Developing at speed in a heavily regulated environment

RAICo Responsible Innovation Session
Nottingham, 26 March 2024

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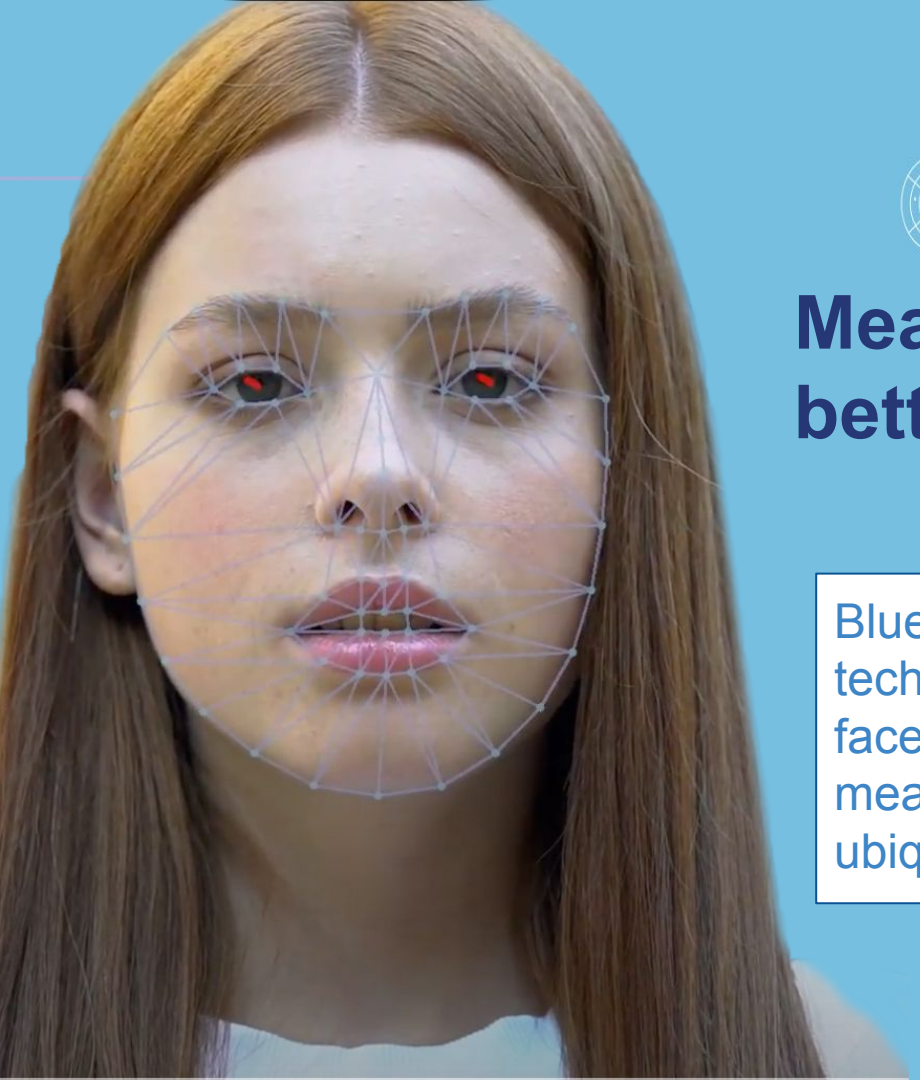
BLUESKEYE AI

This will not stand man!

BLUESKEYE AI

Every day, hundreds of millions of people go to bed anxious, depressed, unhappy, with no peace of mind of knowing what to do tomorrow to make their lives better.

Behaviomedical conditions including anxiety and depression are diagnosed too late, which removes valuable opportunities for early intervention. What's more, patients lack the language and tools to measure and communicate their mental state with clinicians, friends, and family. This also robs clinicians of the ability to assess progress between and even at check-in points, further delaying timely diagnosis and treatment delivery.



BLUESKEYE AI

Measuring the mind, for a better future together

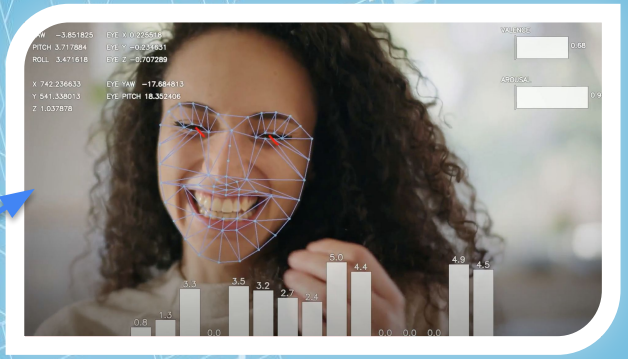
BlueSkeye AI aim to create the most-used technology for ethical machine understanding of face and voice behaviour you can trust to measure your mind through the use of ubiquitously available, affordable technology.

BlueSkeye AI: Delivering scalable, on-edge, clinical grade human sensing technologies

BLUESKEYE AI

CORE TECHNOLOGY

State of the art analysis of **facial muscle actions, gaze, head actions** and other face and voice biomarkers to infer **mood**, **mental states** and **clinical conditions**



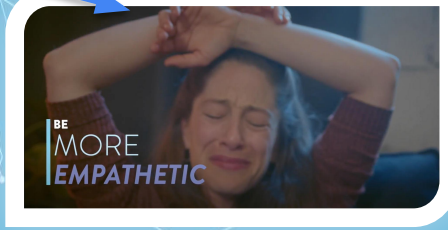
ECOSYSTEM ENABLING

Study support tools:
Health Foundation Platform

Software Development Kits:
B-Automotive
B-Healthy

CLINICAL GRADE TECHNOLOGY

Everything built ready for medical device certification. Depression and mood analysis solutions for pregnant women will be a medical device.



AI challenges

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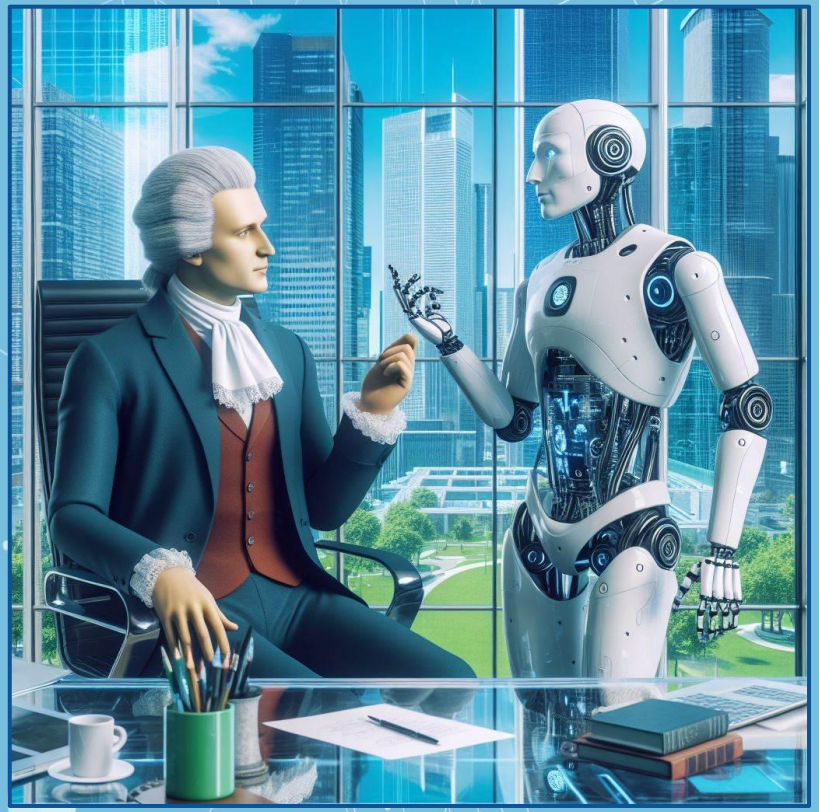
- Trustworthiness
  - Reasonably well understood but shouldn't be confused with trust
- Privacy
  - This is largely covered by GDPR etc
- Regulatory framework
  - Medical devices, automotive safety, AI
  - UK, EU, USA
  - Horizontal vs vertical regulation
  - Completely new challenges of assessing medical devices that constantly change
- Changes to clinical pathways
  - Keeping the clinician in the loop whilst trusting AI's capabilities
  - Integration into existing workflows and systems
  - The need to learn how to use the tools - experience over time
- Patients will be using AI at home
  - Like PROMs… but much more radical in its abilities
  - Who's responsible for follow-up of a home test?
  - Avoiding people using AI and trusting it is of the same quality as a clinician's view

EU AI Act regulation

BLUESKEYE AI

1. Coming into force very rapidly - prohibition from c. Nov 2024
2. Emotion Recognition Systems (ERS) are prohibited in Educational Institutions and the workplace except for health and safety reasons
3. ERSs are always high risk and thus require CE Marking
    a. Not all required standards are in place yet
4. You must always inform a user that an ERS is used



EU AI Act regulation

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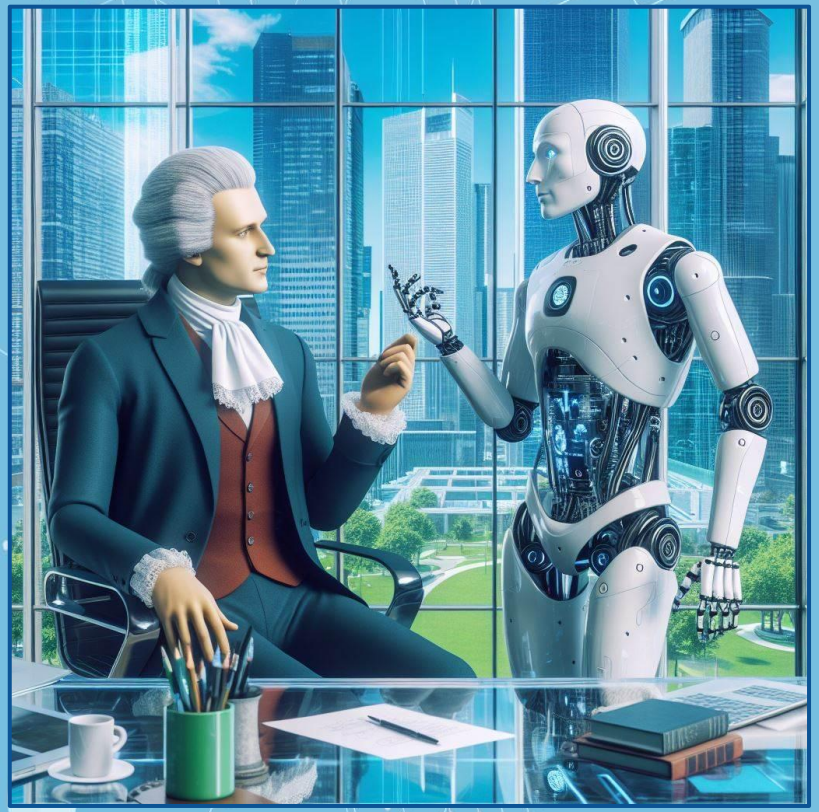
An Emotion Recognition System is defined rather vaguely:

“an AI system for the purpose of identifying or inferring emotions or intentions of natural persons on the basis of their biometric data. This refers to emotions or intentions such as happiness, sadness, anger, surprise, disgust, embarrassment, excitement, shame, contempt, satisfaction and amusement. It does not include physical states, such as pain or fatigue. It refers for example to systems used in detecting the state of fatigue of professional pilots or drivers for the purpose of preventing accidents. It does also not include the mere detection of readily apparent expressions, gestures or movements, unless they are used for identifying or inferring emotions. These expressions can be basic facial expressions such as a frown or a smile, or gestures such as the movement of hands, arms or head, or characteristics of a person’s voice, for example a raised voice or whispering.”



BLUESKEYE's approach to innovation

BLUESKEYE AI

1. We face the challenges head-on and in full transparency with the team
2. Ethical design choices created constraints that force innovation
3. There is overhead to creating regulated products
4. Keep parallel regulated and unregulated products
    a. Iterate quickly with unregulated products
    b. Invest in regulated products after you know what works
    c. E.g. Avocado vs TrueBlue
5. Celebrate failure
6. Keep team communication inclusive and frequent whilst ensuring everyone knows who's accountable and responsible

BLUESKEYE AI

- We enjoy a challenge
- We have a highly educated and specialist team full of existing and growing expertise
- We don't let the hard things stop us from our mission, we find a way through and want to be ground breaking
- We know when to ask for help - from each other and from external sources
- We remain flexible in the ways we work - be it through prioritising work flows or creating supporting policies

There's something to be said for decoupling the innovative / exploratory elements (R&D) from the parts of the business that are subject to regulation; establishing the boundary between the two, so allowing free reign in the parts where it's safe to do so.

Also, agility and regulation aren't necessarily at odds with one-another. You can remain compliant while still delivering in an agile / iterative manner.

Working in highly compliant areas doesn't cost time. If we work smarter by utilising the right tools in the right way we can ensure that we are compliant with minor changes to our existing processes.

A great example would be the dependency on traceability for most standards by simply ensuring that our git system can speak to our project management system and that our QA team link into our project management system. It means we can track every step of the process from initial requirements generation with relevant acceptance criteria which we link the code changes that realise them requirements via github which also captures code reviews then when our QA team test them changes they test against the acceptance criteria and document their report in the initial ticket on Jira.

We deliver continuous incremental value to clients through well structured client engagements.

Clinical grade ethical AI is a fundamental principle of our business. As such best (AI) practice is integral to everything we do, it isn't something added in at the end to just tick the compliance box

Ethical AI is not just a part of our commercial compliance strategy, but an integral pillar of our work culture on all levels of operations.

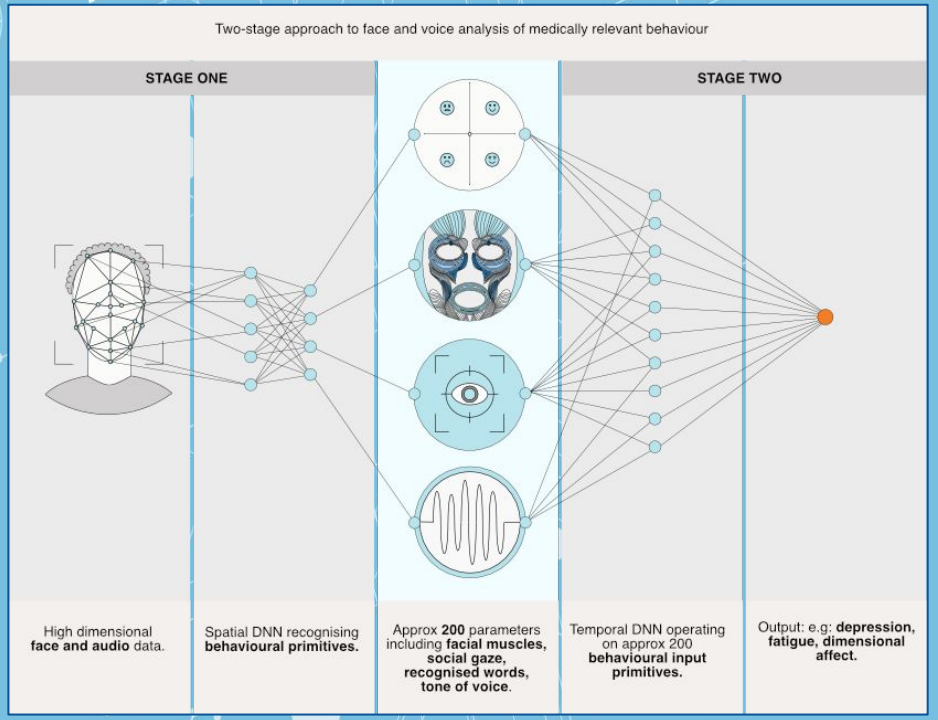
We are focussed on delivering high standard solutions keeping the end customer in mind, which gives us insights for innovation. The regulatory environment gives us scaffolding to deliver what we say we value!

Enabling privacy and remove bias

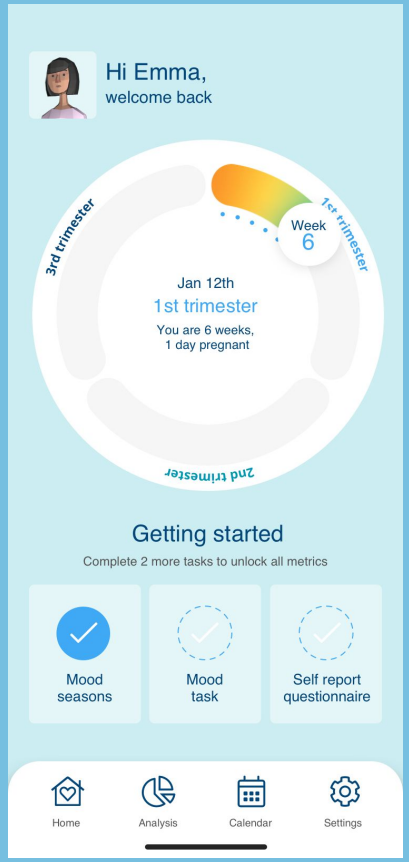
BLUESKEYE AI

BLUESKEYE AI employs a unique two-stage approach to measuring medically relevant face and voice data

1. First stage detects face and voice biomarkers (facial muscle actions, gaze, tone of voice etc.) from video.
2. Second stage turns behaviour primitives into behaviour insights including mood and depression recognition.
3. Benefits include:
    a. We can use separate training sets:
        i. millions needed for stage one,
        ii. only thousands needed for stage two.
    b. Separation of concerns:
        i. First stage addresses high-dimensional data appearance issues including appearance-based bias
        ii. Second stage addresses temporal issues and culture-based bias
    c. The first stage has high-dimensional input (meaning more data is needed) but does not require medical grade data
    d. The second stage often requires medical grade data but the input is very low-dimensional (meaning less data is needed)



TrueBlue Clinical Trial



BLUESKEYE AI

Application

- Using face and voice sensing technology for early identification of mental illness
- Reducing the prevalence of poor mental health amongst pregnant women
- Empowering individuals to self manage mental health

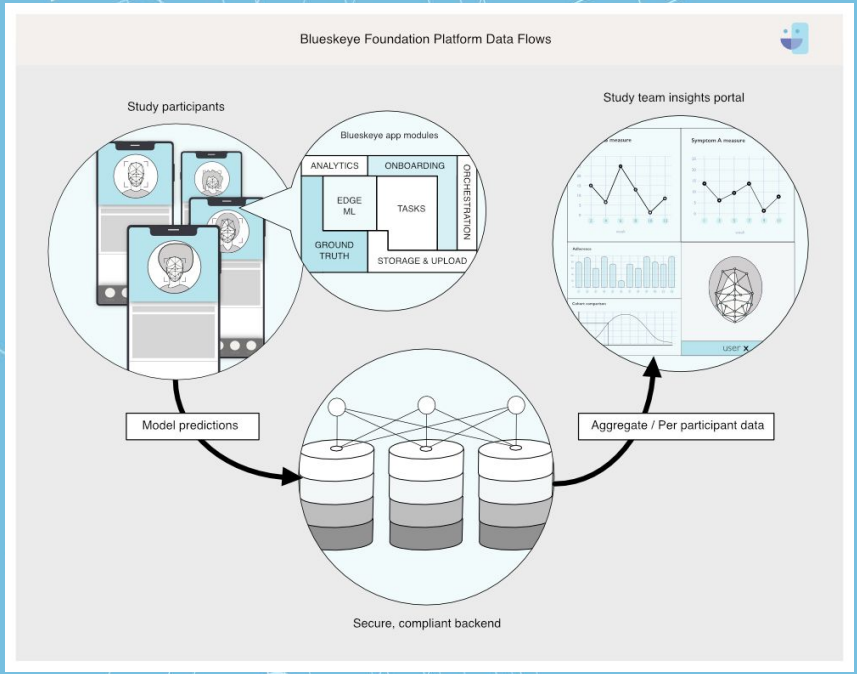
Clinical Safety, efficacy & improved population health

Working with NHS trusts in Nottinghamshire to evidence the clinical safety in the use of an app for pregnant women to inform mental health assessments

Health Foundation Platform

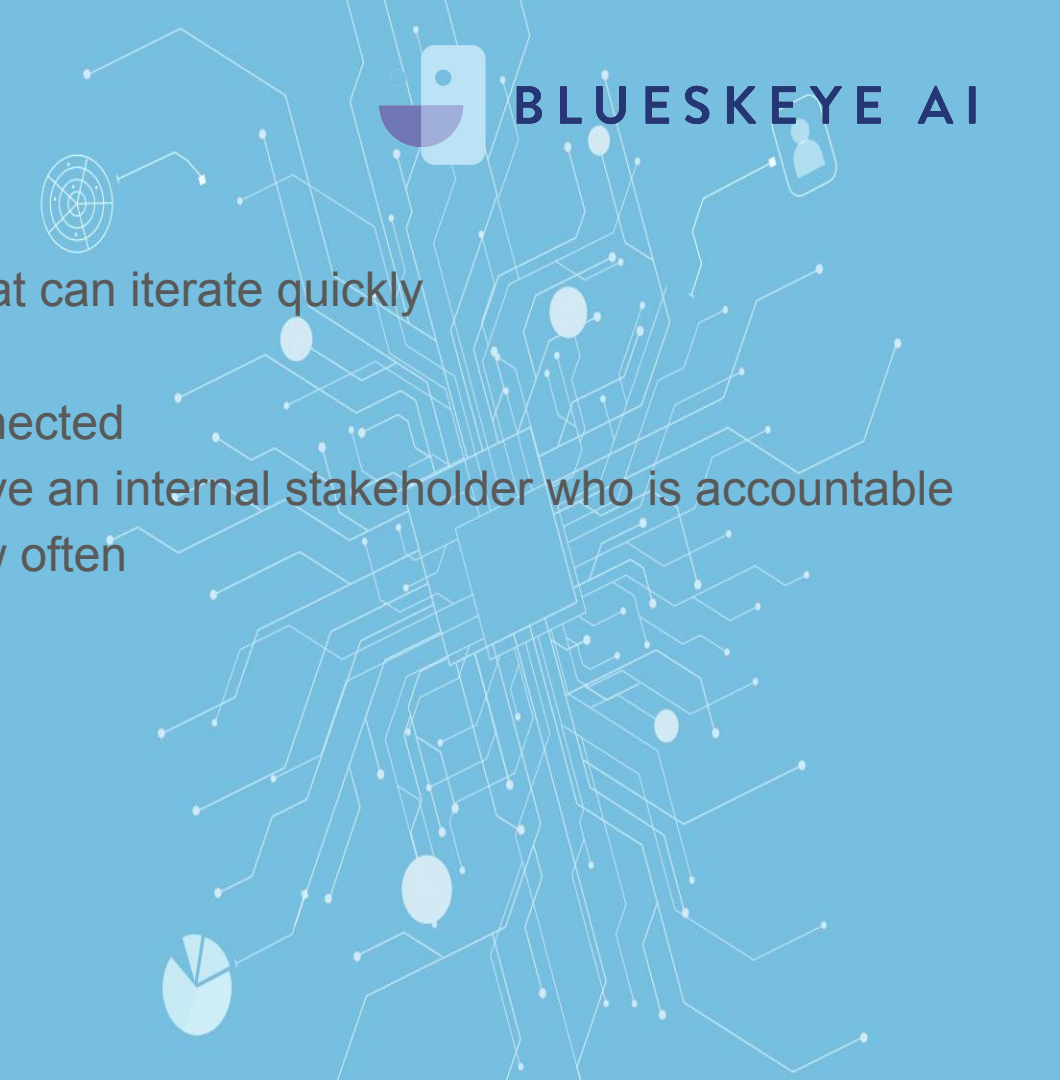
BLUESKEYE AI

1. We do things the hard way so our customers don't have to:
   a. Deploying the first stage on edge is hard!
   b. Developing it as if it were a medical device is costly!
2. We only store anonymous output of first stage and our customers can do research on that.
3. Health Foundation Platform is developed under QMS and has a technical file.
4. Follows relevant regulatory standards:
   a. HIPAA compliant,
   b. GDPR compliant,
   c. ISO 27001 certified,
   d. On track to be ISO 13485 certified,
   e. EU AI Act compliant.

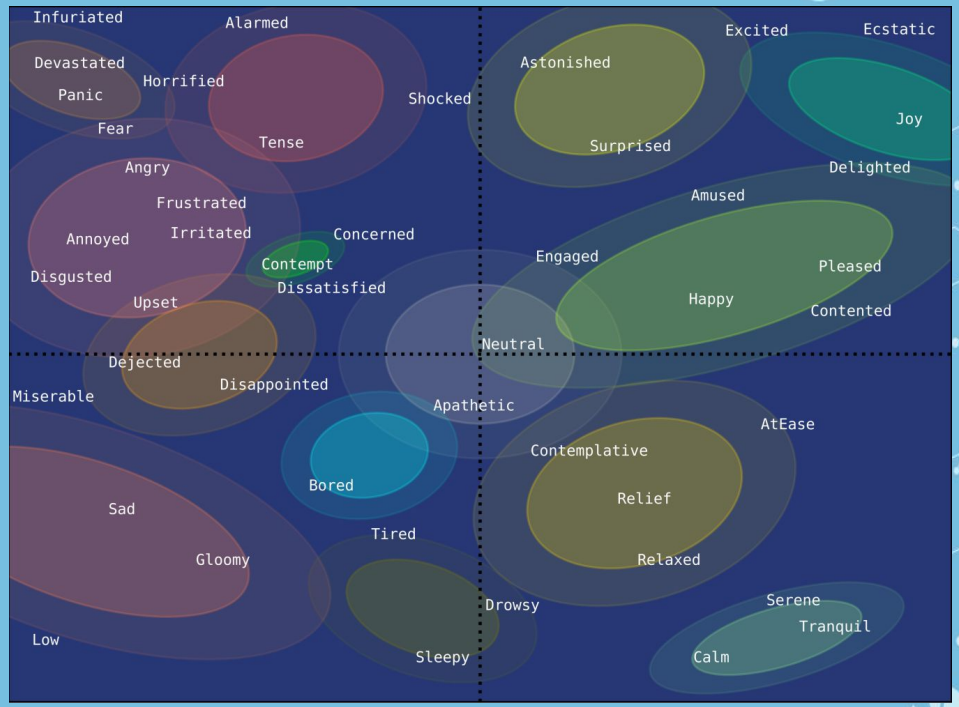


Key takeaways

1. Have non-regulated versions that can iterate quickly
2. Use software e.g. Vanta
3. Keep teams small and well connected
4. Rely on external experts but have an internal stakeholder who is accountable
5. Define RACIs clearly and review often



Thank you


Infuriated
Alarmed
Devastated
Horrified
Panic
Shocked
Fear
Tense
Angry
Frustrated
Annoyed
Irritated
Concerned
Contempt
Disgusted
Dissatisfied
Upset
Dejected
Disappointed
Miserable
Bored
Sad
Tired
Gloomy
Low
Sleepy
Drowsy
Apathetic
Neutral
Excited
Ecstatic
Astonished
Joy
Surprised
Delighted
Amused
Engaged
Pleased
Happy
Contented
AtEase
Contemplative
Relief
Relaxed
Serene
Tranquil
Calm