeremy Clancy
Researcher

Background
Jeremy works on clinical research development for a leading pharmaceutical company. He lives in San Francisco, California.

Jeremy helps design clinical trials, and his responsibilities include developing inclusion/exclusion criteria for trial participants, selecting trial sites, deciding patient visit frequency and data collection procedure, and etc. When a trial is underway, he visits trial sites to understand how well the process is followed on the ground, and if any data is missed in the collection process. He uses the feedback to improve design for future clinical trials.

Lately there has been a push to make clinical trials more personalized and proactive against patient dropouts in his company.

Goals & Motivations
Given how costly clinical trials are, Jeremy wants to ensure they are properly designed, and all data needed for measuring drug efficacy and getting FDA approval is collected in the process.

Frustrations
Jeremy finds it challenging to think of all the data that should be collected before the start of a trial. When a trial fails to produce positive results, he doesn’t know if it is due to the design or execution, as the level of expertise for staff tends to vary a lot across different sites. Additionally, patients dropout can lead to trial delays and even invalidate a trial’s potential findings. Jeremy would like to bake preventative measures in his design to mitigate these dropout risks.
Solution Details

Based on our user research and several rounds of idea iteration, we have created high fidelity screen designs and developed high level architecture for the envisioned solution.

User Flow

Below diagrams and screens walk through how Clinico patients upload their data and how research institutions can then access that data.

Patient Side

**Overall Flow**
Key Screen 1
Patient creates own health profile based on disease indication, medication, location

Key Screen 2
Data Dashboard then displays all the data they’ve uploaded (light blue indicates that there is data, dark blue indicates that data has not yet been uploaded)
Key Screen 3
Patient reviews any clinical trials/medical facilities they've been a part of

Key Screen 4
Patient account payments information to track payments from research institutions
Researchers search by company/drug/therapeutic area

Key Screen 1
Researchers search by company/drug/therapeutic area
Key Screen 2
Researchers specify inclusion/exclusion criteria based on the type of trial they’re recruiting or looking for.

Key Screen 3
Researchers are presented with search results based on similarity of patient groups and similarity of trials.
Key Screen 4

Trial summary. Researchers can see similar trials and reviews of trials from patient perspective.

Key Screen 5

Researches can generate their own patient data by surveying patients of previous trials or patients interested in trials.
Business Model

It’s important to us as a team that we are creating a product with a viable business model. Please see the details below. We believe that pharmaceutical companies will pay to gain access to data that of their competitors (that is rightfully owned and shared by patients on our Clinico network). This pricing is based on our knowledge of the market, current average spend of pharmaceutical companies on patient-level external data (i.e. Genentech was reported as recently purchasing patient-level data from 23andme for $3,000 per patient).

1. Charge organizations based on a subscription model
2. Pay patients through profit-sharing model

<table>
<thead>
<tr>
<th>STARTER</th>
<th>BASIC</th>
<th>FULL</th>
</tr>
</thead>
<tbody>
<tr>
<td>FREE</td>
<td>$50-100k/month*</td>
<td>$100-200k/month*</td>
</tr>
</tbody>
</table>
| - Aggregate statistics
  - Preview patient populations
| - Full access to data
  - Data analytics tools
  - Starter benefits
| - Open communication with patient
  - Starter + Basic benefits
Revenue Model

So given our business model, what is the scale of our impact?

Global Clinical Trials Market

$40B

Clinico SOM

$1.3B

Patient Recruitment: 30% of CT Budget

Clinico SOM: 10% market share
Grow, Keep, Get Customer Strategy

Getting customers is really hard. We have outlined a strategy to not only get customers, how best to keep them and continue to grow our company to be a scalable, sustainable model.

GET
- Provide samples of insights and data available to pharma companies
- Direct sales to small-to-mid cap pharma/biotech companies who are interested in knowing what the bigger players are doing and how best to compete

KEEP
- High quality customer service
- High quality data, that’s “sliceable” to a level that’s helpful and useful to guide sponsor company research
- Continue to grow database of patients and disease areas

GROW
- Expansion outside of cancer + diabetes to other specialty disease areas
- Expansion to additional services outside of data sharing (ie: community management, patient engagement, retention)
- Expansion of analytics capabilities (not just more data, but how do we make this data as meaningful as possible, and aggregated in a way that’s meaningful and useful)
Demand Generation Map

We know that to generate demand among our customers we need to put aside a significant budget to raise our brand awareness among the community. This is our plan to do that.

**Demand Generation Budget**

- **One on one meetings**: $25k/year for 20 companies
- **Pharma/Biotech conferences**: $10k * 5 events
- **Blockchain conferences**: $10k * 5 events
- **Health Tech Groups**
- **Blockchain Groups**
- **Research Journals/Blogs**
- **Sponsored content**: $2k for 5 publications

Budget ~$125k/year
Competitive Landscape

It’s important that we have an understanding of other companies out there trying to do what we’re doing. Here we have outlined the competitive landscape. Ed also recently published an article on Medium that outlines a deep-dive view into what these companies are offering and what gaps are still left in the market.

Health Data Marketplace

- EHR
  - MedChain
  - HealthWizz
  - HealthLinkages

Genomics Data

- zenome
- LUNA
- EncrypGen
- syapse

Phone-based Health Data

- CoverUS

General Consumer Data Sharing

- BITMARK
- YouBase
- wibson
- datum
Key Partners

Partners are critical to ensuring our success. Here we’ve outlined our relationships below.

<table>
<thead>
<tr>
<th>Name or Description of Potential or Actual Partners</th>
<th>What you Want or Get from Them?</th>
<th>What They Want or Get from You (Must have?!)</th>
<th>Current Status (Hypothesis? In discussion?, …)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Former Clinical Trial Patients</td>
<td>Request their data, upload to our system</td>
<td>Pay them for an initial contribution to our system</td>
<td>In discussion, need to develop a plan to outreach to a ton of patients</td>
</tr>
<tr>
<td>Patient Advocacy Groups</td>
<td>To help recruit past patients that maybe the first contributors to our platform</td>
<td>Providing an additional way to support their patients (compensation and access to a community)</td>
<td>Hypothesis, have ID’ed a few groups, and now to reach out and start making partnerships</td>
</tr>
<tr>
<td>Data Capture Companies</td>
<td>Converting medical data to digital data</td>
<td>Partnership with our system, we could provide them with more customers</td>
<td>Critical part of our success and data management and that they’d be willing to collaborate</td>
</tr>
</tbody>
</table>
The solution architecture describes how our website can be powered using scalable services from a cloud service such as Amazon Web Services. As shown above, clients can connect to the website using a mobile or full sized client. This connects them to the API service which activates a web server. This web server serves the pages and information as requested by the user. The data is stored in a combination of MS SQL Server instance in combination with Amazon S3 file storage services for non-structured data like images of scans or prescriptions. The SQL Server stores most of the information including the log transactions for all data interactions. Services take the data and store it in aggregate form to the Redshift columnar database for to enable high performance for the analysis queries from the web server.

Data Architecture

The data model that will power Clinico has a few constraints and we narrowed it down to the following properties:

1. It should be able to model the different entities that are interacting with the system while capturing their multifaceted interaction.
2. It should be able to store the different kinds of data that will eventually be collected and stored from the patient. This should include types of data that we have not currently come across.
3. It should be able to accurately and granularly store the interactions each entity makes to the
data including all reads, writes and updates.

Below are key entities of the data model along with a brief explanation. It should be noted that all
identities are modelled as as LONGINT, names as VARCHAR unless otherwise specified:

1. **Patient** - this entity models the users of the system. We store demographic information,
   payment information as well as information that will be used to search for the user from a
   research perspective.
2. **Purchaser** - This entity represents the purchasers i.e. the users of the data available on our
   platform. Their interactions with the data are heavily logged in `access_log_transactions`. We also
   note to see whether a purchaser is also an entity the patient has interacted with during their
   medical history. This enables us to provide the user with granular privacy settings that blacklists
   certain entities from viewing their records.
3. **Permissions** - This self explanatory table stores the permissions a user has given for each of their
   health records.
4. **Health_Admin/Trial_conductor** - this entity represents the entities that provides the health
   services to our users, and the entities from which the patient has access the health records.
5. **Trial** - This contains metadata and information about trials that were conducted by a conductor
   and an entity that allows patients to link their data to, if applicable. This will be the entity that
   will be updated with information about quality and shown in search results as appropriate.
6. **Patient_record** - This entity gives us an overview of the high level data batch of data provided by
   a patient during each upload batch. This could be at multiple levels of granularity, which will be
   captured in other tables.
7. **Patient_record_detail** - This table captures the detailed record of the users health record. This
   includes the type of record, the raw as well as process record. This is connected to a data type
   table which provides more context for how each record of the type is stored, and provides
   context and details for how the data needs to be process by any ETL or reporting process
   reading or performing aggregations from this table.
8. **User_task & user_task_detail** - These are very similar to the tables described above, except that
   they provide the researchers an ability to provide flexible tasks for a user to complete, and also
   contains the ability to track their completion.
Conclusion

We hope that by putting power back into the patients hands, we can create a future where patients are active partners in creating life-changing medicines for those who need it most.

Clinico, for us, is a true culmination of our experience at the School of Information. This idea started in the fall of our first year, where we all worked together and won “Best Potential Startup” at the CalHacks hackathon. Since then the idea has changed as we’ve pivoted. We’ve been able to integrate learnings from our core classes and electives - thinking not only about the privacy, security, and market dynamics, but also of the social impact on our users, the business case, and the data structure that would serve as the backbone of our system.

Through this project, we’ve delved into the technical and the theoretical, and we’re proud to graduate from the I School having worked and built this together, while learning and growing ourselves. With Clinico, we want to turn the pharmaceutical industry upside-down. Even though our time at the I School has come an end, we’re only getting started.

Future Considerations

In the future, we want to consider clinical trial recruitment and think through how a system like this could be used by pharmaceutical companies to recruit patients for clinical trials in a more targeted, patient-centered way. Right now the need is great and there is no solution that allows pharmaceutical companies a targeted way to find people who are most likely to be engaged in a trial. They rely on broad advertising (billboards, radio) or by way of a physician. There is no current solution that puts the patients at the center of the recruitment process or allows patients to be compensated for their time and effort while looking for or being screened for a trial.

We believe the market for this space to be a big. For example, the global clinical trials market is a $40B annual market. One third of all trial expenses are dedicated to patient recruitment. If we were to capture just 10% of that market, we’re then entering a $1.3B share of market. We believe the
recruitment angle is the best hook to get pharma listening and we look forward to exploring this idea further.

We also want to further explore how blockchain can enable and disable what we’re trying to do. There is a lot of buzz about blockchain application in healthcare, but there is also quite a bit of hesitation around its implementation. We want to think strategically about blockchain as a tool, not as a solution, and we look forward to continue to unpack this in the future months.

While we are proud of what we built for our final project, we’re also excited that this project has earned recognition outside of the School of Information. Namely, at the Haas’ Launch Accelerator Program and at the Frontier Innovation Awards. Through these channels, we’ve pitched to over 20 VCs, gaining feedback along the way about the viability of our idea. We’re currently one of 15 finalist teams at the Frontier Innovation Awards competing for a $1M term sheet. We’re proud to represent the I School community in this way.
Appendix

Potential patient data types to be stored in the system based on user research

<table>
<thead>
<tr>
<th>Document / data type</th>
<th>Example</th>
<th>Data format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td>Name</td>
<td>Structured data in DB</td>
</tr>
<tr>
<td></td>
<td>Contact info</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Data of birth</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Medical history</td>
<td></td>
<td>Structured data in DB</td>
</tr>
<tr>
<td>Lab and test results</td>
<td>Blood pressure</td>
<td>PDF / png</td>
</tr>
<tr>
<td></td>
<td>Urinalysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blood urea nitrogen (BUN), creatinine, and glucose</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CT scan</td>
<td></td>
</tr>
<tr>
<td>Doctor visit notes</td>
<td></td>
<td>Free text</td>
</tr>
<tr>
<td>Side effects reports</td>
<td></td>
<td>Free text</td>
</tr>
<tr>
<td>Discharge summaries</td>
<td></td>
<td>Free text</td>
</tr>
<tr>
<td>Medications</td>
<td></td>
<td>Free text</td>
</tr>
<tr>
<td>Immunizations</td>
<td></td>
<td>PDF / png</td>
</tr>
<tr>
<td>Allergies</td>
<td></td>
<td>Free text</td>
</tr>
</tbody>
</table>

Other studies that have informed the creation of our solution

- [Systematic review of participants’ attitudes towards data sharing: a thematic synthesis](#)
- [Attitudes of research participants and the general public towards genomic data sharing: a systematic literature review](#)
- *(An older paper)* [The Use of Medical Records in Research: What Do Patients Want?](#)