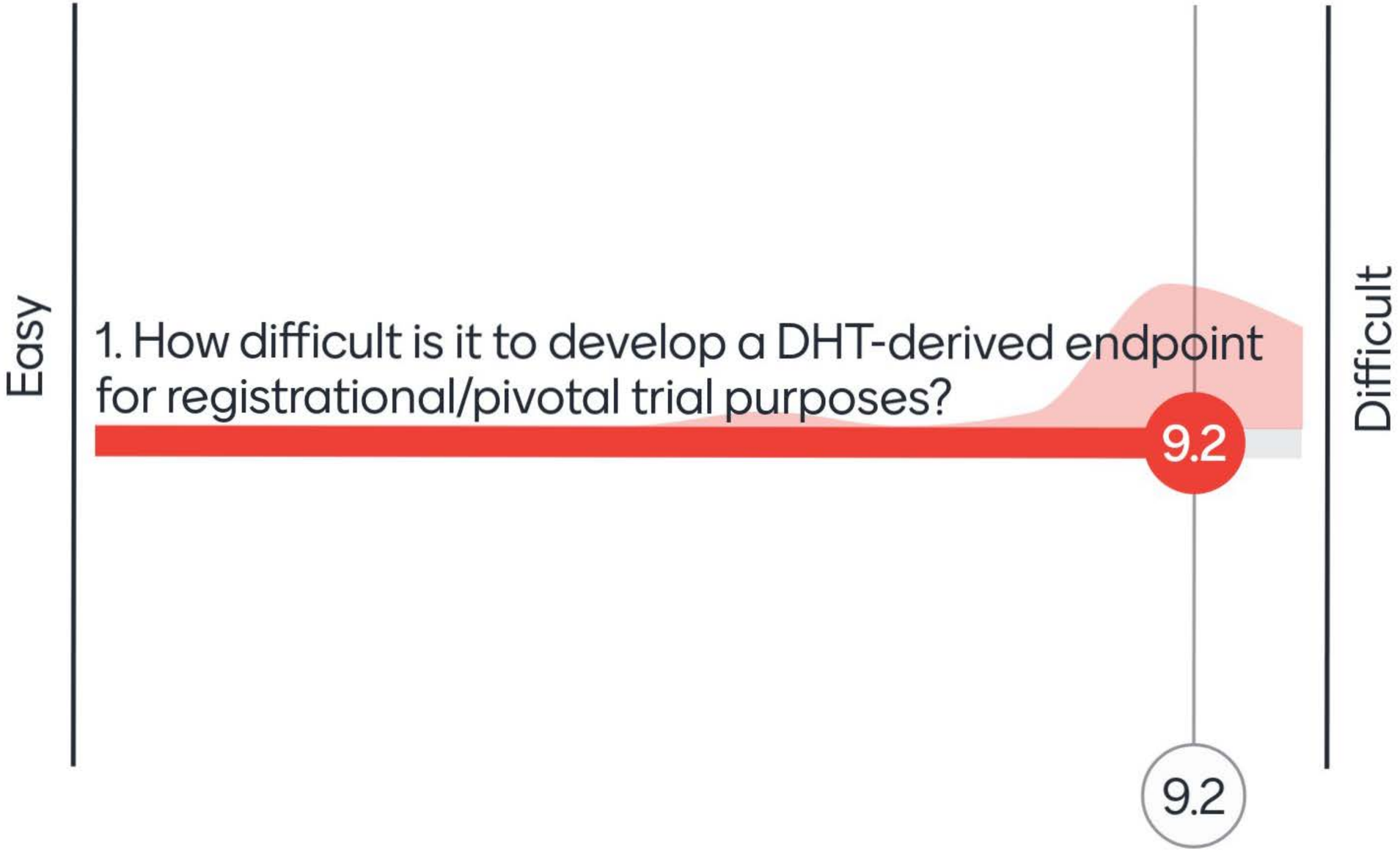
Easy
1. How difficult is it to develop a DHT-derived endpoint for registrational/pivotal trial purposes?
9.2
Difficult
9.2

What types of measures captured by a DHT are easier to develop (i.e. what measures are the low hanging fruit)?

What are the main incentives to collaboration when developing novel DHT-derived endpoints?

efficiency

harmonization

better outcomes for patients!!

First-mover advantage

Minimize duplication

faster time to market

Regulatory acceptance

cost savings

Faster endpoint regulatory acceptance

What are the main incentives to collaboration when developing novel DHT-derived endpoints?

Speed

Timelines

Cost

economies of scale

Cost

Improve healthcare

Complementing different expertises

Reduce the redundant effort on what is a very large challenge

Not having to re-do validation studies

What are the main incentives to collaboration when developing novel DHT-derived endpoints?

equity

more fit for purpose

infrastructure efficiencies

Distribute risk

Tech company needs expertise of others (patients, health professionals, etc). Reducing waste and focussing on things that really matter.

duplication of efforts

What are the main disincentives to collaborate?

IP

competition

competitive advantage

intellection property concerns

Gives away proprietary strategy

loss of market share

IP

competition

Too many cooks

What are the main disincentives to collaborate?

Long lag time in collaboration contracts...

time

competitive concerns

intellectual property

Organizational alignment heiarchy

Competitive advantage

You only get a portion of the benefit your collaboration brings

Can't share competitive intelligence

Lack of validation

What are the main disincentives to collaborate?

intellectual property issues

No ROI for work put in

limited success for qualification

It's difficult! Lack of efficient collaboration mechanisms

Timeliness vs. studies

Start-up costs

Aversion, in all aspects of healthcare, to anything new

Time

IP

What are the main disincentives to collaborate?

Who will reimburse the tech company?

lack of tangible outcomes after extensive investment

profit

Allows competitors to move more quickly by leveraging your investment

cultural differences

Don't always get intended benefit

Number of people who need to align

If focussed on different diseases to current program

funding

What are the main disincentives to collaborate?

academia

clinicians

access to patient populations

financial support

What kind of incentives need to be created?

Public funding

Regulatory pressure

IP protection

make it easier, more standardized

financial

mandate it

Show benefit on everyone's timelines

greater certainty of regulatory acceptance

Cost sharing models for analytical validation studies

What kind of incentives need to be created?

Third party funding

help people understand win-win scenarios

reduce work for individual company

Regulatory support

create standardized collaboration frameworks that are effective

Widely accepted standards

Recognition

enable access to new entrants - startups, academia, etc.

Embed quicker into trials

What kind of incentives need to be created?

Identifying key outcomes that matter to patients and other decision-makers where a DHT could help i.e. identify the gaps in the market. Reduces the risk.

As with PROs, lowered uncertainty and commoditization will open the field.

find low hanging fruit - post marketing environment, non-competitive spaceset

Distribute risk and cost but privatize benefit

Some type of Regulatory benefit

co creation insights

Know where to start, eg for pharma start with the local affiliates or with Head quarters

Show a model for RoI

Demonstrated speed/reduced cost of development

What kind of incentives need to be created?

Expedited regulatory adoption from collaborated solutions

Relevance across diseases

Fast track COA Qualification

Require 'skin in the game' to benefit (avoid tragedy of the commons)

look across segments Life sciences, providers, payor - include partners across the ecosystem including

Who should be collaborating to advance the adoption of novel DHT-derived endpoints?/ Who are the key groups to make collaboration happen?

What tools do those groups need?

$$$

Modern collaboration environments

Data

Collaborative organizations

Understand the need to evolve (what's in it for me)

STandardized IP framworks

Regulatory guidelines

Patient input

equal power dynamics

What tools do those groups need?

incentives from payers or regulators

Opportunities to meet and discuss the issues

Ways to find each other

Standards Framework

Funding

shared "sandbox"

Mechanism to publish joint interests

Regulatory guidelines

what is the value this will bring to group x

What tools do those groups need?

The will

money

Anonymised data sharing

updated medical guidance

Understanding of current practices in drug development

Knowledge of the landscape and what has been done before

Consortia, guidances, data standards, early adopters

IP expertise - basic

How this will transform care

Bringing various cultures (tech, sponsor, patient) together will require ___ .

$$$

Appropriate incentives

understanding of the differences

Transparency

alignment to the rationale (why are we doing this)

Patience

patience

patience

Trust

Bringing various cultures (tech, sponsor, patient) together will require ___ .

incentives

effective ways of partnering

Co creation

a more cohesive regulatory framework

neutral third party

common goal

Regulatory incentives

Time

Leadership on all sides

Bringing various cultures (tech, sponsor, patient) together will require ___ .

Respect. Understanding.

Adequate financial support

trust

common goal

humor

An integrated platform

financial support

trusted non conflicted leadership

interfaces that can bridge between them - without requiring much expertise in the other's domain

Bringing various cultures (tech, sponsor, patient) together will require ___ .

A defined common goal

open mindedness

valuing diversity in thinking

understanding of concerns/objections

transparency

Take time for exploration togethher

A shared vision

Empathy

Respected leadership committed to true change

Bringing various cultures (tech, sponsor, patient) together will require ___ .

The concept that solutions are everyone's responsibility

realistic expectations

What are 2-3 elements where reuse could most benefit the endpoint development process? Where in the process can we leverage existing evidence?

- Verification and validation of the tech
- endpoint definition
- endpoint interpretation
- verification and validation of endpoint
- what can we learn from COVID?
- V&V
- Data and open-source
- Usability
- re-use and re-purposing of tech components

What are 2-3 elements where reuse could most benefit the endpoint development process? Where in the process can we leverage existing evidence?

verification of sensor tech

Handling missing data

The use of control data to establish normal range

COVID Wearable + clinical data from multiple sources

verification and validation steps of the DHT, befor evalidatining it in a disease

Lessons from case study success to inform development of policies

Developing concept of interest

validation

There are around 7 core outcomes common to most chronic conditions. Focus on these.

What are 2-3 elements where reuse could most benefit the endpoint development process? Where in the process can we leverage existing evidence?

deliver data sooner for patients

Validated devices/methods database

common interpretation

Sharing of studies obtaining patient input

Statistical methodologies, e.g. handling missing data

addressing privacy concerns

Analytical validation of higher level physiologic constructs that then only requires validation of measures in a disease state

Algorithm lockdowns

Algorithm development

What are 2-3 elements where reuse could most benefit the endpoint development process? Where in the process can we leverage existing evidence?

Statistical methods for handling missing data/voluminous data

Across-device verification & validation (enable analysis across studies)

Anonymised data sharing

progressing the discussion. there is such apprehension and fear of investment. continuing the dialogue and shared experiences and ambitions.

What is my role in 'DHT-derived endpoint adoption'? What can I do to create change?

- Be an innovation and collaboration catalyst
- Change agent within my organization/function
- collaborate to provide early input
- Generate early evidence. Share data when I can
- Support the Open Wearables Initiative
- Ideate on novel approaches to existing challenges
- Work with consortia
- Keep on looking voor colaboration
- Help validate DHT endpoints and help to understand meaningful change to patient populations

What is my role in 'DHT-derived endpoint adoption'? What can I do to create change?

Be a leader and liaison between the collective industry needs and the regulators involved in facilitating DHT adoption

Identify and disseminate evidence about what outcomes matter to patients and other decision-makers.

identify potential DHT endpoints for patient

Share use cases

Publish results of work

as a leader, researcher, and DHT trialist, I will keep advocate, educate, and foster collaboration to advance NDE adoption

Keep pushing pharma internally to engage in collaborations and not do everything internally. Engage with FDA early and often.

Use/promote CTTI's final recs & resources