

# **MYR - THE REPRODUCIBLE RESEARCH TOKEN**

MyIRE, Inc., June 2018

Medical and scientific research is facing a crisis of reproducibility and fraud.<sup>1, 2</sup> The number of published scientific studies is on the rise,<sup>3</sup> but so is the number of studies retracted due to fraud or found to be otherwise irreproducible.<sup>4</sup> We believe a significant contributor to the crises of reproducibility and fraud is that the marketplace lacks a comprehensive scientific software platform which supports all stages of a clinical study – from hypothesis generation and budgeting to regulatory submissions and study publications. Instead, researchers today are faced with numerous, disparate and closed-source tools offered by multiple software vendors to support various stages of any study, with such tools not readily supporting interoperability or the fluid transfer of data from one stage to the next or amongst multiple organizations or groups within an organization – thereby challenging the integrity of study data. We believe that such impediments to data integrity and transferability, as well as the failure of many existing software tools to mandate consistency in the execution of protocols, contribute not only to the crises of reproducibility and fraud, but also to high costs and waste associated with medical and scientific research and to poor medical advice and patient care.

In this white paper, we present My Integrated Research Environment (“MyIRE”) as a novel technology that we believe will increase clinical trial throughput and simultaneously increase their process and data integrity. As a comprehensive scientific software platform, MyIRE is designed to provide end-to-end support for clinical trials supported by blockchain-enabled features to facilitate data integrity and transferability, as well as to confirm consistency of protocol execution, and therefore generate improved study results through reproducibility. We present a disruptive economic model showing how we anticipate this result will be achieved for a fraction of the cost associated with, and resulting from, using existing tools. We believe this combination of a novel technology and the proposed economic model provides a compelling case for a new cryptocurrency token.

## 1. SUMMARY

Most published research results are not reproducible.<sup>5</sup>

We believe the most significant factors contributing to high rates of irreproducibility are the lack of documentation and standardization in experimental methods which we attribute, in large part, to poor interoperability among disparate scientific software tools. Because no existing software adequately addresses all of the needs of research scientists, most researchers are forced to use many scientific software tools from a variety of vendors. Unfortunately, these varied scientific software tools often do not directly interface with each other - even tools offered by a single vendor. Consequently, researchers are left working against and around the tools at their disposal. The resulting “telephone game of research software tools” creates hugely unproductive silos that hinder the scientific research process by degrading process and data integrity, resulting in an inefficient process and repeatedly flawed conclusions.

The problems associated with these communication silos are further exacerbated by closed-source tools with their lack of source code transparency and inconsistent availability. In addition, the inability of users to generate code modifications to closed-source tools for broad availability in support of reproducible research further aggravates the problem. A study conducted by one clinical trial investigator (an “Investigator”) using a particular closed-source tool may be incapable of replication by another Investigator using a different closed-source tool (or even the same closed-

---

<sup>1</sup> John Ioannidis. “The Reproducibility Wars: Successful, Unsuccessful, Uninterpretable, Exact, Conceptual, Triangulated, Contested Replication.” *Clinical Chemistry* 63:5 (Mar 2017).

<sup>2</sup> Andrew M. Stern, Arturo Casadevall, R. Grant Steen, Ferric C. Fang. “Financial Costs and Personal Consequences of Research Misconduct Resulting in Retracted Publications.” *eLIFE* (14 Aug 2014) 10.7554/eLife.02956.

<sup>3</sup> Clinicaltrials.gov. “Trends, Charts, and Maps.” 14 May 2018. 15 May 2018.

<sup>4</sup> Michael Roston. “Retracted Scientific Studies: A Growing List.” *The New York Times*. 28 May 2015.

<sup>5</sup> Marcus R. Munafò, Brian A. Nosek, Dorothy V. M. Bishop, Katherine S. Button, Christopher D. Chambers, Nathalie Percie du Sert, Uri Simonsohn, Eric-Jan Wagenmakers, Jennifer J. Ware, John P. A. Ioannidis. “A Manifesto for Reproducible Science.” *Nature* 1 (10 Jan. 2017).

source tool with source code updates) for a variety of reasons – for example, the Investigators may be unable to code identical study instructions mandated by the protocol. In contrast, an open-source tool would offer transparency, consistency of availability and the ability to make code modifications broadly available. Accordingly, to combat the foregoing problems, we have designed the core of the MyIRE platform to be open source.

MyIRE is a complex, customizable software that modularly composes clinical trials and avoids disjointed technologies. MyIRE borrows from the computer science world, where an "Integrated Development Environment" allows developers to collaborate worldwide using shared, standardized tools. MyIRE uses the modular composition of clinical trials, in connection with blockchain technology, to provide process and data integrity for medical and scientific research.

MyIRE's disruptive economic model shows how we believe this technologic solution could be scaled for a fraction of the cost associated with using existing tools. We believe this model is fundamental to the creation of a marketplace for reproducible, reusable digital research objects capable of operating in a highly regulated environment.

## 2. PROBLEM: The Reproducibility Crisis and Increase in Scientific Article Retractions

### 2.1. Summary

Scientific research is a consensus-based process whereby researchers develop hypotheses – specific statements of prediction regarding a phenomenon occurring in the universe – and then test those hypotheses. Advancements in scientific research occur when researchers share their hypotheses and test results through publication in a manner that facilitates reproducibility. Scientists reproduce results of published predictions in order to verify them. When scientific research results are not reproducible by others, scientists waste precious time and money and the results are called into question. In medical science, clinicians, patients, and regulators rely on scientific research to make healthcare decisions. Many clinicians and patients do not recognize how pervasive the problem of published but unreproducible scientific research is, and how profoundly it affects care delivered and received.<sup>6</sup> Clinical trial results may be misleading or not useful for patients, and guidelines (which many clinicians rely on to guide treatment decisions) may not adequately acknowledge the poor quality of the data on which they are based.<sup>6</sup> Medical stories in mass media often do not meet criteria for accuracy, and many stories exaggerate benefit and minimize harms. We believe that the use of the MyIRE platform will support reproducible research and help to address these problems.

### 2.2. The Reproducibility Crisis

In 2005, Dr. John Ioannidis argued that most published research findings in his own field of biomedicine probably were false.<sup>7</sup> Ioannidis' argument applied to everything from epidemiology to molecular biology to clinical drug trials<sup>7</sup> Ioannidis accompanied his first article, which provided theoretical arguments for the existence of a reproducibility crisis, with a second article that provided convincing evidence of its reality. Ioannidis compared 49 highly cited articles in clinical research to later studies on the same subjects. 45 of these articles had claimed an effective intervention, but "7 (16%) were contradicted by subsequent studies, 7 others (16%) had found effects that were stronger than those of subsequent studies, 20 (44%) were reproduced, and 11 (24%) remained largely unchallenged."<sup>8</sup> In other words, subsequent investigations provided support for fewer than half of these influential publications. A 2014 article co-authored by Ioannidis on 37 re-analyses of data from randomized clinical trials also found that 13 of the re-analyses (35%) "led to interpretations different from that of the original article."<sup>8</sup>

Subsequent evidence confirmed that the crisis of reproducibility had compromised entire disciplines. In 2012 the biotechnology firm Amgen tried to reproduce 53 "landmark" studies in hematology and oncology but could only

---

<sup>6</sup> John P.A. Ioannidis, Michael E. Stuart, Shannon Brownlee, Sheri A. Strite. "How to Survive the Medical Information Mess." *European Journal of Clinical Investigation*. 47 (2017) p. 795

<sup>7</sup> John Ioannidis. "Why Most Published Resource Findings Are False." 30 Aug. 2005/26 May 2018. <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124>

<sup>8</sup> David Randall, Christopher Welser. "The Irreproducibility Crisis of Modern Science." *National Association of Scholars*. April 2018: 25.

replicate six.<sup>9</sup> In that same year, the director of the Center for Drug Evaluation and Research at the Food and Drug Administration estimated that up to three-quarters of published biomarker associations could not be replicated.<sup>9</sup> A 2015 article in *Science* that presented the results of 100 replication studies of articles published in prominent psychological journals found that only 36% of the replication studies produced statistically significant results, compared with 97% of the original studies.<sup>9</sup> An analysis of 98 psychology papers published in 2015 by 90 teams of researchers managed to replicate satisfactorily the results of only 39% of the studies investigated. Ioannidis' alarming papers crystallized the scientific community's awareness of the reproducibility crisis—and not just among scientists conducting medical research. Ioannidis said that his arguments probably applied to “many current scientific fields.”

The MyIRE platform is specifically designed to address the critically important issue of reproducibility highlighted by Ioannidis. By enforcing data integrity and process integrity, MyIRE is designed to ensure reproducibility.

### 2.3. Retractions and Fraud

The percentage of articles retracted because of fraud is roughly 10 times higher than it was in 1975.<sup>10</sup> Indeed, a review of more than 2,000 articles retracted by major journals revealed that more than two-thirds were retracted because of some type of fraud.<sup>10</sup> Some studies indicate that hundreds of thousands of patients have been placed at risk of improper medical care due to enrollment in fraudulent studies or the administration of treatment based on fraudulent studies.<sup>11</sup> In China, scientific fraud is considered so serious that it is now punishable by death.<sup>12</sup>

Retraction Watch estimates that roughly 500-600 papers are retracted per year,<sup>13</sup> which is roughly equal to the 2017 monthly average number of registered studies with posted results.<sup>14</sup> As one example of the cost of these retractions, every paper retracted because of research misconduct costs about \$400,000 in funds from the US National Institutes of Health (NIH).<sup>15</sup> Accordingly, if 500 papers are retracted per year and two-thirds of the retractions are due to fraud, then fraudulent articles cost the NIH \$133 million per year – a cost that we believe could be significantly reduced through the use of the MyIRE platform.

For example, in 2016, Duke University was sued under the federal False Claims Act.<sup>16</sup> The lawsuit alleges that \$200 million of research grants were based on fraudulent data. Duke has admitted that data was altered. Under the whistleblower statute, Duke could be fined \$600 million if it loses this case.<sup>16</sup> This potential \$800 million loss for Duke is significant, especially when compared to the \$946 million Duke spends annually on scientific research.<sup>17</sup> We believe that using the MyIRE platform could prevent the use of altered data and the potentially adverse financial consequences resulting from the use of such data. In addition, in 2017 The University of Illinois at Chicago paid \$3.1 million after a researcher falsified data to conceal misconduct.<sup>18</sup> We believe falsification is another issue that may be preventable through the use of the MyIRE platform.

<sup>9</sup> David Randall, Christopher Welsler. “The Irreproducibility Crisis of Modern Science.” National Association of Scholars. April 2018: 26.

<sup>10</sup> Cory Franklin. “Commentary: Should You Put Your Trust in Medical Research.” Chicago Tribune. 8 Jun 2015.

<sup>11</sup> Andrew M. Stern, Arturo Casadevall, R. Grant Steen, Ferric C. Fang. “Financial Costs and Personal Consequences of Research Misconduct Resulting in Retracted Publications.” *eLIFE* (2014) 10.7554/eLife.02956.

<sup>12</sup> Ivan Oransky, Adam Marcus. “Chinese Courts Call for Death Penalty for Researchers who Commit Fraud.” *Stat*. 23 Jun. 2017.

<sup>13</sup> Alison McCook. “Retractions rise to nearly 700 in fiscal year 2015.” Retraction Watch. 24 Mar. 2016. <<https://retractionwatch.com/2016/03/24/retractions-rise-to-nearly-700-in-fiscal-year-2015-and-psst-this-is-our-3000th-post/>>.

<sup>14</sup> Clinical Trials.gov. 15 May 2018. 16 May 2018. <<https://clinicaltrials.gov/ct2/resources/trends/>>.

<sup>15</sup> Kerry Grens. “The Price Tag of Scientific Fraud.” *The Scientist Magazine*. 15 Aug. 2014.

<sup>16</sup> Ray Gronberg. “Responding to Whistleblower’s Claims, Duke Admits Research Data Falsification.” *The Herald Sun*. 2 Jul. 2017.

<sup>17</sup> BestColleges.com. “Highest Research & Development Spending.” 16 May 2018.

<<https://www.bestcolleges.com/features/colleges-with-highest-research-and-development-expenditures/>>.

<sup>18</sup> Jodi S. Cohen. “The \$3 Million Research Breakdown.” *Propublica*. 26 Apr. 2018

Scientific fraud also incurs non-monetary costs. Reputational harm to researchers and research institutions, damage to researchers' careers (who in some cases have done nothing wrong themselves), the institutional costs of investigating suspected fraud, the misdirection of public policy, and the misleading of other scientists who pursue false leads are also costs and delays worth avoiding.

### 3. SOLUTION

The MyIRE ecosystem will be a comprehensive scientific software platform designed to leverage the benefits of modular, cohesive tools and blockchain technology in order to create transparent, auditable, traceable, tamper-proof and immutable records. It will act as a bridge among organizations and departments that do not readily communicate with each other in highly regulated environments where assuring data provenance is imperative, but not easily achieved.

#### 3.1. Hypothesis

We believe that a cost-effective, researcher-friendly scientific software platform for easily conducting reproducible research can enable more research to be produced for a fraction of the cost and time currently expended.

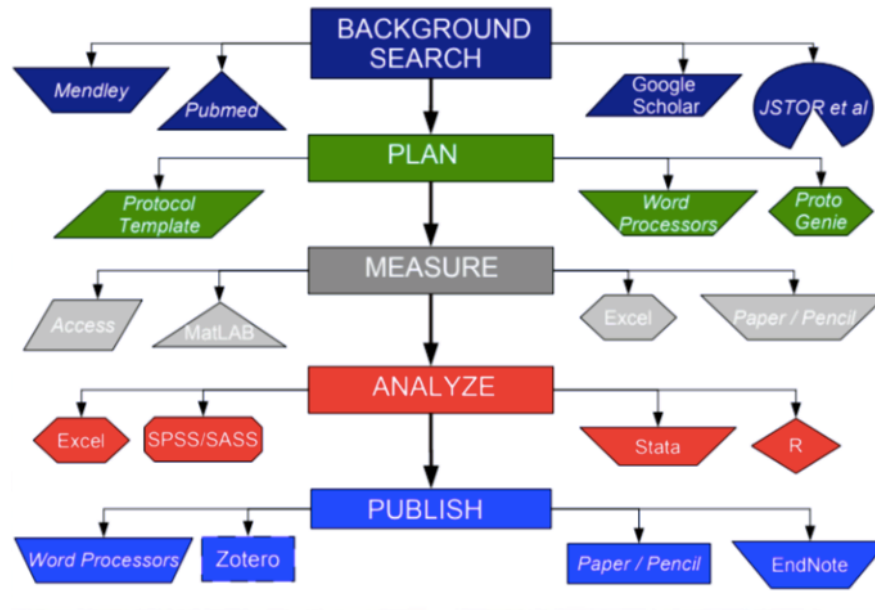
We believe that a contribution-based rewards model is an incentive-aligning, viable strategy toward global reproducible research.

#### 3.2. Rationale

The combination of various design, data, analysis, and presentation processes tend to produce increasingly faulty research findings with each additional technology used. This phenomenon is called bias. Bias can be reduced, and reproducibility enhanced, through standards in design, data, analysis and presentation deployed through the use of a comprehensive technology platform with features to encourage transparency and consistency.

Currently, scientific claims are created and asserted via software but conveyed in text-based research publications. Researchers must use many scientific software tools from a variety of vendors and then must convert the software-based results from such various tools into text publications. That conversion process all too often generates imprecision and inaccuracies, which affects reproducibility.

The graphic below presents an illustration of the competitors' tools that Investigators today would use to complete a clinical trial, from background search through publication.



Often, these tools enforce reporting requirements rather than helping Investigators or scientists create reproducible processes of inquiry. In addition, tools offered by a single vendor as well as tools offered by different vendors often do not directly interface with each other, and this “telephone game of research software tools” creates silos that hinder the scientific research process, resulting in inefficient, repeatedly flawed conclusions. As a result, we believe that both process and data integrity degrade with each additional technology that researchers must use. As described above, these communication silos are further exacerbated by closed-source tools.

Digital research objects (“DROs”), on the other hand, are gaining popularity as a standard for identifying research components and reducing bias. DROs can include all of the necessary digital tools such as code, data, scripts, workflows, applications, services, or intermediate outputs that collectively are used to re-generate the final output of a research study (the text-based paper) and verify the results. Together with the human-readable paper, DROs can provide an authoritative record of research.

DROs can be stored separately from underlying private data and metadata such that they can be moved from one project to another without compromising information privacy boundaries. The capacity to easily and securely exclude private data and metadata from DROs can dramatically reduce barriers to marketplace style sharing. DROs intended for public exposure should be stored separately from underlying private data and metadata such that they can be moved from one project to another without compromising information privacy boundaries.

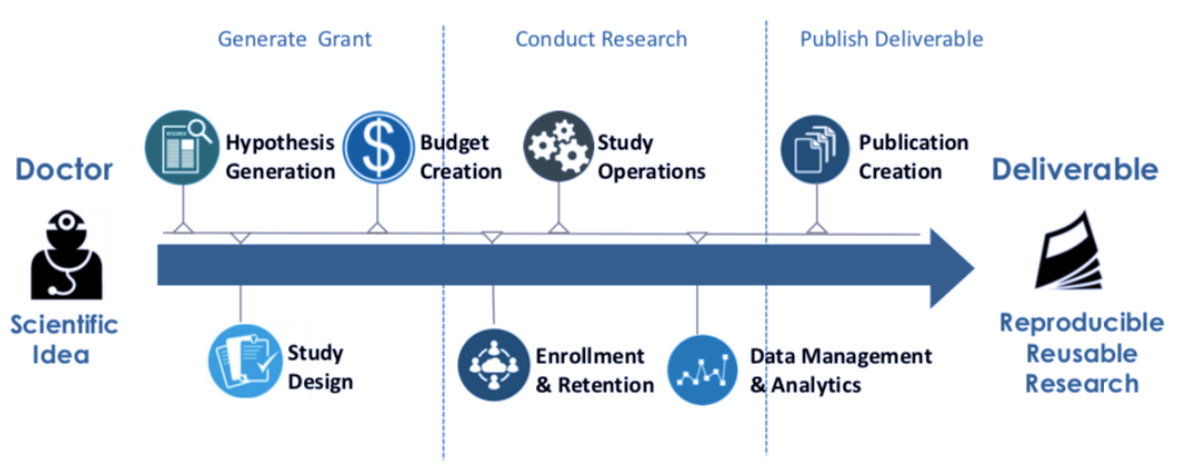
For instance, a form for data collection and the data collected by the form can be stored as separate research objects in a study. The form itself is intellectual property which may be created or licensed by the Investigator. The form’s design, presentation, and analysis methods are all potential sources of bias. If a second Investigator attempts to re-create the form in software, these sources of bias may confound an attempt at reproducibility. Instead of re-creating the form, the same form may be shared through the use of DROs made available by one Investigator to another who seeks to reproduce the study with a separate group of patients without the transfer of the original study participants’ data. With two Investigators using the same digital form to collect data independently, the possibility then exists to combine those two data sets directly because they come from the same form. Both of these consequences tend to increase reproducibility.

An Integrated Research Environment (“IRE”) allows researchers worldwide to collaboratively compose research objects into modular, portable reproducible research projects out of common tools, thereby generating consistent research objects, including electronically as consistent DROs. As reproducibly computable, composable research objects, DROs maintain provenance for process, data and computation integrity, and can facilitate operations in highly regulated hypothesis testing environments such as the Food and Drug Administration (FDA), the Japanese Pharmaceuticals and Medical Devices Agency (JPMDA), or the Federal Information Security Management Act

(FISMA). Based on the IRE model, we have designed the MyIRE platform to facilitate the creation and support of consistent DROs.

MyIRE can leverage modular, cohesive tools and blockchain technology to maintain interoperable process and data integrity through the entire research lifecycle. We do so by enabling DROs to form blockchain blocks that can be audited to provide proof that the objects haven't been altered or fabricated at a later date. Moreover, in the form of blocks, they provide reproducible point-in-time verification of the underlying experiment and its environment. The MyIRE platform will, therefore, be designed so that DROs may be hashed or stored in the blockchain blocks, with such DROs generating data through their application in a study. The MyIRE platform will then be designed to process and store study data either inside or outside of the blockchain, thereby facilitating the privacy of the data and the transferability of the DROs from one Investigator to another to enable reproducible research.

We envision MyIRE becoming a utility for scientific integrity: a sharable distributed system for secure, compliant collaboration on reproducible scientific research, optimized for readily available commercial commodity hardware. As illustrated in the graphic below, MyIRE will provide a seamless, integrated platform that endeavors to negate the issues that arise when using today's variety of disparate and disconnected closed-source tools. And, unlike competitor's tools, by using blockchain technology along with an open-source platform, the MyIRE platform provides its users with the ability to see exactly what code and data was used at any point during the trial process. This means that MyIRE is designed to facilitate the inviolate data and transparency required to provide process and data integrity, and therefore reproducibility.



#### 4. ARCHITECTURE CONSIDERATIONS

We designed the MyIRE platform to possess the following characteristics:

- 4.1. **Privacy:** Mechanisms for the exclusion of private metadata and data from shared work, along with mechanisms to anonymize and exclude personal information lower barriers to marketplace-style sharing. Although blockchain-based, encrypted storage is currently a viable option for storing private study data, we apply the principle of least privilege with regard to data access. This means that every potential accessor of data should only be able to access the information needed for his, her, or their particular purpose.
- 4.2. **Transparency:** An open source platform that increases trust in the baseline operating transparency of clinical trial organizations. The MyIRE ecosystem allows participants to create proprietary clinical studies within the platform and license them as they see fit, without vendor lock-in concerns.
- 4.3. **Immutability:** The ability to identify if and when underlying processes and data have been altered in order to provide a baseline for trust.

- 4.4. **Disputability:** The ability to address disputes or diverging objectives which may arise within the MyIRE community or particular user groups (*e.g.*, institutions conducting clinical trials) by enabling members of the community or group to code “forks” with respect to blockchain-enabled aspects of the underlying platform or of a specific study protocol to take them into one or more differing directions. Distributed governance via blockchain has seen organizational success and popularity; as a result, we plan to build resolution and compatibility mechanisms into the MyIRE platform to allow for dispute resolution with different consensus rules.
- 4.5. **Decentralization:** A decentralized model, which opens the possibility of more transparent usages that are less susceptible to corruption or control by any single entity. We believe a decentralized model would deter those agents (*e.g.*, funding agencies, etc.) who may wish to affect the behavior of others (*e.g.*, researchers) with the purpose of achieving certain desirable outcomes and would encourage the open sharing of useful information possessed by various participants in the scientific community.
- 4.6. **Modularity:** Modular components covering the entire study lifecycle from idea through publication to facilitate the collection of and ability to share data, with studies able to be broken down into components such as through the use of DROs, as discussed above.
- 4.7. **Composability:** Composable interoperability achieved through the use of modular DROs to describe units of work based on projects and their components, and through the use of definable and documentable application program interfaces (“APIs”) operating to support research and data interchange standards. Through such modularity and APIs, components of a research study may then be interchanged for functionally and/or inter-operably equivalent components in other studies. In addition, elements of an individual research study that are not able to be interchanged in a testable, unbiased way may be included in the identified bias of the study.
- 4.8. **Computability/Deployability:** The ability of users of the MyIRE platform to easily share, compose and recompute on shared DROs. The digitized nature of DROs combats the issue of non-digitized modules not being conducive to reuse in substantially the same or similar format as their original use.
- 4.9. **Increased Participation:** A low hardware threshold, by not requiring special hardware, encourages maximum participation. We aim to show that we can sustainably reach global reproducible research with MyIRE's economic model.

## 5. THE MYR TOKEN

### 5.1. MYR Summary

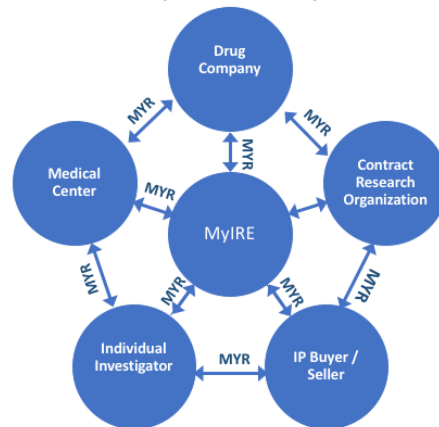
In order to power the MyIRE platform for the conduct of reproducible research, a native cryptocurrency, the MyIRE (“MYR”) token, will be created and distributed to network participants. MYR tokens will be the underlying economic unit of the MyIRE marketplace. We believe freely available and public standards such as ERC20, ERC223, etc., to be core to the instantly scalable business models that cryptocurrencies facilitate.

The MYR token will allow value created in the system to be captured by the system itself. Just as almost all countries have their own currency, requiring transactions on the MyIRE platform to be in MYR will set up incentives to remain in the system. If all transactions were in, for example, ether (the native cryptocurrency of Ethereum), then participants would not be storing value in the MyIRE platform. By requiring that transactions use MYR, participants will become claim holders on the system, which we believe will generate the same incentives that have helped ecosystems like Ethereum (and many so-called “alt-coins”) explode into active and diverse communities. Meanwhile, systems without their own native coin or with a “pegged” coin (*e.g.*, Mastercoin)<sup>19</sup> have struggled to develop growing or even sustainable communities or all-important network effects.

---

<sup>19</sup> Trevor Koverko, Chris Housser. “Polymath The Securities Token Platform.” Feb. 2018. 16 May 2018. <<https://polymath.network/whitepaper.html>>.

## The MyIRE Ecosystem



### 5.2. Token Economics

We believe there are strong demand drivers for the MYR token.

#### 5.2.1. For Use with the MyIRE Platform

To use the MyIRE platform, users must purchase MYR tokens. Prospective users will only be able to purchase the products, services, and modules offered by or through the MyIRE platform with MYR tokens. Moreover, only paying clients of MyIRE will have access to the ecosystem.

#### 5.2.2. Increase in Offered Products and Services

We believe the value of the MYR token will increase as the number and value of products offered by or through the MyIRE platform increases. We believe that more offered products and services will increase demand for access to the MyIRE platform, thereby increasing demand for MYR tokens.

#### 5.2.3. Increase in Liquidity

We believe that more participants in the MyIRE ecosystem will increase the liquidity of the MYR token. We believe that a more liquid token can lead to more stability and higher value.

#### 5.2.4. Transaction Fee

MYR will be a revenue generator for MyIRE, Inc. In addition to the subscriptions fees MyIRE will collect from users of the platform, we plan to charge a percentage-based transaction fee – to be paid with MYR tokens - on each purchase between third parties within the MyIRE ecosystem. We believe this fee will create a recurring and increasing revenue stream for MyIRE, Inc. and also increase demand and value for MYR tokens.

## 6. PROOF OF CONCEPT

Our four-node proof of concept infrastructure consists of Network, Infrastructure, Compute, and Storage nodes. We used non-specialty, commercially available hardware with machines consuming 50% maximum capacity in terms of processing, RAM, and storage. Power optimization was not taken into account. Rather, the potential for maximal participation was targeted by optimizing for mass commercial availability. Control plane segregation, separation of concerns, and principles of least privilege were three factors also considered in our design.

Internal validity and end-user acceptance of individual modules was tested via deployment across multiple organizations. We put into place legally binding contracts for decentralization of those modules with differential

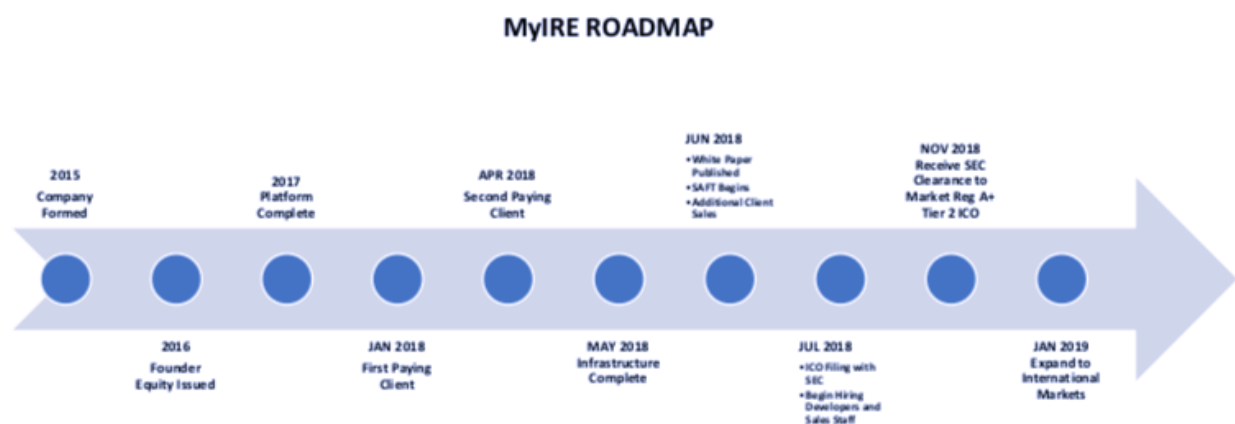


privacy restrictions that may be regulated. Module provenance and history were stored with the capacity for each organization to verify integrity. Modules were stored separately from data owned by each organization, so data integrity and module integrity can be verified independently.

Modules comprising the process of creating a hypothesis, testing it, and publishing the results were composed into projects. Multiple projects were run through the system. The results of one of the projects are ready to submit for peer review with the expectation that the results will be published in a journal with a reference to MyIRE. That project will be repeatable, in the manner described above, by anyone and anywhere -- thereby minimizing instrumental bias. The project was forked to a different node of the same specification. Alterations were made to individual data collection elements within the forked study. Interfaces remained interoperable and the project was auto-documenting. Underlying data was not transferred between machines.

## 7. ROADMAP

Our history is summarized below.



Our plan is to complete an initial coin offering (ICO) using the Regulation A+ Tier 2 rules adopted by the Securities and Exchange Commission (SEC). This process will require that offering documents to be filed with, reviewed by, and “qualified” by the SEC. This type of filing is advantageous, because (i) we may use public advertising or general solicitation to market the offering (ii) purchases are not limited to only “accredited investors”, and (iii) there will be no sales restrictions on the tokens, therefore allowing the establishment of trading markets (iv) the filing requires audited financial statements from MyIRE as well as periodic disclosure of MyIRE financial information, which increases transparency between MyIRE and users of the MYR token

## 8. MARKET FUNDAMENTALS

MyIRE is a participant in a large and growing industry.

### 8.1. Medical Research

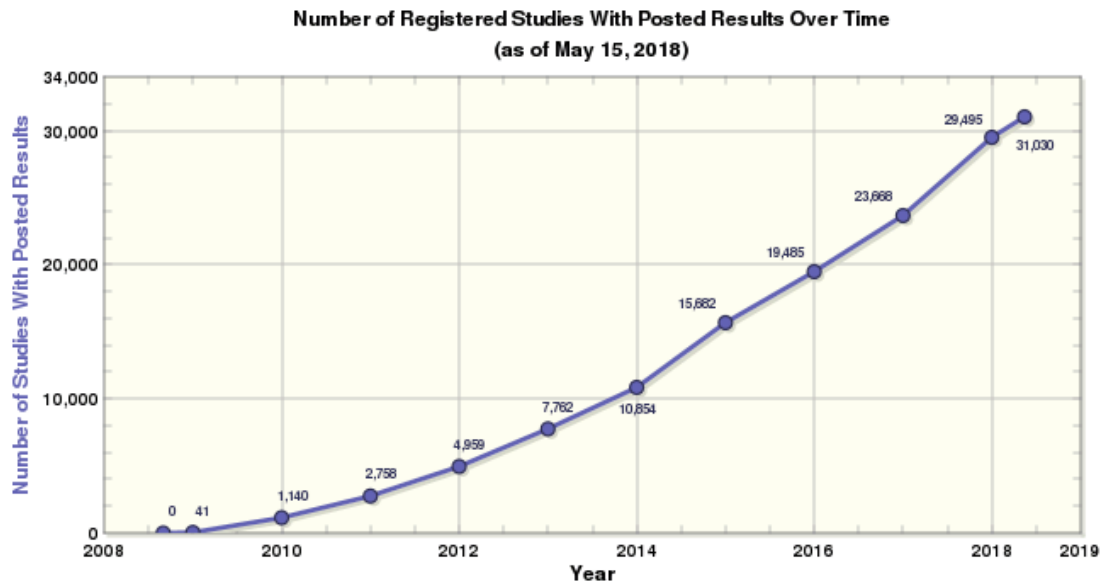
Worldwide, over \$100 billion is invested every year in supporting biomedical research, which results in an estimated one-million research publications per year.<sup>20</sup> Spending trends are positively impacted as a result of several factors, including major biopharmaceutical companies’ efforts to replenish revenues lost from the so-called “patent cliff” of recent years, increased access to capital by the small and midcap biotechnology industry, and recent increases in pharmaceutical approvals by regulatory authorities.<sup>21</sup>

<sup>20</sup> Ian Chalmers, Paul Glasziou. “Avoidable Waste in the Production and Reporting of Research Evidence.” *Lancet* 374 (2009) 86-89.

<sup>21</sup> IQVIA Holdings 10K. 31 Dec. 2017: 7.

## 8.2. Clinical Trials

The strong market factors for medical research are also reflected in the large increase in the number of clinical trials. According to ClinicalTrials.gov, the number of registered clinical studies with posted results grew from 19,485 in 2016 to 31,030 today, an increase of almost 60% (see below graph).<sup>22</sup>



Source: <https://ClinicalTrials.gov>

However, costs are ballooning. Studies estimate that it now costs somewhere between \$161 million and \$2 billion to bring a new drug to market.<sup>23</sup> One particularly well-known and often cited paper by DiMasi arrives at a total pre-approval cost estimate of \$802 million in 2000 dollars to develop a single drug. Inflated to 2018 dollars, this estimate is \$1.17 billion.<sup>23</sup> More recent estimates of drug development costs are around \$1.3 billion to \$1.7 billion.<sup>23</sup> Although experts debate the accuracy of various cost estimates, there is widespread agreement that clinical trial costs are substantial and rising. According to a 2007 article as cited by Collier, the average cost of developing a drug had risen at a rate 7.4% higher than inflation over the past two decades, mostly due to rising clinical trial costs.<sup>24</sup> Moreover, clinical trial protocols have become increasingly complex, involving numerous assessments, exploratory endpoints, biomarkers, biopsies, and so on, consequently increasing the administrative burden and overall costs of trials.

The industry is also plagued by massive waste and inefficiency. A 2014 study in Nature Biotech showed that only 32% of drugs have a probability of making it to Phase 3 trials, and only one in 10 drugs overall actually makes it to market.<sup>25</sup>

<sup>22</sup> Clinicaltrials.gov. 15 May 2018. 16 May 2018. <<https://clinicaltrials.gov/ct2/resources/trends>>.

<sup>23</sup> Aylin Sertkaya, Anna Birkenbach, Ayesha Berlind, John Eyraud. "Examination of Clinical Trial Costs and Barriers for Drug Development." Eastern Research Group, Inc. 25 Jul. 2014: viii, 4-1.

<sup>24</sup> Aylin Sertkaya, Hui-Hsing Wong, Amber Jessu, Trinidad Beleche. "Key Cost Drivers of Pharmaceutical Clinical Trials in the United States." Clinical Trials 13 (2016) 118.

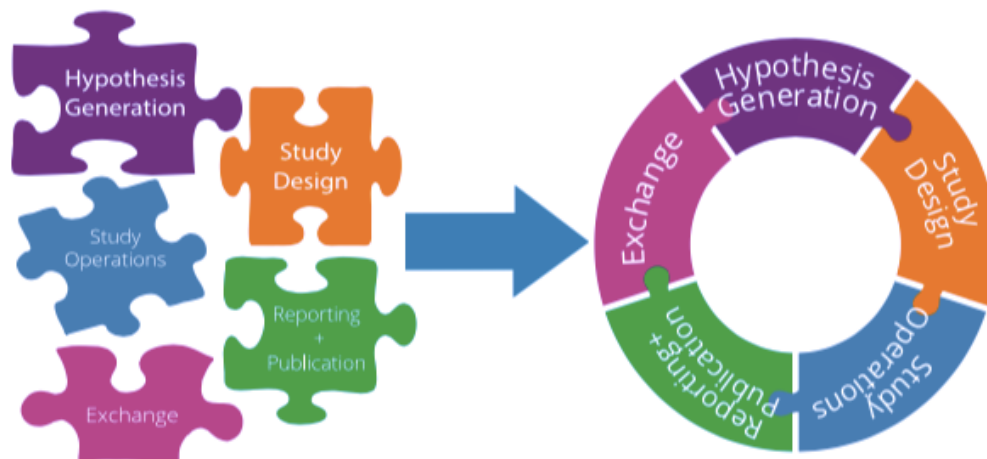
<sup>25</sup> Russ Huss. "The High Price of Failed Clinical Trials: Time to Rethink the Model." Clinical Leader. 3 Oct. 2016. <<https://www.clinicalleader.com/doc/the-high-price-of-failed-clinical-trials-time-to-rethink-the-model-0001>>.

## 9. VALUE PROPOSITION

We believe the MyIRE platform presents a highly attractive business model that is well equipped to address these issues. We also believe that the increased efficiencies that come with using MyIRE will dramatically lower the time and cost barriers needed to create and collaborate on repeatable clinical trials, while also producing results in compliance with applicable laws and regulations. We expect that this cost-effective, Investigator-friendly platform for easily conducting reproducible research will enable more research to be produced at a fraction of the cost and time currently expended. We believe this contribution-based rewards model is an incentive-aligning, viable strategy toward global reproducible research.

### 9.1. Compelling Product Offering

According to Medidata, one of the industry leaders in clinical trials software, up to 25 discrete systems run on a single trial with isolated data repositories.<sup>26</sup> Medidata claims to cover 13.5 of the top 14 trial processes and to have the most complete platform in the industry.<sup>26</sup> As illustrated in the graphic below, we believe the MyIRE platform provides a single, end-to-end integrated solution that works with and contains the functionality of all the current competing tools.



The features of MyIRE’s integrated modules are described below.

- 9.1.1. Hypothesis Generation: Searchable electronic notebook, global citation search, facilitated PubMed search; the ability to highlight, annotate, and tag works, automated bibliography management, automated outline generation, and a guided structured literature review.
- 9.1.2. Study Design: Historical version control, on-the-fly protocol revisions, continuously adaptive trial design, triggers for adverse events, intuitive visual case report form design, intuitive visual study timeline, budget creation, grant management.
- 9.1.3. Study Operations: Expense and invoice tracking, detailed audit log, fine grained access control, participant engagement portal, safe data sharing “rooms”, integrated R software and Python software statistical analysis.
- 9.1.4. Reporting and Publication: Automated citation of study components; exportation for regulatory, compliance, and review; designed for direct PubMed submission, automatic bibliography creation; designed for Clinical Data Interchange Consortium (CDISC) formats, Health Level 7 (HL7) data

<sup>26</sup> Medidata. “2017 Financial Analyst Day.” p. 18 9 Nov. 2017. 16 May 2018. <<http://investor.mdsol.com/events-and-presentations/events>>.

transfer standards, and Electronic Technical Document (ECTD) standards; and interoperability with existing software products.

- 9.1.5. Exchange: Database of reproducible research resources, expertly curated licensable content, author-defined content licensing, designed for secure Health Insurance and Portability and Accountability Act (HIPAA) client collaboration, create derivative works by licensing research.

## 9.2. A Large and Increasing Number of Studies

In 2017, there were 29,201 new studies registered with Clinicaltrials.gov.<sup>27</sup> In addition, the number of studies registered each year has been increasing steadily.<sup>27</sup> The 29,201 studies in 2017 is an increase of 27,082 over the 2,119 registered studies in 2000, which is equal to an annualized growth rate of approximately 17%.<sup>Error! Bookmark not defined.</sup> We believe the tailwind created by this rapid industry growth will add to the growth we expect MyIRE to realize by taking market share from existing competitors.

## 9.3. High Recurring Revenue Model

We believe that approximately half of MyIRE's revenue stream will be subscription based, driven by monthly charges for the life of a clinical trial. Recurring revenue translates to a less variable, more predictable revenue stream. MyIRE participants will be incentivized to maintain a subscription in order to continue to receive necessary updates, upgrades, access to the MyIRE ecosystem, and any “forks” to blockchain-enabled features.

## 9.4. Low Cost Alternative

We believe the modules we sold to our initial customers were one-tenth the cost of competing products even though we sold those modules at full price. We believe we can be the low-cost provider for all our modules.

Furthermore, US law requires the results of medical research for drugs approved by the US Food and Drug Administration to be submitted to a database called ClinicalTrials.gov. Researchers who do not post results within a year of trial completion risk losing grants and can be fined as much as \$10,000 per day.<sup>28</sup> However, according to a 2015 article in +AllTrials, 50% of trial results are not published.<sup>29</sup> When using the MyIRE platform, papers may be automatically generated by the platform at the completion of the trial, thereby lessening the obstacles that lead to results not being published. We believe this ease of publication will lead to cheaper publication without the risk of fines or other penalties that occur when papers are not published or not published on time.

## 9.5. Outstanding Operating Leverage and Return on Assets

Our initial infrastructure is already operational. Going forward, we believe the hardware costs to add an additional customer location will be approximately \$13,000 per location. Assuming that an additional customer location has only one study for that location, we believe the payback period for that capital investment will be approximately 12 months. If that additional customer location has two studies for that location, we approximate that the payback period for the incremental hardware would be reduced to one month. It is important to note, however, that we believe the equipment purchased for the additional customer will conservatively support 100 studies. Therefore, assuming 100 studies for that additional customer's location, we estimate the payback period for the additional hardware cost will be approximately one day.

---

<sup>27</sup> Clinicaltrials.gov. “Trends, Charts, and Maps.” 14 May 2018. 15 May 2018.

<<https://clinicaltrials.gov/ct2/resources/trends>>

<sup>28</sup> Federal Register. “Clinical Trials Registration and Results Information Submission.” 21 Sep 2016/29 May 2018.

<<https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission>>

<sup>29</sup> +AllTrials. “Half of All Clinical Trials Have Never Reported Results.” 20 Aug. 2015.

<<http://www.alltrials.net/news/half-of-all-trials-unreported/>>.

## 9.6. High Margins

Because of operating leverage and a low fixed cost structure, we believe MyIRE will ultimately achieve EBIT margins in excess of 50%.

## 9.7. Dispersed Customer Base

Due to the fact that the medical research field is highly fragmented, such a widely dispersed potential customer base reduces the risk that as the MyIRE network grows, it will become overly reliant on a small number of large customers.

## 9.8. Barriers to Entry

The MyIRE platform is a complex, customizable software. Even though we have designed the core of the MyIRE platform to be open source, a competitor would need to commit significant resources and time to replicate it. Also, the healthcare industry in which MyIRE will operate is highly regulated and subject to a complex set of healthcare laws and regulations, including, among others, the Health Information Technology for Economic and Clinical Health Act (HITECH), and HIPAA. We believe that creating and operating a software product like MyIRE that is also compliant with the substantial requirements of healthcare regulations presents meaningful barriers to entry for competitors.

## 9.9. Future Markets

We believe there are also excellent future growth opportunities for MyIRE outside of the healthcare industry. For instance, the processes for the development of new seeds for agriculture is similar to those used for drug design in the medical field. Accordingly, we believe agricultural companies could increase the efficiency of their product development cycle by incorporating MyIRE into their research and development process.

## 9.10. Faster Research

We believe researchers will complete trials at a faster pace when using the MyIRE platform versus competing products. With the MyIRE platform, workflows become reproducible, which reduces the cycle time from ideation through regulatory approval. We believe the impact will be more research done more quickly and for less cost.

# 10. COMPETITION

## 10.1. Other Cryptocurrencies

While we are unaware of direct competitors to the MYR currency, there are companies that use blockchain technology in a similar way.

- ✓ *Grid Coin* provides an open-source volunteer computing grid which combines the processing power of all individual users for the purposes of scientific research.
- ✓ *Steemit* is a social media platform where everyone gets paid for creating and curating content. It leverages a digital points system for digital rewards.
- ✓ *Bitnation* is a decentralized borderless "voluntary nation" establishing a jurisdiction of contracts and rules, based on Ethereum
- ✓ *Sia* is a decentralized storage platform secured by blockchain technology that leverages underutilized hard drive capacity around the world to create a data storage marketplace.
- ✓ *Dash* is an incentivized peer-to-peer network. Miners are rewarded for securing the blockchain and masternodes are rewarded for validating, storing and serving the blockchain to users.
- ✓ *Monero* provides benefits of a decentralized cryptocurrency. Monero uses ring signatures, ring confidential transactions, and stealth addresses to obfuscate the origins, amounts, and destinations of all transactions.
- ✓ *IOTA* is a distributed ledger that stores transactions as a stream of individual transactions entangled together instead of blocks and stored in sequential chains.

- ✓ *Bytecoin* requires a few parties involved in transactions to sign it in order for the funds to be released. “Multisig” allows for the creation of native escrow services, foundation board wallets, and services with other sophisticated money transfer requirements.
- ✓ *Cure Coin* incentivizes the donation of computational resources, such as GPU’s and CPU’s.

## 10.2. Similar to Domain

The market for clinical trial solutions is highly competitive and rapidly evolving. It is subject to changing technology, shifting customer needs, changes in laws and regulations, and frequent introductions of new products and services. We believe we compete or will compete with firms such as Medidata Solutions, Inc., Allscripts Healthcare Solutions, Veeam, Oracle, Salesforce, IQVIA (formerly Quintiles IMS), Charles River Laboratories, Oracle, Parallax Health Sciences, Cerner Corporation, PRA Health Sciences, Inc. and other large-scale technology providers that offer a range of products and services that compete with MyIRE’s solutions. We also compete with a number of vendors offering applications and systems that compete with MyIRE in specific areas, such as ERT, CRF Health, Bracket, DataTrak International, Inc., Medrio, Inc., Merge Healthcare (an IBM Company), and OmniComm Systems, Inc. We will compete on the basis of several factors, including the following:

- ✓ innovation, breadth and depth of solution offerings;
- ✓ platform capabilities and solution functionality and features;
- ✓ workforce skill set;
- ✓ scalability and upgrade pathways and support;
- ✓ speed, performance, and ease of use of our solutions;
- ✓ product reliability and infrastructure accessibility and security;
- ✓ regulatory compliance;
- ✓ breadth and strength of partnerships;
- ✓ interoperability;
- ✓ financial stability;
- ✓ depth of expertise and quality of our global professional services and customer support; and
- ✓ sales and marketing capabilities, including the ability to create and communicate operational value.

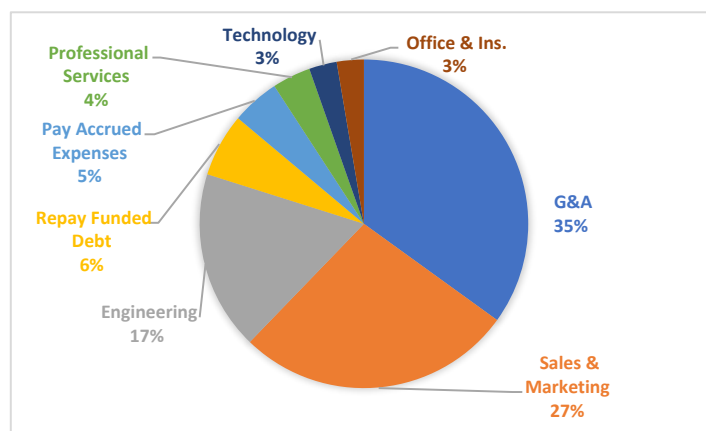
Although most of our potential competitors have greater name recognition, longer operating histories, more product offerings, and greater financial, technological, and other resources than we do, we believe that we compete favorably with our competitors on the basis of these factors.

## 11. USE CASES

Participants in the MyIRE ecosystem will be able to capture clinical trial processes, presentation, and data in a usable digital format so that the entire archive can be transferred to another user and used again quickly and easily, as well as to combine research projects in a wide pool with a design to maintaining privacy boundaries. The MyIRE platform is also contemplated to include functionality that will allow MyIRE ecosystem participants to monetize research work product and other intellectual property, and engage other MyIRE platform participants to perform research, through the use of the MyIRE token.

## 12. USE OF FUNDS

The chart below shows the anticipated breakdown for funds received from the Simple Agreement for Future Tokens (SAFT) and ICO.



Approximately 44% of the proceeds will be used for engineering staff to support the technical needs of a growing customer base; and sales and marketing expenses to generate additional sales.

## 13. EXECUTIVES AND ADVISORS

Mark Graves, Jr. is one of our founders, and the developer of the MyIRE platform. Mr. Graves has served as our chief executive officer, president and chief technical officer since the company was founded in December 2015. Mr. Graves began a clinical research career while still a teenager and has years of experience designing and delivering clinical and preclinical trials. He earned a bachelor's degree from Northwestern University and attended Northwestern University's Feinberg School of Medicine for two years. Mr. Graves brings to the company unique perspective and insights regarding the strategic and operational opportunities and challenges, economic and industry trends, and competitive and financial positioning of our business.

Mark Graves Sr., MD is one of our founders. Dr. Graves is an internist, and is affiliated with Deaconess Hospital in Evansville, IN. He received his medical degree from University of Pittsburgh School of Medicine and has been in practice for more than 20 years. Dr. Graves is a clinical investigator and has worked on more than 100 clinical trials of medications and devices. Dr. Graves has experience in designing trials, writing informed consents, writing protocols, interacting with the IRB, following regulations, and managing and analyzing trial data. Dr. Graves brings to the company significant operational, regulatory, and financial experience as a physician and clinical investigator.

Gregory Folz, CCRP is one of our founders. Mr. Folz is the Administrative Director of Research for the Deaconess Research Institute, where he has overseen the conduct of more than 800 clinical trials. Mr. Folz was recently recognized as "2018 Top 20 Innovators" in the clinical research industry; and is the recipient of the 2016 SCRS Site Tank Award for Innovation, and a finalist for the Society for Clinical Research Site's 2015 Innovation Award for patient recruitment. Mr. Folz serves as a national consultant and speaker on the development of clinical research operations and business structures and has assisted more than a dozen US hospital systems, networks, and physician groups on the strategic growth of their clinical research initiatives. Mr. Folz brings a wealth of clinical trial experience and relationships to the company.

David Giljohann, PhD, has served as a company advisor since 2015, and is the founder/CEO of Exicure, a clinical stage biotechnology company developing a new class of immunomodulatory and gene regulating drugs against validated targets. Dr. Giljohann has been recognized for his work with a Materials Research Society Gold Award, Baxter Innovation Award, Rappaport Award for Research Excellence, NSEC Outstanding Research Award, and as a finalist in the National Inventors Hall of Fame Collegiate Inventors Competition. He was also named to the Analytical Scientist's "Top 40 Under 40 Power List" in 2014. Dr. Giljohann has contributed to over 25 manuscripts and over 100 patents and applications. Dr. Giljohann obtained his Ph.D. in 2009 from Northwestern University. Dr. Giljohann

brings to the company significant operational, regulatory, and financial experience as a chief executive and director in the healthcare industry.

Massimo DiPierro, PhD has served as a company advisor since 2016. Dr. DiPierro is an Associate Professor with tenure at DePaul University in the School of Computing. He is the inventor and chief architect of the Web2Py free open source full-stack framework for rapid development of fast, scalable, secure and portable database-driven web-based applications. Dr. DiPierro has a MSc in Physics from Università di Pisa, and a PhD in Physics from the University of Southampton. He brings 25 years of research IT experience to the company, and a deep understanding of software platforms and data security.

Amer S. Abdullah has served as a company advisor since 2016. Mr. Abdullah spent 10 years with JP Morgan Risk Management structuring and selling derivative products and government bonds. Mr. Abdullah left banking and became an entrepreneur and business owner. Mr. Abdullah earned a bachelor's degree from the University of Chicago. He brings financial and operational expertise to the company.

Michael Stark has served as a company advisor since 2016. He is the Founder and a General Partner at Crosslink Capital where he oversees all investment activities and serves as a portfolio manager for the firm's emerging growth, long/short funds, and all crossover funds. Before forming Crosslink, Mr. Stark was the director of research and an equity analyst at Robertson Stevens covering the semiconductor and software industries. Prior to that, Mr. Stark worked at Intel Corporation. He earned a bachelor's degree from Northwestern University, and an MBA from the University of Michigan. Mr. Stark brings a vast amount of industry and financial expertise to the company.

Michael Harbin has served as a company advisor since 2017. Mr. Harbin is a lifelong entrepreneur with over 20 years' experience in technical operations. He is currently the chief technology officer for VacayHome Connect LLC, a software company that connects vacation rental suppliers to leading sales channels across the world. Mr. Harbin is also co-founder of Whitetail Airlines, a software company that utilizes blockchain technology and digital currencies to deliver more choices to price conscience and brand-agnostic travelers through an "asset-light" distribution model. Mr. Harbin has studied ICOs extensively over the last several years and brings the resulting expertise to the company, as well as a great deal of operational and transaction expertise.

Alan Brothers has been a company advisor since 2017. Mr. Brothers is an Executive Director of The Remix Project, which offers programs and services to youth looking to enter into the creative industries or further their formal education. Mr. Brothers offers creative and marketing talent to MyIRE.

Mark D. Schindel serves as the company's chief financial officer and has been an advisor since 2017. Mr. Schindel spent almost 15 years working in private equity with some of the industry's largest firms including GTCR Golder Rauner, and American Capital. Mr. Schindel has abundant experience in raising and managing capital, deal structuring, acquisitions, divestitures, and refinancing transactions. He has served on the board of directors of multiple portfolio companies. Prior to joining MyIRE, Mr. Schindel was CFO for a variety of businesses, including a software design and development firm. Mr. Schindel earned a bachelor's degree from the University of Illinois, and an MBA from Northwestern University's Kellogg Graduate School of Management. Mr. Schindel brings to the company financial, analytical, and advisory expertise.

Mark Kent has been a company advisor since 2018. Mr. Kent is the Chief Executive Officer of Women's Health Care in Evansville, IN. Prior to joining Women's Health Care, he was the Regional President of all Humana-owned, Florida-based primary care practices. Mr. Kent was responsible for building upon the success of CAC-Florida Medical Centers with expansion and patient growth. Prior to assuming this position, he was Market Vice President of the Ohio and Indiana Senior Products segment of the East Central Region with Humana. His segment was responsible for helping over 250,000 Medicare Advantage members achieve lifelong well-being. Mr. Kent brings healthcare and management expertise to the company.

Jeffrey Lipkowitz has been a company advisor since 2018. Mr. Lipkowitz has worked in entrepreneurship, consulting and private equity. He has focused on analytics and solution architecture throughout his career. Mr Lipkowitz has championed several industries from health care to capital marketing. He attended Purdue as well at University of Chicago focusing on operation research and analytics respectively. Mr. Lipkowitz adds a great deal of sales and marketing expertise and analytics to MyIRE.



#### 14. LEGAL NOTICE

This white paper (“Summary”) has been provided to you for informational and discussion purposes only. Any reproduction or distribution of this Summary, in whole or in part, or the disclosure of its contents, without the prior written consent of MyIRE, Inc. (the “Company”), is prohibited. This Summary does not constitute an offer to sell, or a solicitation of an offer to buy, the Company’s Simple Agreement for Future Tokens (the “SAFT”) or the MYR tokens (the “Tokens”). Neither the United States Securities and Exchange Commission nor any other federal, state, national or foreign regulatory authority has approved the offering for sale, or purchase of, the SAFT or the Tokens. Furthermore, the foregoing authorities have not confirmed the accuracy or determined the adequacy of this Summary, nor is it intended that the foregoing authorities will do so. Any representation to the contrary is a criminal offense. Certain information contained in this Summary constitutes “forward-looking statements,” which can be identified by the use of forward-looking terminology such as “may”, “will”, “should”, “expect”, “anticipate”, “target”, “project”, “estimate”, “intend”, “continue,” or “believe” or the negatives thereof or other variations thereon or comparable terminology. Due to various risks and uncertainties, actual events, results, or the actual performance of the MyIRE Network and the Tokens may differ materially from those reflected or contemplated in such forward-looking statements, and no undue reliance should be placed on these forward-looking statements, nor should the inclusion of these statements be regarded as the Company’s representation that the MyIRE Network or the Tokens will achieve any strategy, objectives, or other plans. This Summary describes our current vision for the MyIRE Network. While we intend to realize this vision, please recognize that it is dependent on quite a number of factors and subject to quite a number of risks, many of which are outside of our control. It is entirely possible that the MyIRE Network will never be implemented or adopted, or that only a portion of our vision will be realized. We do not guarantee, represent or warrant any of the statements in this Summary, because they are based on our current beliefs, expectations and assumptions, about which there can be no assurance due to various anticipated and unanticipated events that may occur. Please know that we plan to work hard to achieve the vision laid out in this Summary, but that there are no assurances that our efforts will result in the full or partial realization of the MyIRE Network. Blockchain, cryptocurrencies and other aspects of our technology are in their infancy and will be subject to many challenges, competition and a changing regulatory environment. We will try to update our community as things grow and change but undertake no obligation to do so.