CLINICAL TRIALS OF THE FUTURE ~ 2030

Prepared for Day One – Healthcare innovation incubator

Agathe Acchiardo, Founder, Think Next

12th September, 2023

| DayOne Accelerator

DayOne Health 4.0 – your international digital health accelerator

BACK FUTURE PART II

FUTURE, YOU SAY?

STRATEGIC FORESIGHT
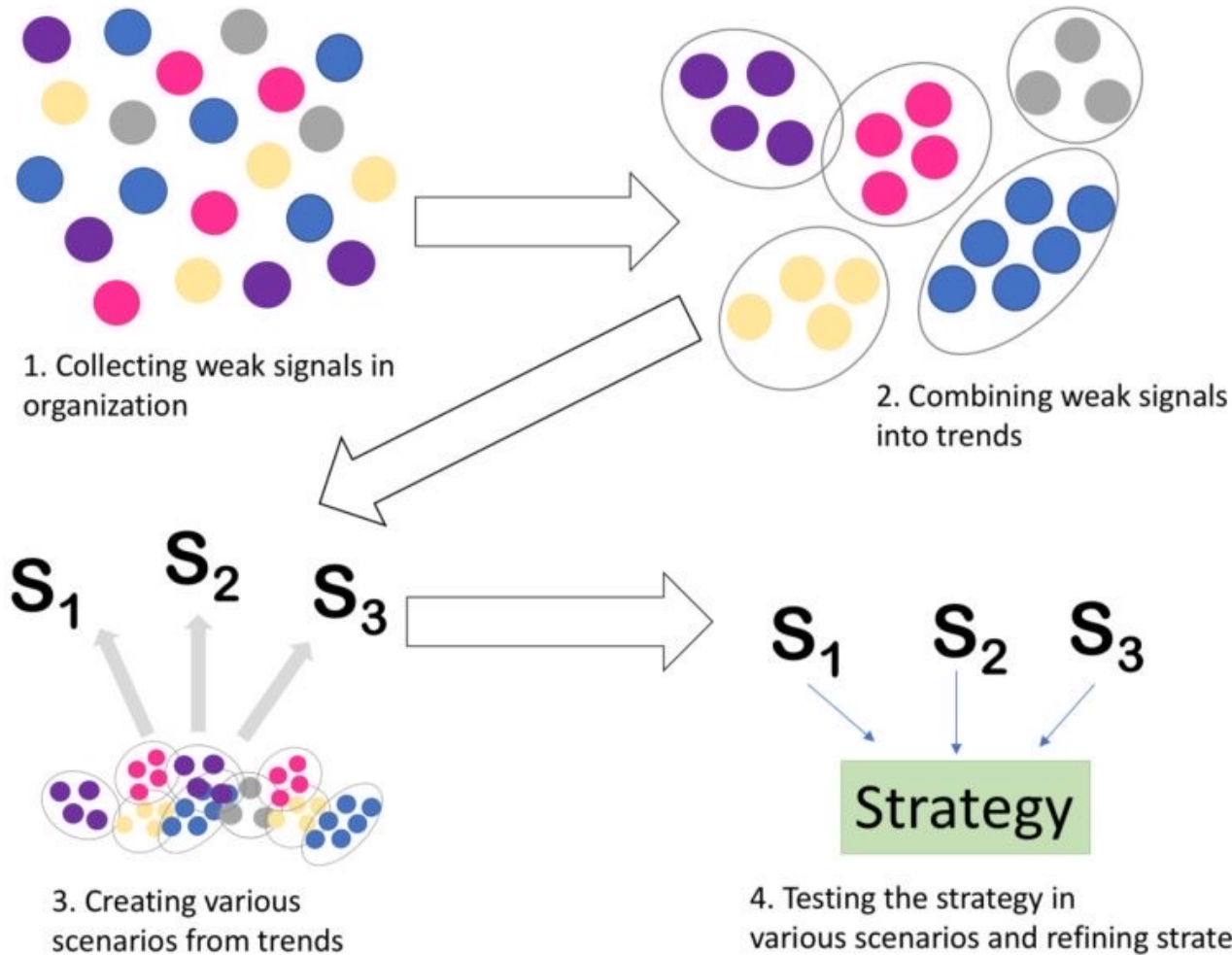
Weak signals, trends and scenarios

Weak signals
innovations
Start-ups / funding
Patient insights
Data
Legislative framework
New words

Trend
A narrative to make sense of the signals
One trend = many signals
One signal = one or several trends

1. Collecting weak signals in organization

2. Combining weak signals into trends

S_1 S_2 S_3

3. Creating various scenarios from trends

S_1 S_2 S_3

Strategy

4. Testing the strategy in various scenarios and refining strategy

Quick words on 'trends'

1 Reflecting a change of attitudes, behaviors or beliefs from people (e.g patients/doctors)

2 With an upward trajectory – more and more early signals, stronger & stronger

3 With clear and actionable implications in terms of business opportunities

4 Developing & maturing in 5-10 years timeframe

5 Different speed of change in different countries and demographics – from fringe to mainstream

6 Consistent with broader changes and with other trends

How to use trends...

Not all trends are relevant for everyone!

Thought provocation for...
👉 your product development
👉 your user adoption
👉 your PR or communication strategy
👉 your value proposition or business model

Agenda: 5 emerging themes

PEOPLE, NOT PATIENTS

ALL INCLUSIVE CLINICAL TRIALS

SUSTAINABILITY COMES TO HEALTHCARE

TAPPING INTO THE DIGINOME

THERE'S AI IN 'TRIALS'

PEOPLE, NOT PATIENTS

EMPATHY PATIENT-HCP INTERACTIONS

**42%
of patients** sometimes feel like the doctor lacks empathy

**50%
of patients with** CT experience say 'more sensitivity, empathy or appreciation by staff' would make them more likely to take part again

EMPATHY: FROM 'NICE-TO-HAVE' TO 'MUST-HAVE'

Co-creation & co-design at the forefront

TED

MEET PATIENTS WHERE THEY ARE: AT HOME

35% of patients struggle to attend in-person appointments with their doctor

Not urban/rural divide but lifecycle and generational

64% of patients said that digital tech (televisits or wearables), would make their trial participation much easier, **to share medical information from the comfort of their own home**

UNDERSTANDING WHAT MATTERS IN PEOPLE'S LIVES: A HOLISTIC VIEW

31%
of patients with a chronic condition say that it has had a large impact on their sex life

Sexual dysfunction in a cohort of patients with moderate-to-severe atopic dermatitis. Influence of dupilumab treatment

Laura Linares-Gonzalez [1] [2], Ignacio Lozano-Lozano [1] [2], Luis Gutierrez-Rojas [3] [4] [5], Ricardo Ruiz-Villaverde [1] [2], Mario Lozano-Lozano [2] [6] [7]

Affiliations + expand

Effect of Dupilumab on Sexual Desire in Adult Patients with Moderate to Severe Atopic Dermatitis

Maddalena Napolitano, Conceptualization, Data curation, Writing – review & editing,[1] Gabriella Fabbrocini, Data curation, Writing – review & editing,[2] Sara Kastl, Data curation,[3] Teresa Battista, Data curation, Writing – original draft,[2] Adriana Di Guida, Data curation,[2] Fabrizio Martora, Data curation, Writing – original draft, Writing – review & editing, Visualization,[2,*] Vincenzo Picone, Investigation, Data curation, Writing – original draft, Supervision,[2] Virginia Ventura, Investigation, Writing – original draft,[2] and Cataldo Patruno, Software, Validation, Data curation, Writing – review & editing, Visualization, Supervision[4]

QOL AT THE FOREFRONT... BUT BEWARE!

The Leicester Cough Questionnaire
19 QoL items, missing #1 concern for women

4. In the last 2 weeks, have you felt in control of your cough?

1	2	3	4	5	6	7
None of the time	Hardly any of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time

5. How often during the last 2 weeks have you felt embarrassed by your coughing?

1	2	3	4	5	6	7
All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time

6. In the last 2 weeks, my cough has made me feel anxious

1	2	3	4	5	6	7
All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time

7. In the last 2 weeks, my cough has interfered with my job, or other daily tasks

1	2	3	4	5	6	7
All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time

8. In the last 2 weeks, I felt that my cough interfered with the overall enjoyment of my life

1	2	3	4	5	6	7
All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time

9. In the last 2 weeks, exposure to paints or fumes has made me cough

1	2	3	4	5	6	7
All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time

In the last 2 weeks, has your cough disturbed your sleep?

	3	4	5	6	7
time	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time

times a day have you had coughing bouts?

	3 Several times during the day	4 Some times during the day	5 Occasionally through the day	6 Rarely	7 None

made me feel frustrated

	3	4	5	6	7
	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time

made me feel fed up

	3	4	5	6	7
	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time

ed from a hoarse voice as a result of your cough?

	3	4	5	6	7
	A good bit of the time	Some of the time	A little of the time	Hardly any of the time	None of the time

of energy?

	4	5	6	7
time	Some of the time	A good bit of the time	Most of the time	All of the time

y indicate serious illness?

	5	6	7
	A little of the time	Hardly any of the time	None of the time

VOTING & BRAINSTORM

What are we not measuring but could/should measure to monitor patients 'quality of life' during clinical trials?

Share your thoughts on Mentimeter
Using QR code or link in your browser
https://www.menti.com/al75zp6osrp6

BRAINSTORM

What are we not measuring but could/should measure to monitor patients 'quality of life' during clinical trials?

35 responses

Different impact on each patient	Impact of eating well and not eating welll	How much frustration the person has. .	Impact on family life	Mental Health
Do you get paid enough to participate?	Number of missed or incomplete visits	How many times they had to re read and sign on to the clinical trial T&Cs	Number of selfies taken	alternatives that consider, for example, other types of therapy
Financial impact	Sex Health. Joint family activities. But this really depends on a clinical trial and investigated drug.	Feeling of being in a progressive healing	Ease and speed of onboarding	Measuring their interactions on social media could be an indicator of mental well being
Indirect stress factors like an arguement with family members.	Basic nps of the trial	Whether people is afraid to death, or not anymore	Did they understand the study materials	
Nutrional aspects	3rd party reations (family, friends)	Caregiver feedback	Effect on work	
Frequency and nature of physical activity measured by a watch or wearable	How happy they are with the remuneration or benefits that is provided as a consequence of the trail.		Impact on work / career	
Patient satisfaction	Patient's expectations and unmet needs	Level of happiness...		
Emotional support	Mental health, work, vitality	Happiness		
Impact on sleep	Amount of time required per week to participate	Experience at the site		

THOUGHT STARTERS

...what can you do to make your solution more 'human-friendly'?

...what have you done to co-create and co-design your solution with patients?

...how might we support people participating in clinical trials to 'regain control'?

...how might we contribute to the collection of exploratory endpoints that put quality of life at the forefront?

THOUGHTS & IDEAS

PEOPLE, NOT PATIENTS

START DOING...

DO MORE OF...

DO DIFFERENTLY

ALL INCLUSIVE CLINICAL TRIALS

RISING THE BAR ON DIVERSITY & INCLUSION

STAT+

Take a deep breath: Asthma drug study failed to include Black and Puerto Rican children who could benefit most

By Ed Silverman 🐦 Dec. 8, 2021

Reprints

90% of kids enrolled were white on Sanofi/ Regeneron trial
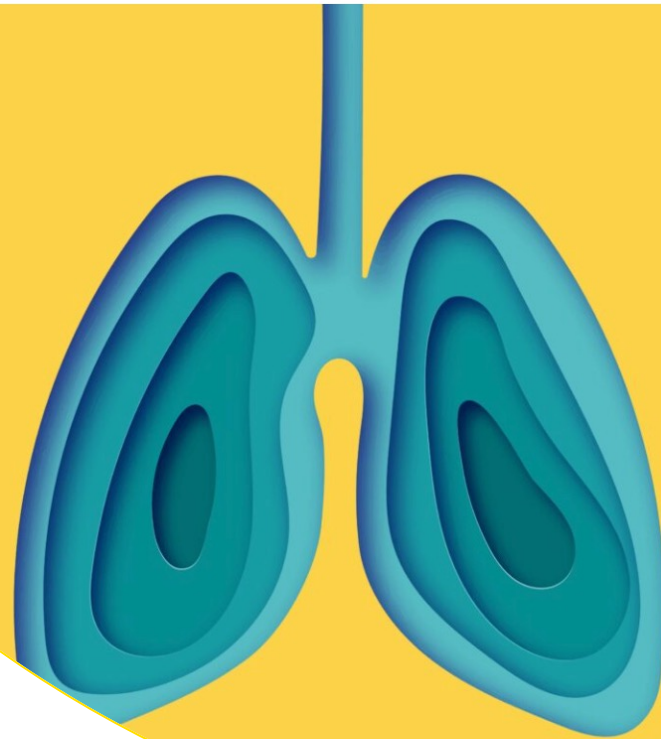
POWER, PATIENT-FRIENDLY RECRUITMENT WITH DIVERSITY

Power

About Us   For Researchers   For Sponsors

Where patients find promising new treatments

Browse clinical trials by condition, location, and drug type.

Condition	Location	Distance	Age
Type Condition	⌖ Nearest City	Any ⌄	Type Age

🔬 31k+ Clinical Trials   🏢 100k Researchers   ⚕ 10k+ Medical Conditions   🏢 50k+ Cities

44% of their 300,000 platform users are non-white (2022)
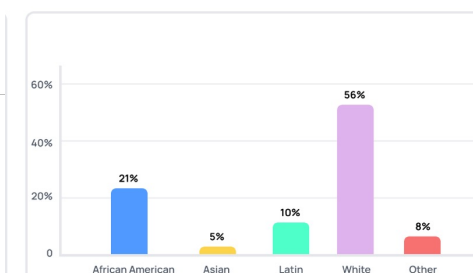
Diverse patient profiles
Over 40% of our patients are non-white. Power is democratizing access to clinical trials and connecting with patients who have historically been left out of research.

African American 21%   Asian 5%   Latin 10%   White 56%   Other 8%

ACCESSIBLE WEBSITE FOR PEOPLE WITH VISUAL-IMPAIRMENT OR COGNITIVE DISORDERS

BRAINSTORMING

List as many possible drivers for lack of diversity, bias or discrimination in the context of healthcare

Share your thoughts on Mentimeter
Using QR code or link in your browser
https://www.menti.com/al75zp6osrp6

BRAINSTORMING

List as many possible drivers for lack of diversity, bias or discrimination in the context of healthcare

32 responses

Health literacy	Identify of caregiver or researchers, their bias	Location of providers	History of complaints	Rare desease
Disease understanding	Not a big market	Geographic area	Selection of sites for trials (geography/population/wealth)	Time
Lack of representation in hospitals	Low income RegionRural areas	Gender sensetive scales	Fear	
Site selection	Easier data analysis	Race		
Site facility	Recycling components of old protocols or recruitment processes	Country selection		
Clinical trials are run at hospitals and agreement is signed with a hospital. There are things covered by trials and some are not. It is a risk to CRO to sign with small hospital with diversity.	Access to sites / pharmacy	political ideology		
All the above	Insurance premiums	Age		
Location where trial is running	Insurance coverage	Community stigma		
Country	Lack of awareness	Impact of pre-existing published literature and medical education materials		

THE PATIENT VIEW

27% of patients have already felt dismissed or discriminated by a healthcare professional

ASSUMED REASONS FOR DISCRIMINATION OR DISMISSAL

Age	Weight	Mental health, neurodivergence	Lifestyle habits	Health choices	Education, income	Gender or gender identification	Ethnicity	Marital, family status	Citizenship, immigration status	Sexual orientation, LGBTQ
27%	24%	23%	23%	22%	17%	17%	14%	13%	10%	10%
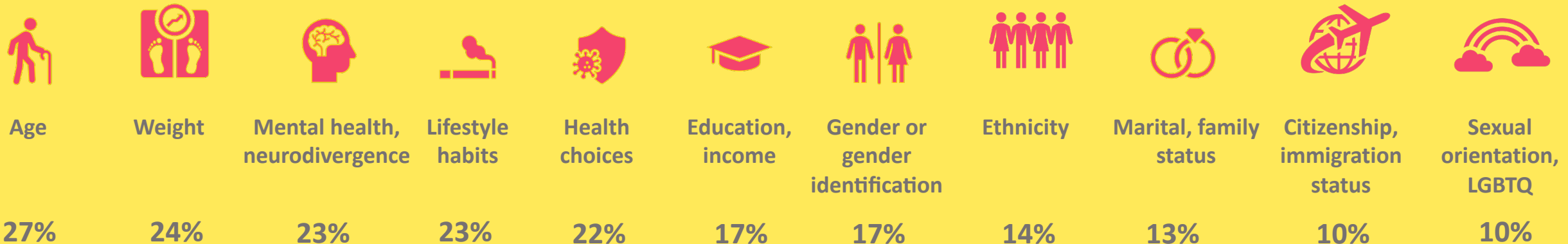
THOUGHT STARTERS

...how can you gain awareness of the limitations of your solution in terms of D&I?

...how might you design solution(s) as inclusive as possible, considering *all kinds* of users (e.g. neurodiversity, vision-impairment, etc...)

...how might you support the agenda for more diverse and inclusive tools in all the different aspects of a clinical trial?

THOUGHTS & IDEAS

ALL INCLUSIVE CLINICAL TRIALS

START DOING...

DO MORE OF...

DO DIFFERENTLY

SUSTAINABILITY COMES TO HEALTHCARE

QUIZ

What's the estimated carbon footprint of clinical trials, in Millions tons CO_2 equivalent per year?

Share your thoughts on Mentimeter
Using QR code or link in your browser
https://www.menti.com/al75zp6osrp6
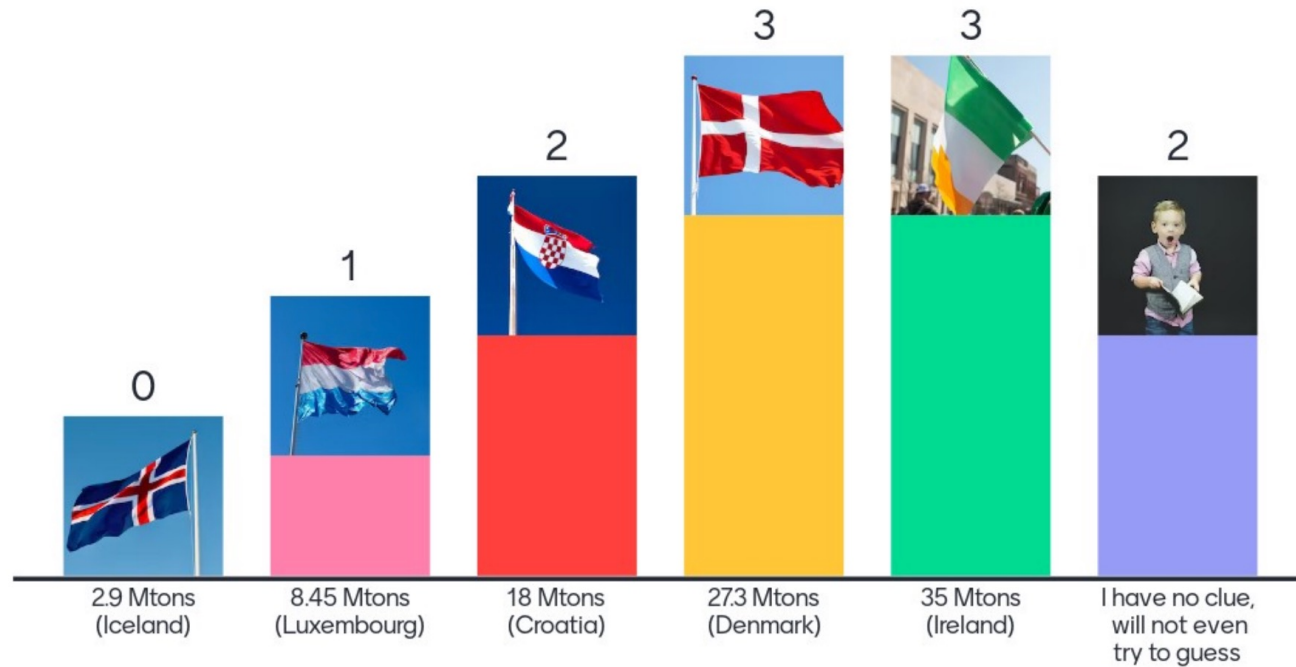
THE CARBON FOOTPRINT OF CLINICAL TRIALS: SAME AS DENMARK

27.5 Millions tons of CO_2e

Source: https://shcoalition.org/clinical-trials/, https://edgar.jrc.ec.europa.eu/report_2022

CARBON TARGETS IN CLINICAL TRIALS

AstraZeneca hopes to make clinical trial operations carbon-negative by 2030

AstraZeneca is working with its collaborators to ensure the changes are not just internal but across the entire chain footprint.

>90% of the carbon footprint from a big pharma comes from its suppliers

AZ Sustainability Initiatives

Supplier Guidebook – August 2023

"

*There is a need **to develop standardised, validated methods and tools** for healthcare environments to assist stakeholders to make informed decisions **about reduction of carbon emissions from digital health interventions**.*

"

"Assessing the carbon footprint in digital health interventions: a scoping review"

J Am Med Inform Assoc, Dec 2022

THOUGHT STARTERS

... how might we assess and measure the sustainability impact of your solution?

... how might you prepare for ESG/sustainability assessment requests from big pharma partners?

... how might you turn sustainability into one of your 'selling points'?

THOUGHTS & IDEAS

SUSTAINABILITY COMES TO HEALTHCARE

START DOING...

DO MORE OF...

DO DIFFERENTLY

TAPPING INTO THE 'DIGINOME'

EMBLEEMA EDEN PROJECT

EDEN
(Epilepsy Digital Experience Navigator)

A first of its kind digital ecosystem fully built on Embleema technology connecting patients, caregivers, providers & researchers to advance care & research in epilepsy

EPILEPSY FOUNDATION

Otsuka

Eisai

For The First Time, There Is A Patient-First Network That Is Changing The Way People View, Control, Use And Benefit From Their Data.

patients & caregivers are in **full control of the data** they contribute towards clinical research

patients & caregivers receive **customized insights, data and other digital services** to help better manage their epilepsy

EDEN's data is available to every stakeholder, provided the patient has consented **effectively breaking data silos**

we are opening a new era of clinical research **driven by patients & democratizing the collection of data** & its benefits

"For me to get insights and predictive analysis about my health, risk factors etc"

#2 reason to share PGHD

DHEALTH FOUNDATION: TOKENISATION TO INCENTIVIZE DATA-SHARING

The dHealth Wallet

The dHealth wallet is a non custodial client (wallet) that allows users to interact with dApps in the dHealth Ecosystem and view and maintain your DHP balance. The dHealth Wallet additionally supports signing of all dHealth transactions.

ynload the Wallet ↓
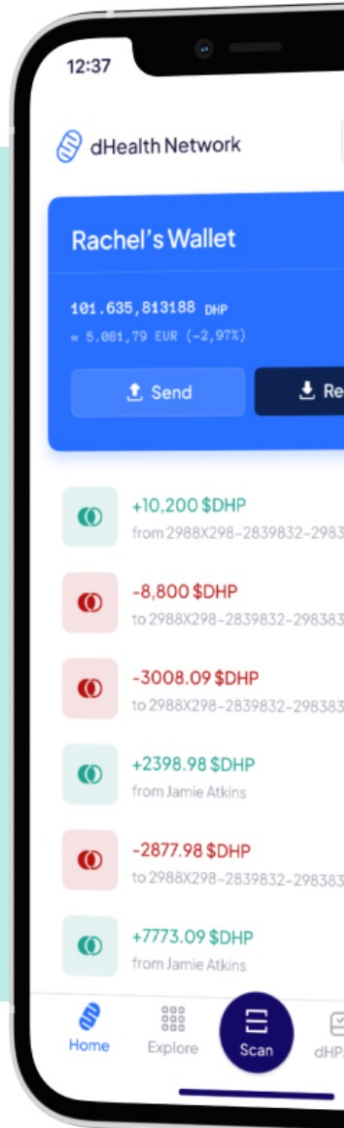
DATA PHILANTHROPY (WEF, Davos, 2011)

Why You Should Donate Your Medical Data When You Die

EU unveils new data rules, including 'data-altruism' clause

We like to call it pill-anthropy.

61% of patients agree that if their health data were anonymized, they would be ready to share them to be integrated in a larger dataset for scientific research

THOUGHT STARTERS

... how might we foster trust in data-sharing from our partners *and* users?

... how can you give back to your users (e.g. with insights or knowledge being generated by their data contribution) to make it a worthwhile data trade for them?

... how might we create, integrate or tap into larger data ecosystems for better pattern recognition?

THOUGHTS & IDEAS

TAPPING INTO THE DIGINOME

START DOING...

DO MORE OF...

DO DIFFERENTLY

THERE'S AI IN 'TRIALS'

PARTICIPATORY FORESIGHT

POST-IT TIME!

Which use cases of AI
do you see being
**adopted in clinical
trials** in 2030?

BRAINSTORMING

BRAINSTORMING

Which use cases of AI do you see being **adopted in clinical trials** in 2030?

FEASIBILITY

- AI analyses EMR content and gives site-specific feasibility score
- AI match making protocol x site
- AI will tell you the new trend diseases
- Simulate multiple scenario
- Execute a trial only after a simulated one
- AI generated feasibility insights

PRE-CLINICAL & DESIGN

- AI molecule combinatory assessments
- Dose finding
- Patient twin
- Test toxicology with as many models/simulations as possible
- Toxicity foresight
- AI assisted site selection
- Use AI for better & faster site selection
- Live real world control arms
- AI augmented designing
- AI protocol development medical writing

RECRUITMENT & CONDUCT

- Adaptive protocol
- Early stoppage and adaptation
- Patient finding / cohorts builders from raw data (imaging etc)
- Patient onboarding
- AI real time feedback
- Patient/Participant risk triaging
- Creating study materials
- Ai cohort management e.g consent / admin automation
- AI guidance for consent forms and consenting
- AI support for mental health during trials
- Conduct the trial in parallel with an *in silico* one
- There will be no Phase 2 &3 trials. RWD reported will allow developing efficacy & safety monitoring
- Monitor patients wellbeing /mental health with a chip in their brain to predict drop-out
- Statistical analysis and patient population

ANALYSIS

- Automated data processing pipelines
- Augment evidence with AI and modeling and simulation
- Predicted AEs would replace actual AEs
- Early stoppage (mostly for futility)
- AI for faster analysis of imaging (instead of manual work)
- AI comparison to historical studies
- AI suggestion for expansion from groups
- AI suggestion for correcting touchpoints

VOTING

In your views, which % of clinical trials launched in 2030 will include 'some aspects' of AI?

Share your thoughts on Mentimeter
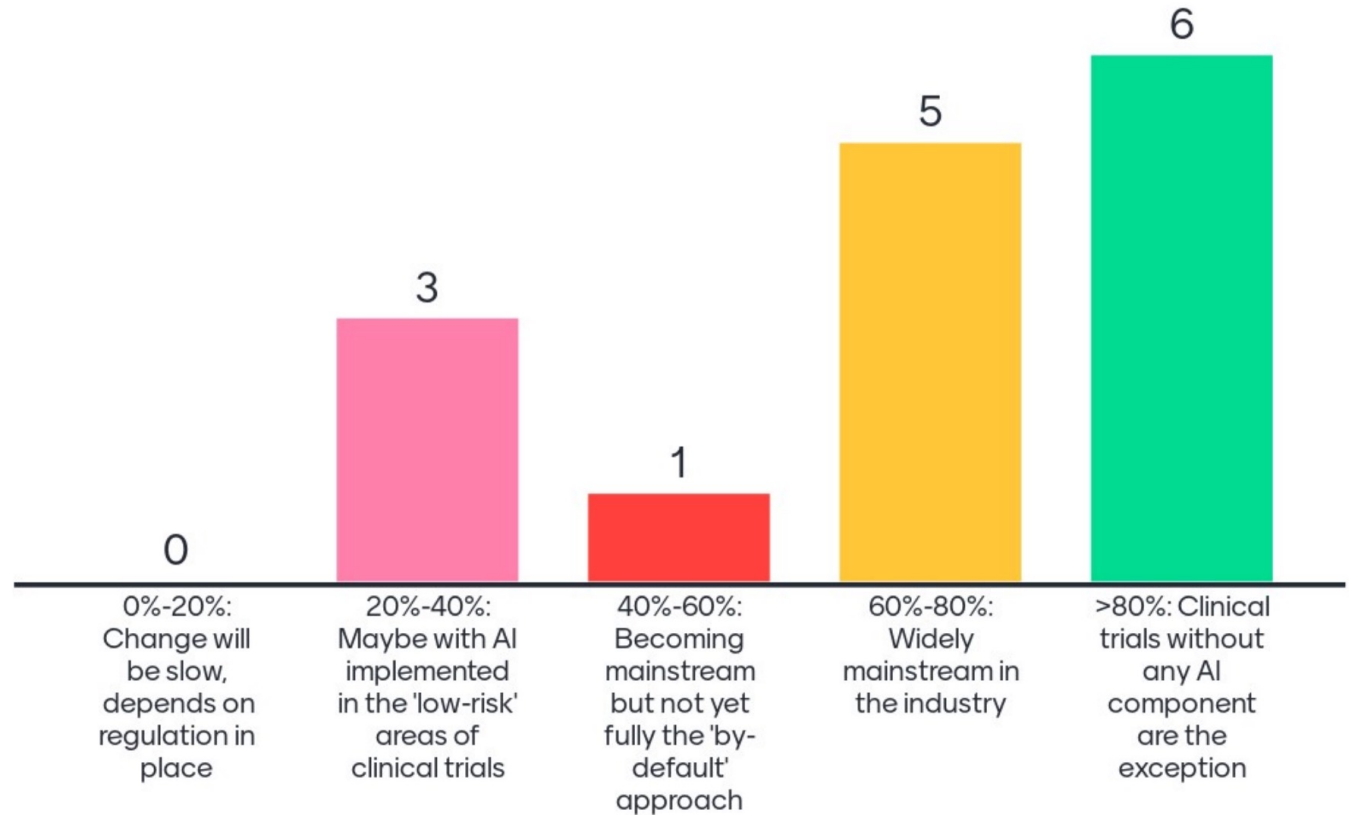Using QR code or link in your browser
https://www.menti.com/al75zp6osrp6

VOTING

In your views, which % of clinical trials launched in 2030 will include 'some aspects' of AI?

0	3	1	5	6
0%-20%: Change will be slow, depends on regulation in place	20%-40%: Maybe with AI implemented in the 'low-risk' areas of clinical trials	40%-60%: Becoming mainstream but not yet fully the 'by-default' approach	60%-80%: Widely mainstream in the industry	>80%: Clinical trials without any AI component are the exception

THOUGHT STARTERS

... how can we build trust in AI in clinical trials – trust from research partners, from HCPs, for patients?

... how can you manage the rising expectation on 'explainable AI'?

THOUGHTS & IDEAS

THERE'S AI IN TRIALS

START DOING...

DO MORE OF...

DO DIFFERENTLY

WRAP UP

TREND MAPPING: MATURITY

VOTING

Fringe   Emerging   Take-off   Strong upwards   Mainstream
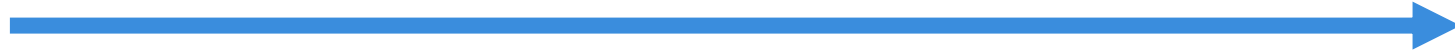
→

TREND MAPPING: MATURITY

Fringe Emerging Take-off Strong upwards Mainstream

THERE'S AI IN 'TRIALS'

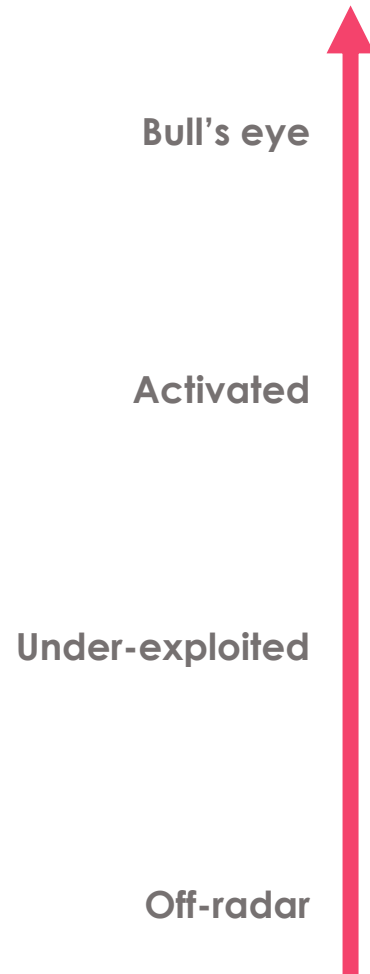**TAPPING INTO THE DIGINOME**

PEOPLE, NOT PATIENTS

ALL INCLUSIVE CLINICAL TRIALS

SUSTAINABILITY COMES TO HEALTHCARE

TREND MAPPING: ACTIVATION

Bull's eye

Activated

Under-exploited

Off-radar

How well am I leveraging or activating this trend?

TREND MAPPING & GAP ANALYSIS

Start-up	People, Not Patients	All inclusive	Sustainability	Diginome	AI in Clinical trials
Start up 1	x	x	x	x	✓✓
Start up 2	✓	x	✓	x	✓✓
Start up 3	✓✓✓	✓✓	x	✓	✓✓✓
Start up 4	✓	✓	x	✓	✓✓
Start up 5	✓✓✓	✓✓	x	✓	x
Start up 6	x	✓✓	✓	✓	✓✓
Start up 7	✓✓	✓✓✓	x	✓	✓
Start up 8	x	✓✓	✓	✓✓	✓✓
Start up 9	✓	✓✓✓	✓✓✓	✓	✓✓✓
Start up 10	✓✓✓	✓✓	x	x	x
Start up 11	x	x	✓✓	x	✓✓✓
Start up 12	✓✓	✓	x	x	✓✓✓
Start up 13	x	✓	x	x	✓✓✓

SELF-ASSESSMENT

- Bull's eye   ✓✓✓
- Activated   ✓✓
- Under-exploited   ✓
- Off-radar   x