Use Case #4

Clinical Trials

Standard Clinical Trials

The Problem

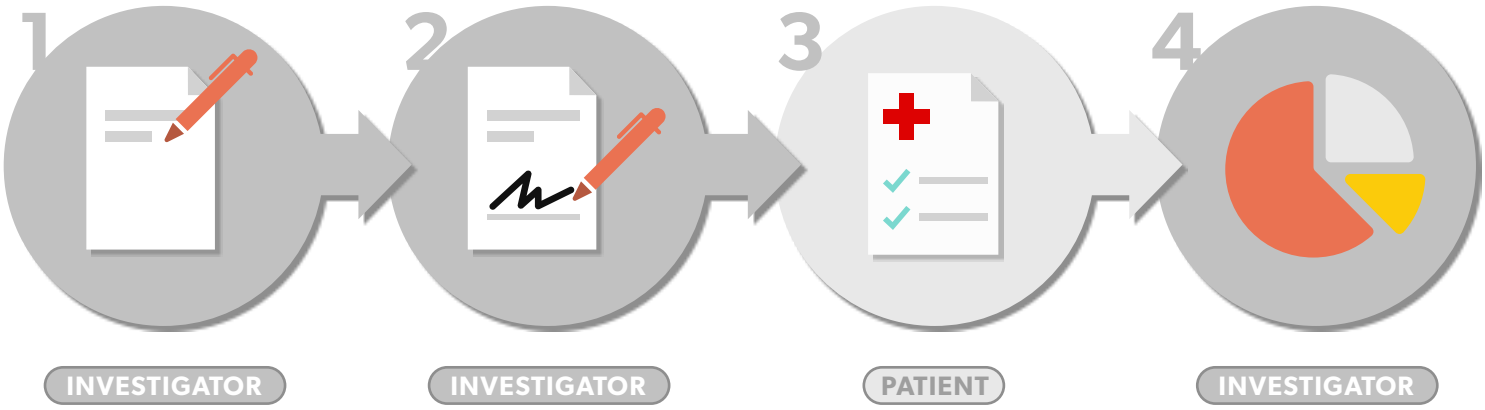
Clinical research is undergoing a crisis of both irreproducibility and hyped up results. The standard procedure for clinical trials today being vulnerable to poor design, opaque methods or data corruption, masked behind a clear lack of transparency.

This crisis has been fostered by conflict of interests, pressure to publish in quantity rather than quality, and to yield positive results to access prestigious journals ("Publish or Perish"). However, step by step, scientific processes can be improved to get closer to its ideal form.

Standard Clinical Trials

Process

Standard Clinical Trial Process



1

Trial Design

The trial must be clearly defined with primary and secondary endpoints, as well as methods of recording and keeping statistics.

2

Patient Enrollment

Patients must give informed and free consent to participate in the trial.

3

Clinical Data Collection

Data is collected through various means and often recorded through double entry.

4

Data Analysis

Data must be analyzed in accordance with the methods defined in the trial protocol.

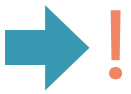
Standard Clinical Trials

Pain Points

Lack of transparency is a major obstacle to a good scientific process

Corruption of the results

Study design, methods and objectives are not always shared prior to a study, allowing modifications to favor the outcome of a favorable trial result. The same applies for the sharing of the data (raw data is often inaccessible), opening a breach for data corruption.



Opacity of study

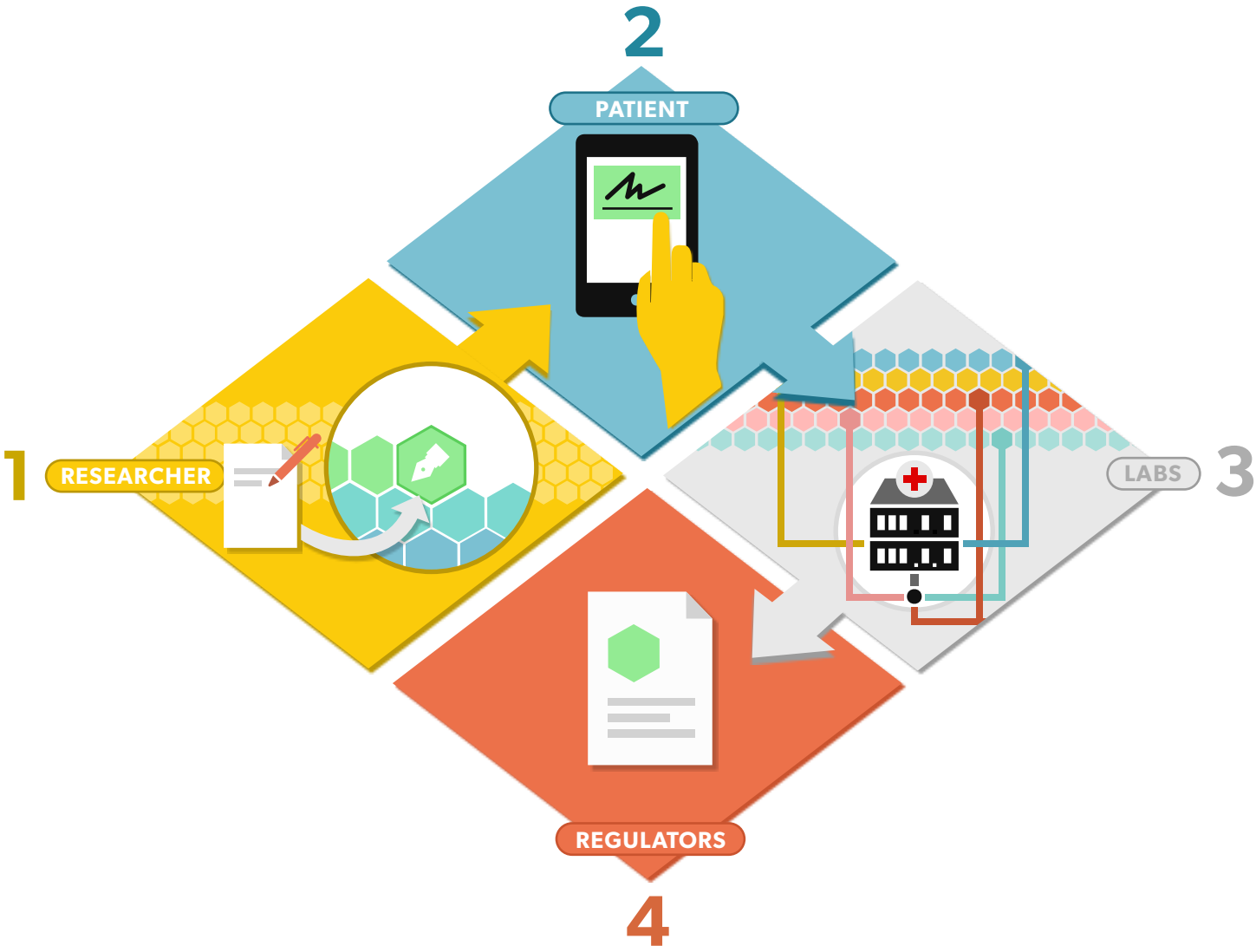
Because the information shared are partial and the study sometimes poorly designed, it makes it difficult, if not impossible for those who may want to reanalyze or replicate the findings.

Trusted Workflow Clinical Trials

The Solution

Leveraging a design based on a crypgraphic audit trail, this solution encourages stronger study design and discourages non legitimate alterations of the study or its data, building more integrity and transparency into the research process.

Trusted Workflow Clinical Trials Process



1

Digital Notarization of Study Design

The original design and methodology of the trial and its objectives are recorded and notarized in the blockchain.

2

Patient Consent Notarization

The investigator must obtain free and informed consent from the patient.

3

Fulfillment and Notarization of Surveys

Patients fill out surveys which are signed and cryptographically notarized into the blockchain, providing a timestamped recorded of the collection of all results.

Raw survey data is securely stored in a research center database.

4

Clinical Trial Audit

With the access to the proofs of the existence of the information, regulators and other researchers can verify the integrity and authenticity of the data and study.

Trusted Workflow Clinical Trials

Benefits

Trusted Workflow Clinical Trials offer the potential for stronger data integrity and improved trial reproducibility.

Prevention of corruption

Proofs of initial protocol design and methods ahead of the study, as well as and chronological proofs of the progress and data collected are stored, enabling to easily audit information and determine if there has been any corruption. As it is proofs of the information and not the data itself that is notarized, confidentiality and security are never compromised.

Trial Transparency

With no more incentives to hide or alter the protocol and the data collected, incentives to share details with the rest of the research community improves, facilitating the replication of the study.

Trusted Workflow Clinical Trials

New Possibilities

The benefits of Trusted Workflow Clinical Trials with Stratumn and Chainscript are unique facets of these new possibilities.

Digital Notarization

Digital files can be signed through a process of cryptographic hashing and timestamping, creating an immutable blockchain record with a unique digital signature.

Universal Traceability

The process through which any document, contract, or piece of media follow and interact with each other can be traced independently of any single actor or system by using publicly available tools.

Proof of Process Reporting

At any point a report can be generated that visualizes and describes in detail dates, times, metadata, and signed cryptographic proofs of any part of a workflow.

hello@stratumn.com