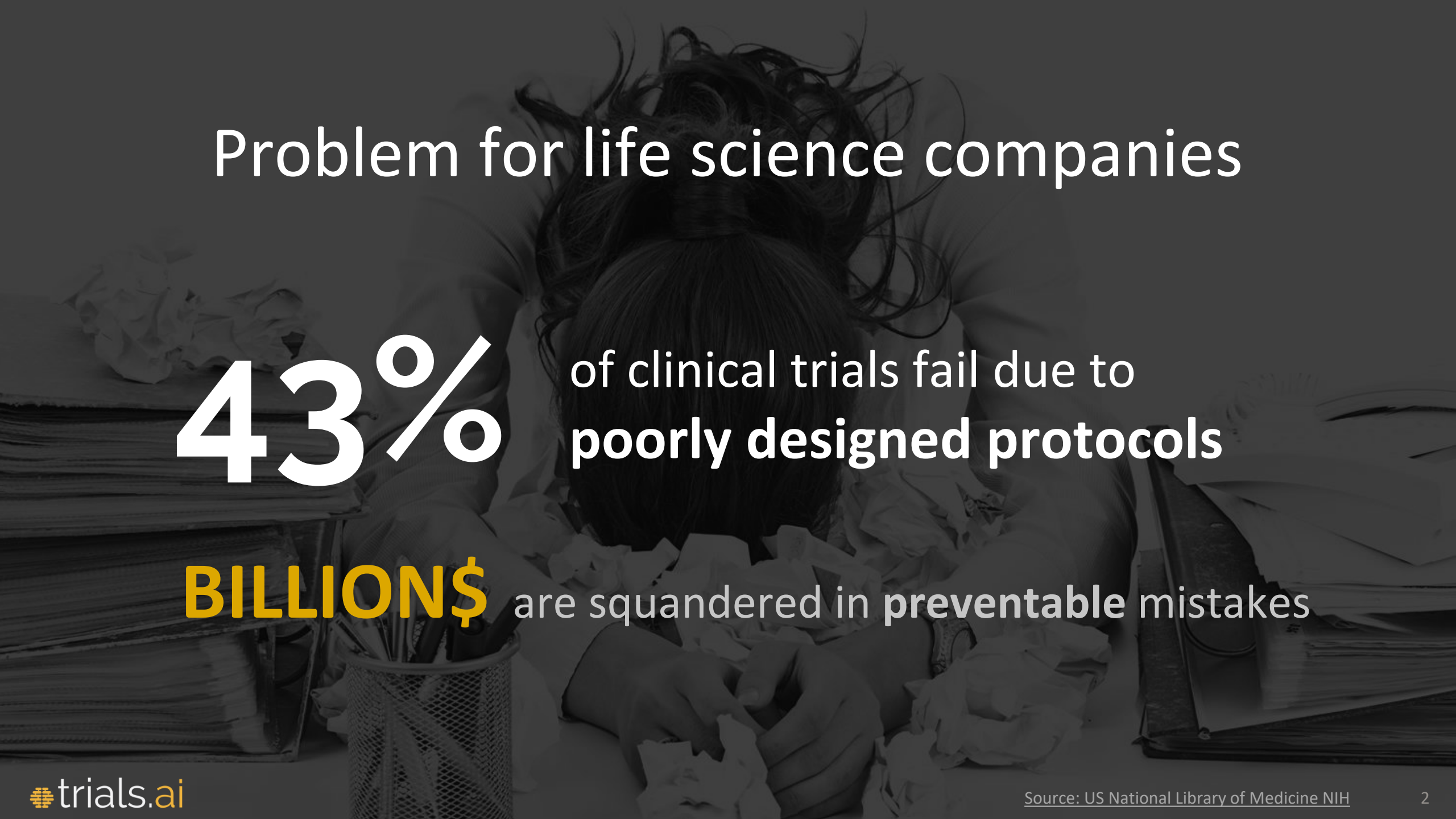
trials.ai

design your clinical trials intelligently

Kim Walpole | CEO/Co-Founder | +1 518-424-2283 | www.trials.ai

Problem for life science companies



43% of clinical trials fail due to **poorly designed protocols**

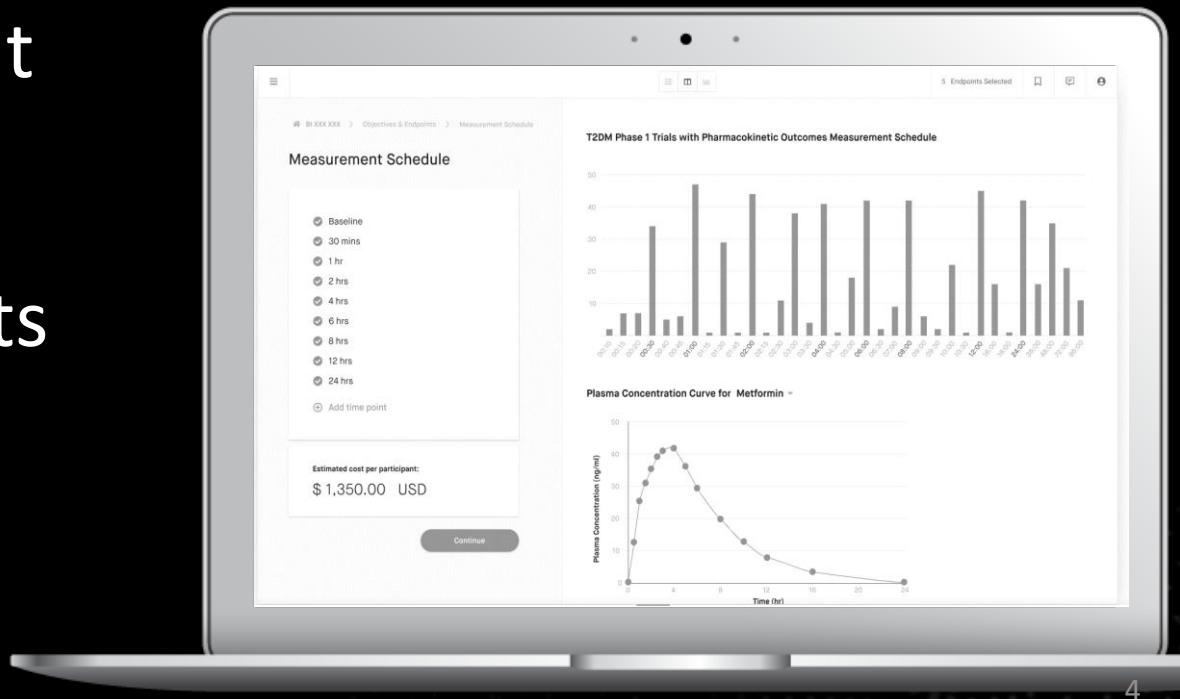
BILLION$ are squandered in **preventable** mistakes

Source: US National Library of Medicine NIH

Companies lose money and patients **don’t have time** to wait

Our Smart Protocol Designer uses AI to automate today's manual processes:

- Predict costly protocol changes (amendments)
- Recommend best recruitment & retention strategies
- Optimize testing & treatments for speed & cost



Use Case

When running a phase 1 study I need to know when to collect blood samples to accurately describe drug activity:

- AUC, Cmax, Tmax, T ½

Consequences for getting it wrong

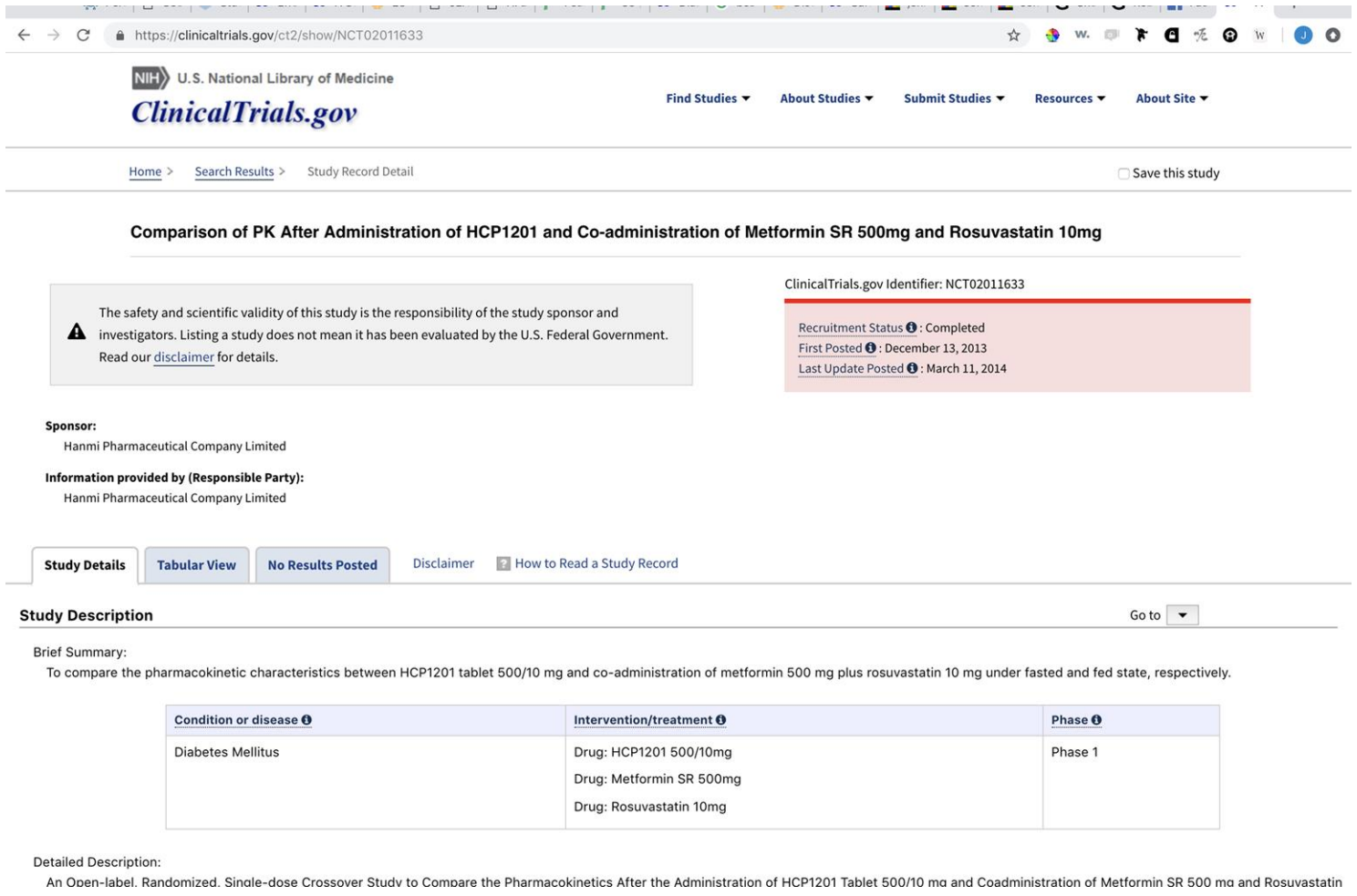
- Insufficient blood samples could lead to a failed trial
- Unnecessary sampling adds risk and complexity - hard to recruit and retain patients
- Blood samples cost[1] between $130 and $300 each

[1] *cost based on UCSD standard lab services 2018*

Retrospective

This trial collected blood samples at 15 different time points[1]

[1] *View study here*



https://clinicaltrials.gov/ct2/show/NCT02011633

U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies | About Studies | Submit Studies | Resources | About Site

Home > Search Results > Study Record Detail

Save this study

Comparison of PK After Administration of HCP1201 and Co-administration of Metformin SR 500mg and Rosuvastatin 10mg

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT02011633

Recruitment Status : Completed
First Posted : December 13, 2013
Last Update Posted : March 11, 2014

Sponsor:
Hanmi Pharmaceutical Company Limited

Information provided by (Responsible Party):
Hanmi Pharmaceutical Company Limited

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

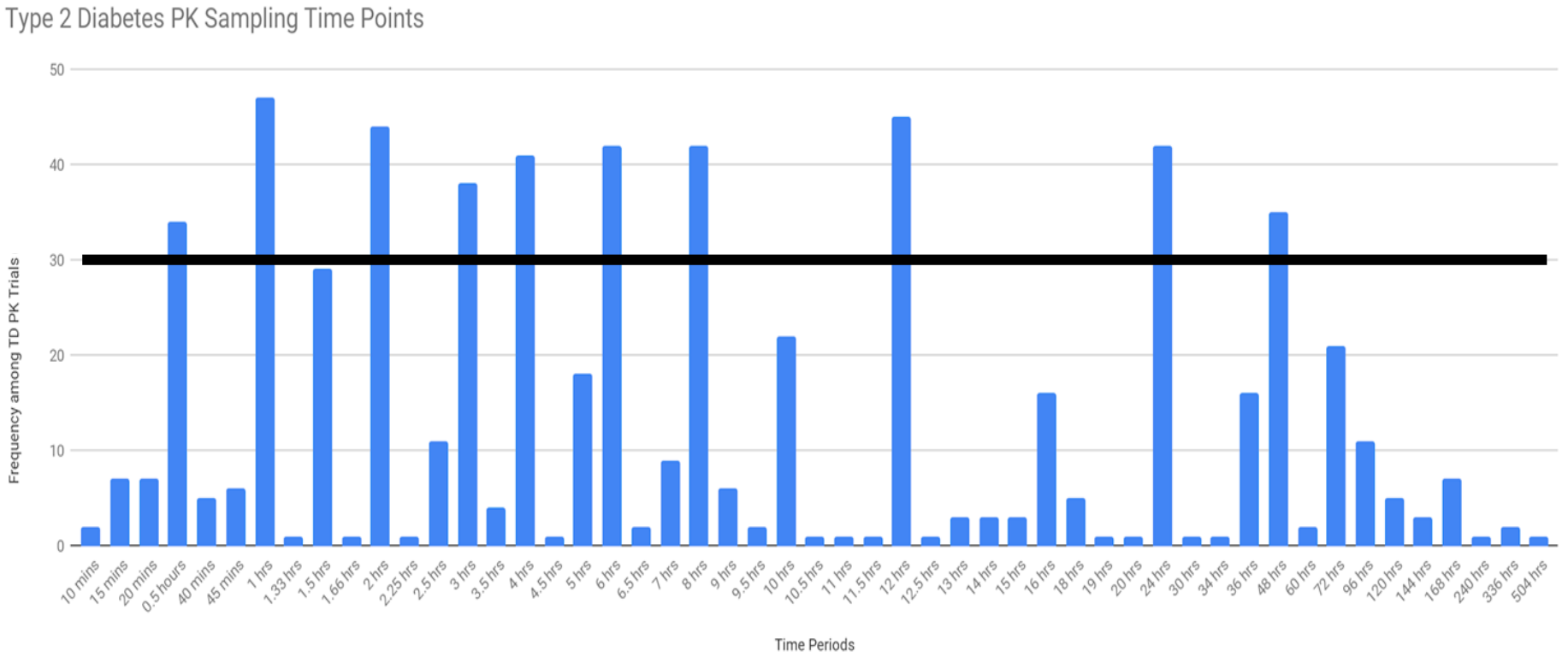
Go to

Brief Summary:
To compare the pharmacokinetic characteristics between HCP1201 tablet 500/10 mg and co-administration of metformin 500 mg plus rosuvastatin 10 mg under fasted and fed state, respectively.

Condition or disease	Intervention/treatment	Phase
Diabetes Mellitus	Drug: HCP1201 500/10mg Drug: Metformin SR 500mg Drug: Rosuvastatin 10mg	Phase 1

Detailed Description:
An Open-label, Randomized, Single-dose Crossover Study to Compare the Pharmacokinetics After the Administration of HCP1201 Tablet 500/10 mg and Coadministration of Metformin SR 500 mg and Rosuvastatin

Looking across 100 similar diabetes studies Trials.ai identified 10 optimal blood sampling time points



trials.ai

[1] *based on most commonly used sample timeline insights through Trials.ai*

Cost savings

Trials.ai would have recommended:

- ⅓ reduction in their sampling timepoints
  - = 5 less samples per patient or 360 total
  - = $108k reduction in lab tests alone

Time & Cost Savings

If that reduction in 360 samples ($108k savings)

led to 10 less patient dropouts ($38.5k per)

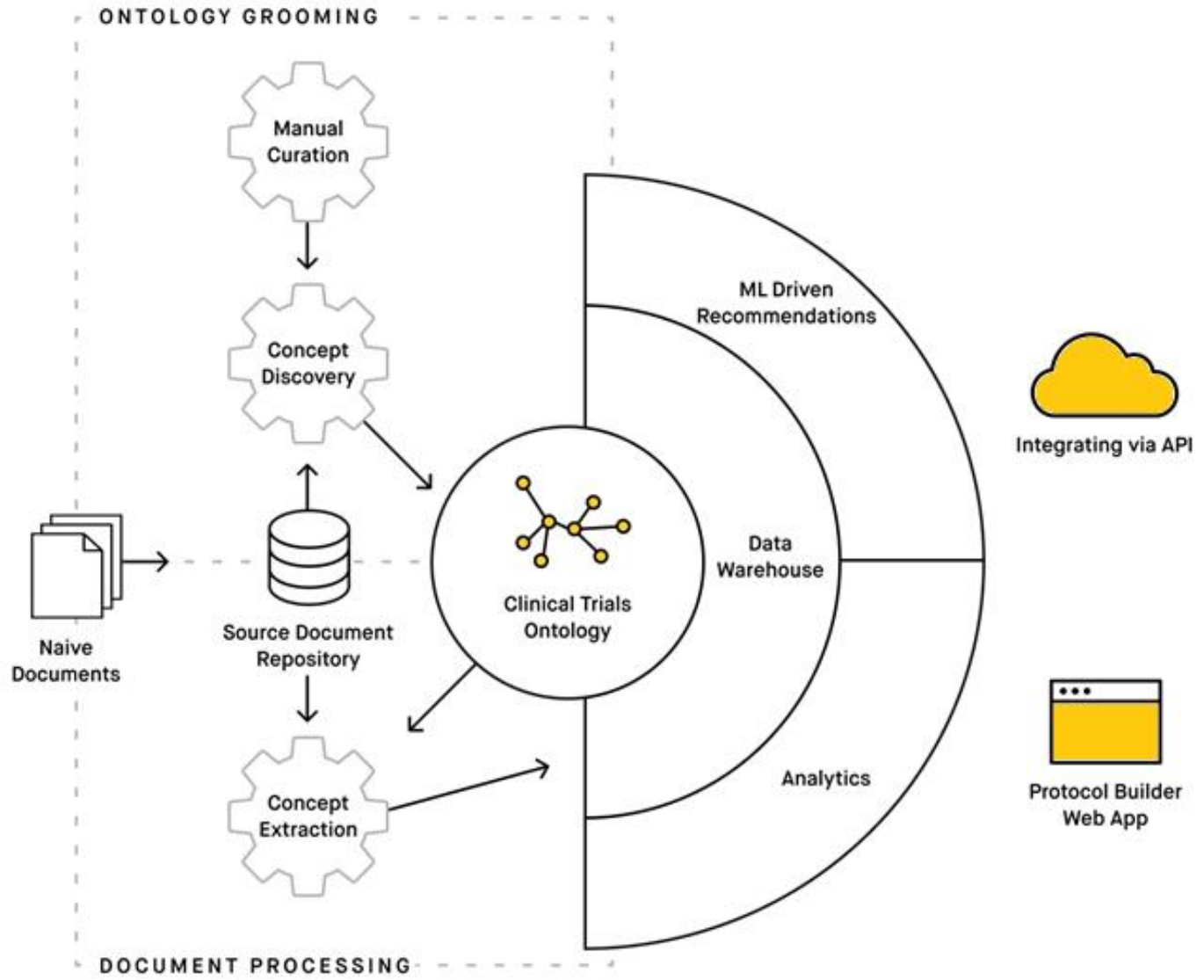
and 1 less protocol change/amendment (61 days delayed)

SAVINGS = 2 MONTHS & $500k

Data-driven protocol decisions

Public & Customer Data

- Synopsis/Protocols
- Clinical Study Reports
- Medical Journals
- Clinical Data
- KOL articles
- Regulatory Bodies
- Drug Labels



Global market opportunity

$65.2 Billion

clinical trial market

$3.7 Billion

addressable market

$5 Billion

total protocol design opportunity

Source: Grandview Market Research

Differentiator: Power in the hands of researchers

clinical trial services | manual

technology platform

therapeutic area agnostic

therapeutic area focus

TransCelerate BIOPHARMA INC.

ProofPilot

trials.ai

DrugDev an IQVIA company

IQVIA

medidata

COVANCE SOLUTIONS MADE REAL

Software-Enabled Clinical Trials

Many companies offer products that span across categories.
To keep the map simple, the logo is in the "primary" product.
Have an update? Leave a comment in the Medium post.

Trial Administration

Protocol design and review

transparency life sciences
VITAL CROWD
ProofPilot
trials.ai
HealthiVibe
AllTrials 0
CLINICAL TRIALS TRANSFORMATION INITIATIVE

Site Selection & Start-Up[1]

DrugDev do more trials
QuintilesIMS
WIRB
CenterWatch
COVANCE
goBalto
ERT
TriNetX
trifecta
teckro.
FIRECREST
CRF HEALTH
mytrus.

Patient Recruitment

Mendel.ai
Driver
Trial$_x$
antidote
Clara
QuintilesIMS
trialbee
DEEP 6
mprove HEALTH
ePatientFinder
ClinicalConnection
SubjectWell
patientslikeme
myHealthTeams
VITALTRAX
STUDYKIK
langland
seeker HEALTH
Be the Partner
trialspark
FindMeCure
myTomorrows

Operational Management[2]

PAREXEL
BIOCLINICA
PERCEPTIVE MyTrials
COVANCE
medidata
ORACLE
SIEBEL
Veeva
thoughtsphere
Longboat
Florence HEALTHCARE
clinical research.io
SimpleTrials
Welkin HEALTH
salesforce health cloud
comprehend
CluePoints
Cyntegrity
greenphire
ClinPay

Drug & Supply Logistics

Slope.io
mesm
4G CLINICAL
endpoint
CENDUIT
Bracket

Patient-Level Data Collection

Patient and Outcome Data Management[3]

Veeva
REDCap
medidata
ClinPlus
OpenClinica
COVANCE
IBM Watson Health
eClinical
ORACLE
QuintilesIMS
medrio
Target Health Inc
ERT
clinCapture
trialbee
Bracket
mprove HEALTH
Clinical Studio
phys iQ
ALMAC
koneksa
yprime
EmpiraMed
xclinical
FORTE
umotif
Viedoc
CRF HEALTH
MedNet
Altavoz
tonic
assisTek
AiCure

Digital Biomarker Collection[4]

Human API
VALIDIC
fitabase
evidation
Biospective
ActiGraph
2net
ResearchKit
koneksa health
verily
AliveCor
PHILIPS
VivifyHealth

Virtual Trials

Science 37
MEDABLE
Sage
evidation
aces HEALTH
CLINPAL
THREAD
aparito
EmpiraMed
monARC BIONETWORKS
mytrus.

0 Unlike the other for-profit ventures on this map, CTTI is a Public-Private partnership & AllTrials is a registered charity
1 Includes startup tools like eConsent and site training
2 Includes clinical trial management systems, risk-based monitoring, site monitoring, payment automation
3 Includes EDC (electronic data capture), eCOA (Electronic Clinical Outcomes Assessment), and ePRO (electronic Patient Reported Outcome)
4 Includes clinically-validated sensors

Subscription Model

Pharma | Biotech | Devices

Inbound Sales:

- Tier 1 Pharma:
  - 9-18 month sales cycle
- Inbound Small/Med sized CRO's:
  - 6-12 month sales cycle

Direct Outbound Sales:

- Biotech & Pharma
- 3 – 6 month sales cycle

PAY AS YOU GO

per active trial running under 10 trials

ENTERPRISE PRICING

Running 10 or more trials per year

Solid mix of passion and experience

Kim Walpole

CEO

12+ years Pharma Consulting

Dr. David Fogel

Chief Scientist

Research Scientist & AI Pioneer

Tom Walpole

CTO

HIPAA Compliant Scalable Systems

Josh Stanley

Product

Product Strategy & Prioritization

Pfizer Genentech MERCK NOVARTIS AMGEN inVentiv Health IEEE Computational Intelligence Society

trials.ai

Advisors are industry experts

Adreas Koester, MD, PhD

Global Head of Clinical Innovation

janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Iqbal Hussein, MD

Worldwide Medical Director

Pfizer

Stephen Jenkins, MD

VP Clinical Research

Allergan

Tom Giles

Business Development Manager

IBM Watson

trials.ai

We get things done

Went to market and tested our hypothesis:

- Built & sold initial trial execution platform to small players
- Learned that greatest opportunity is in Protocol Design
- Reset the business to focus on Protocol Design

We get things done

Developed our Protocol Design Product:

- Patent Pending on our Patient Burden Index TM
- Data processing pipeline
- Clinical Trials Ontology
- Recommendation Algorithms
- Built out our API

We get things done

Resulting in Traction with $7.6M Sales Pipeline (weighted)**:**

- In contract negotiations with 3 of the top 10 Big Pharma companies
- 1 CRO (consultant) proposal - 3 year contract
- Currently generating revenue

Raise & milestones

- Focus on direct sales to build immediate revenue
- Expand platform capabilities
- $3M ARR by Q4 2019

$300k available

$750k Note

$5M CAP

20% discount

5% interest

Kim Walpole
CEO & Co-Founder

U.S.A.
1510 Front St, 400
San Diego, CA 92101

+1-518-314-9413

kim@trials.ai

www.trials.ai