

A full-page background image of an astronaut in a white spacesuit standing on the moon's surface. The astronaut's helmet reflects the lunar landscape and the Earth in the distance. The moon's surface is covered in craters and dust. Several black crosshair markers are overlaid on the image.

Benannte Stellen und die Herausforderungen der MDR / IVDR

Jasminka Roth

Schaffhausen, 10. Oktober 2019

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Consulting services for strategic quality
management and smart process design.

Unsere Wirkungsfelder Was tun wir



Strategische
Intelligenz



Compliance und
Audit-Vorbereitung



Process engineering
und Training

The Tao of Excellence Wer sind wir



Tactical session Workshop - Format

Von Tao of Excellence entwickeltes Workshop-Format

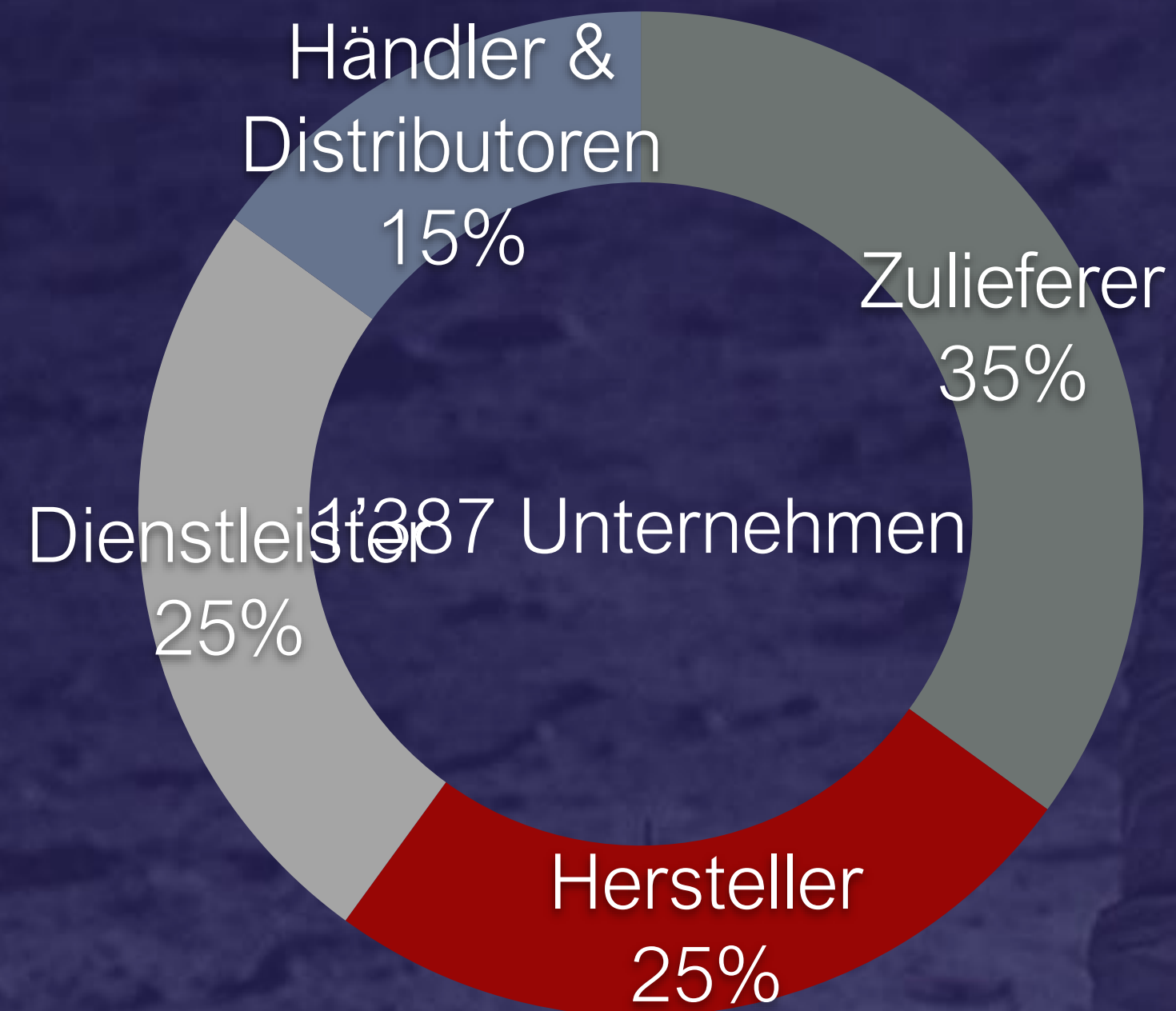
Erlaubt das vertiefte Erarbeiten eines Themas

- Intensiv
- Interaktiv
- Kollaborativ

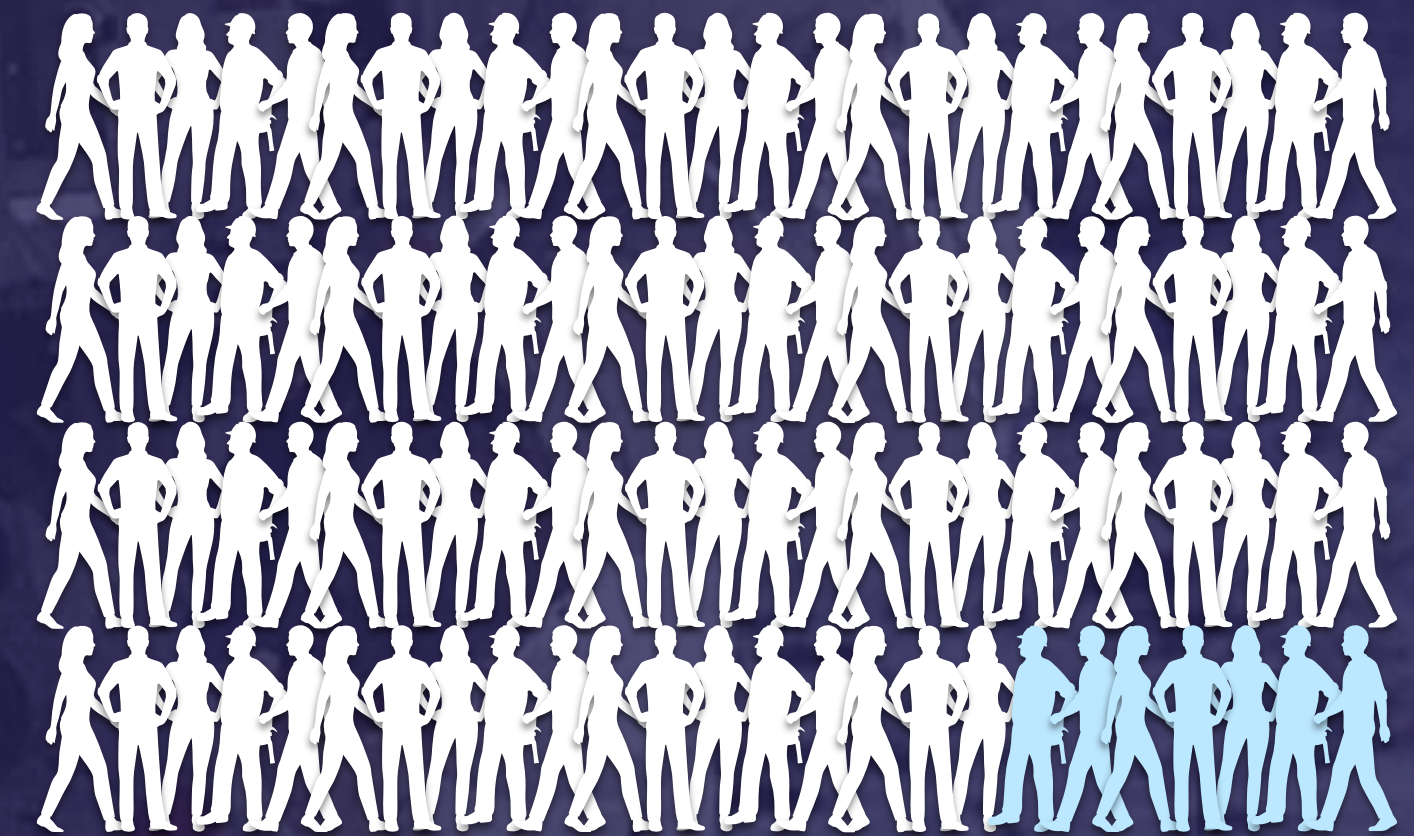


www.menti.com

Medtech Industrie Bedeutung für die Schweiz



58'500 Beschäftigte

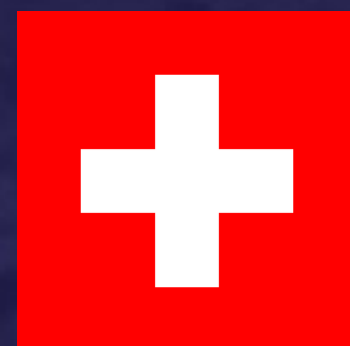


KMU
(<250 Mitarbeiter)

Gross-
unternehmen

Medtech Industrie Bedeutung für die Schweiz

5.4 Mrd CHF Import von:



11.3 Mrd CHF Export nach:



REF 437414S

LOT W23903

STERILE R CE 0123

AxSOS™

For Left Tibia 14 Hole, L227mm

Distal Anterolateral Tibia Plate TS

Distal Anterolaterale Tibia Platte TS

Plaque tibiale distale antérolat. TS

Placa tibial distal anterolateral TS

Placca tibia antero-laterale distale TS

Placa tibial dist.ant.lat. TS

Dist. lat. tibiaplaat TS

Distal anterolateral tibia platta TS

Dist.ant.lat. tibia-skinne TS

Tibialevy, distaal., anterolateraalin TS

Distal anterolateral tibia plate TS

Płytk dyst. prz.-boczna do k. piszcz.

Απω προσθιαπλάγια πλάκα κνήμης

QTY 1

2010-08

Swiss Made

2015-07



*+H820437414S0X



+\$\$3150731W23903X6

stryker

Stryker Trauma AG
CH-2545 Selzach

Distributed in USA by
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430

A subsidiary of Stryker Corp. USA

CAUTION: Federal law in USA restricts this device
to sale by or on the order of a physician or hospital

Patent Pending

Stainless Steel

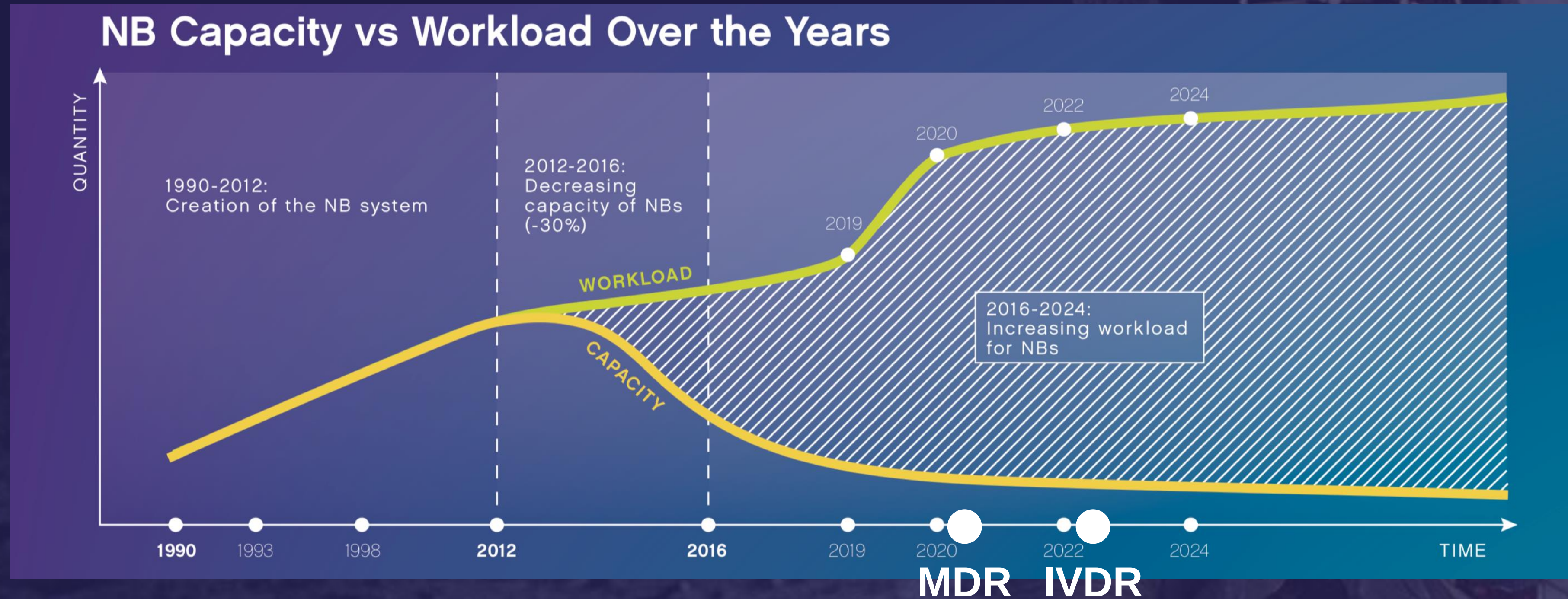


Zulassung von Medizinprodukten in Europa

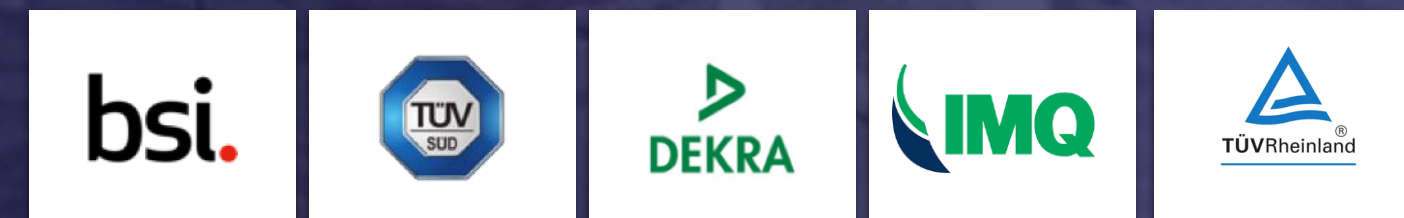
Medizinprodukte sind in Klassen eingeteilt. Je nach Klasse braucht es eine Benannte Stelle / Notified body. Stark vereinfacht:



Benannte Stellen (NB) MDR / IVDR Stand heute



- Total 56 NB für '93/42/EEC Medical devices'
- Total 5 NB für 'Regulation (EU) 2017/745 on medical devices'
- 3 NB treten zurück



Benannte Stellen (NB) MDR / IVDR Stand heute

	MDR	IVDR
Anträge erhalten	40	11
Erstbeurteilungen	38	8
Audits 2018	16	5
2019	15 7 geplant	1 2 noch nicht geplant
Empfehlungen gesprochen	9	



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Regulierung versus Innovation

Deepa Rajagopalan
Schaffhausen, 10. Oktober 2019

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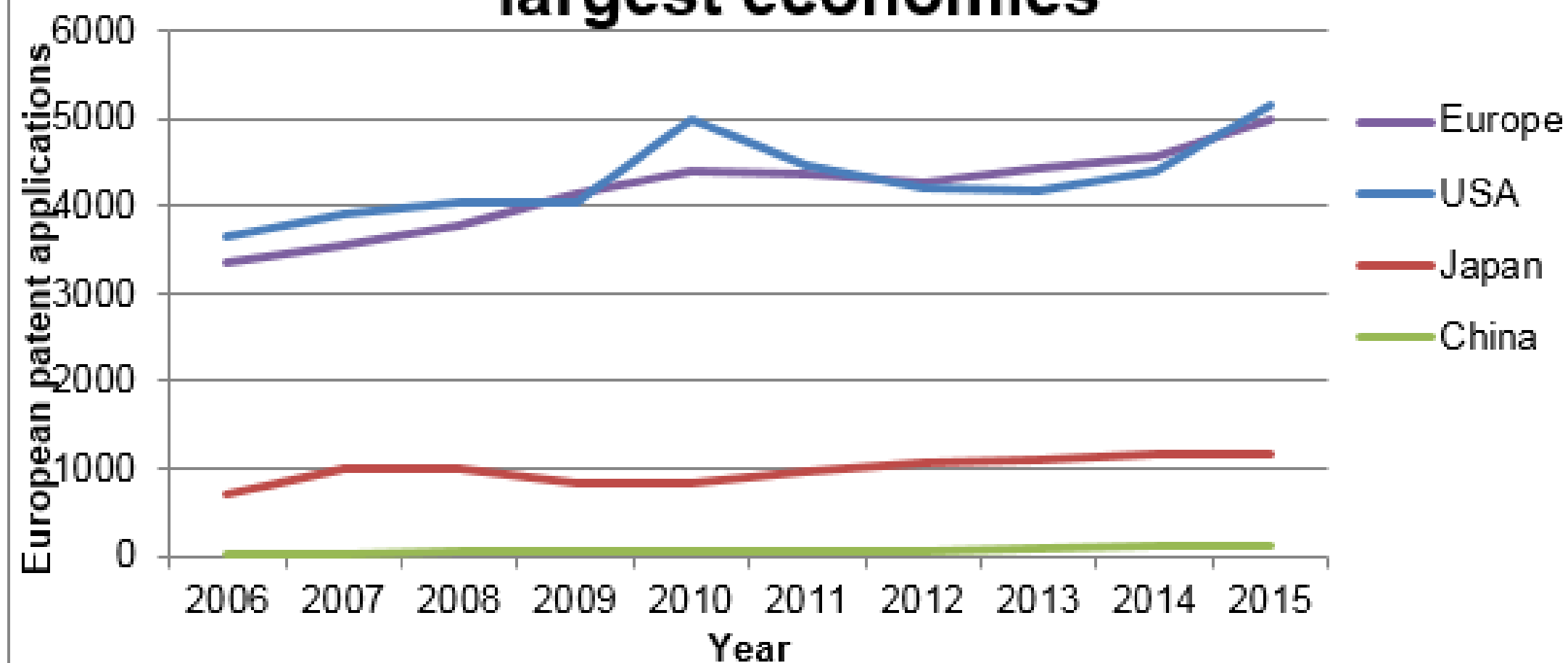
Consulting services for strategic quality
management and smart process design.

What is Innovation ?

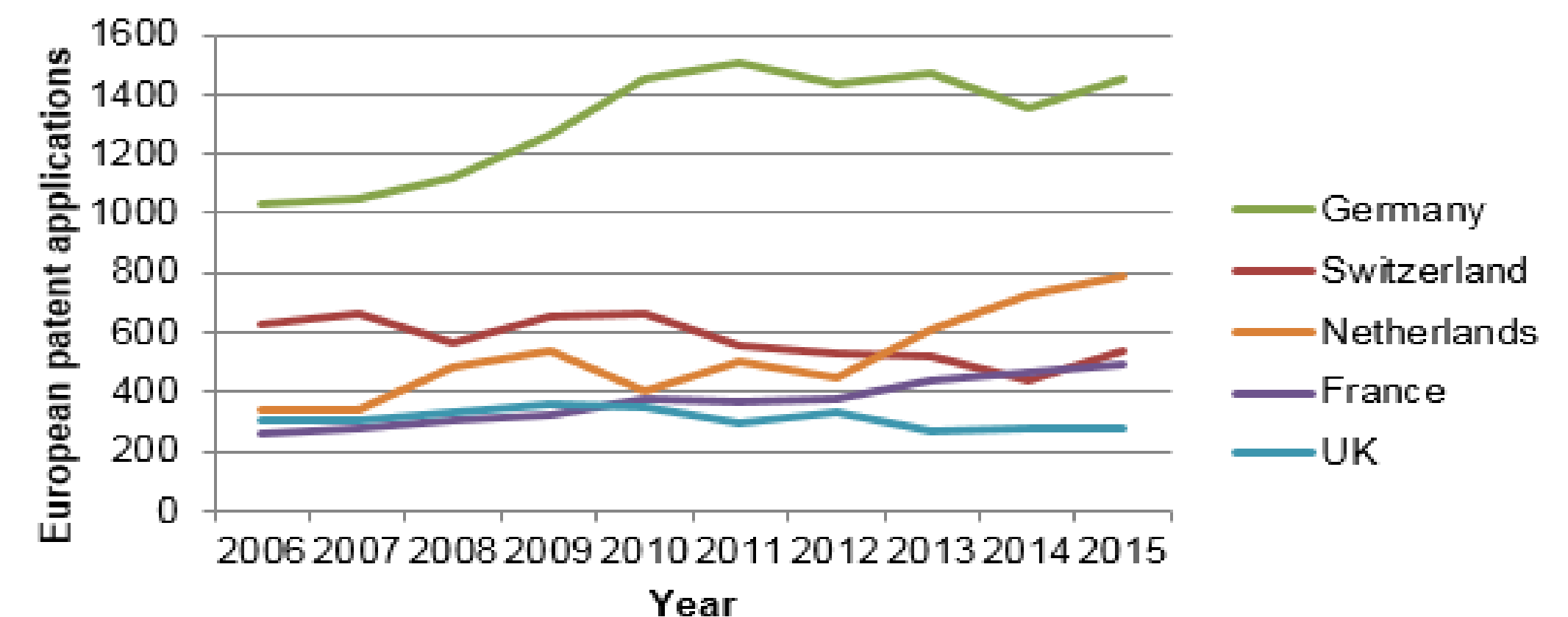
- The process of translating an idea or an invention into goods or service that creates value, for which customers are ready to pay. (*Defintion from the business dictionary*)
- It is a moment where the process of disbelieving kicks in, that there is only one way of doing things
- Innovation could turn out to be a double edged sword
- It is a challenge that needs to be embraced and percolated across the organisation

Innovation trend

European patent applications 2006-2015 for medical technology-related inventions issuing from world's largest economies



European patent applications 2006-2015 for medical technology-related inventions issuing from top 5 European countries



Objective of survey Main questions

Goal of the survey is to find out:

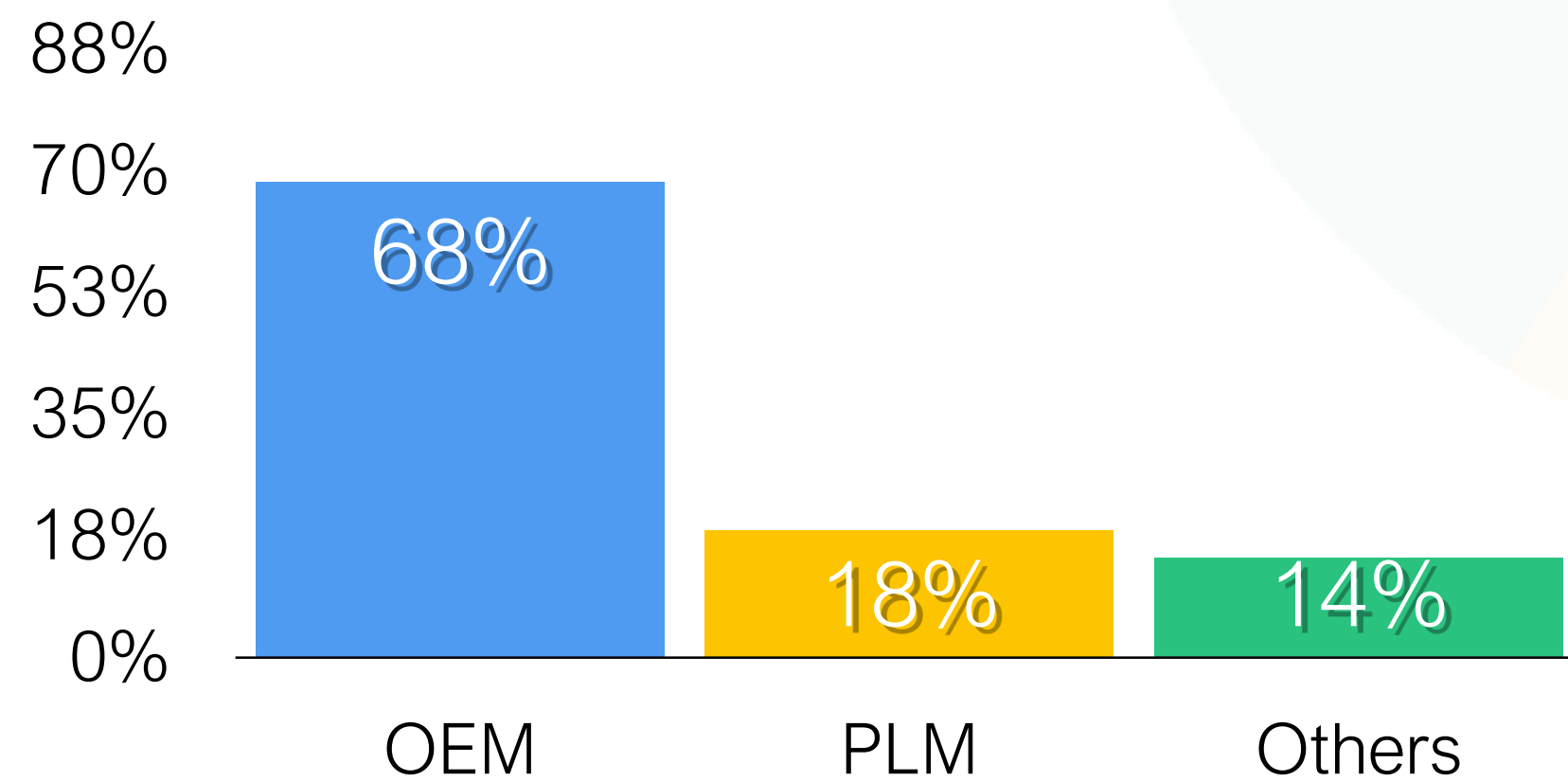
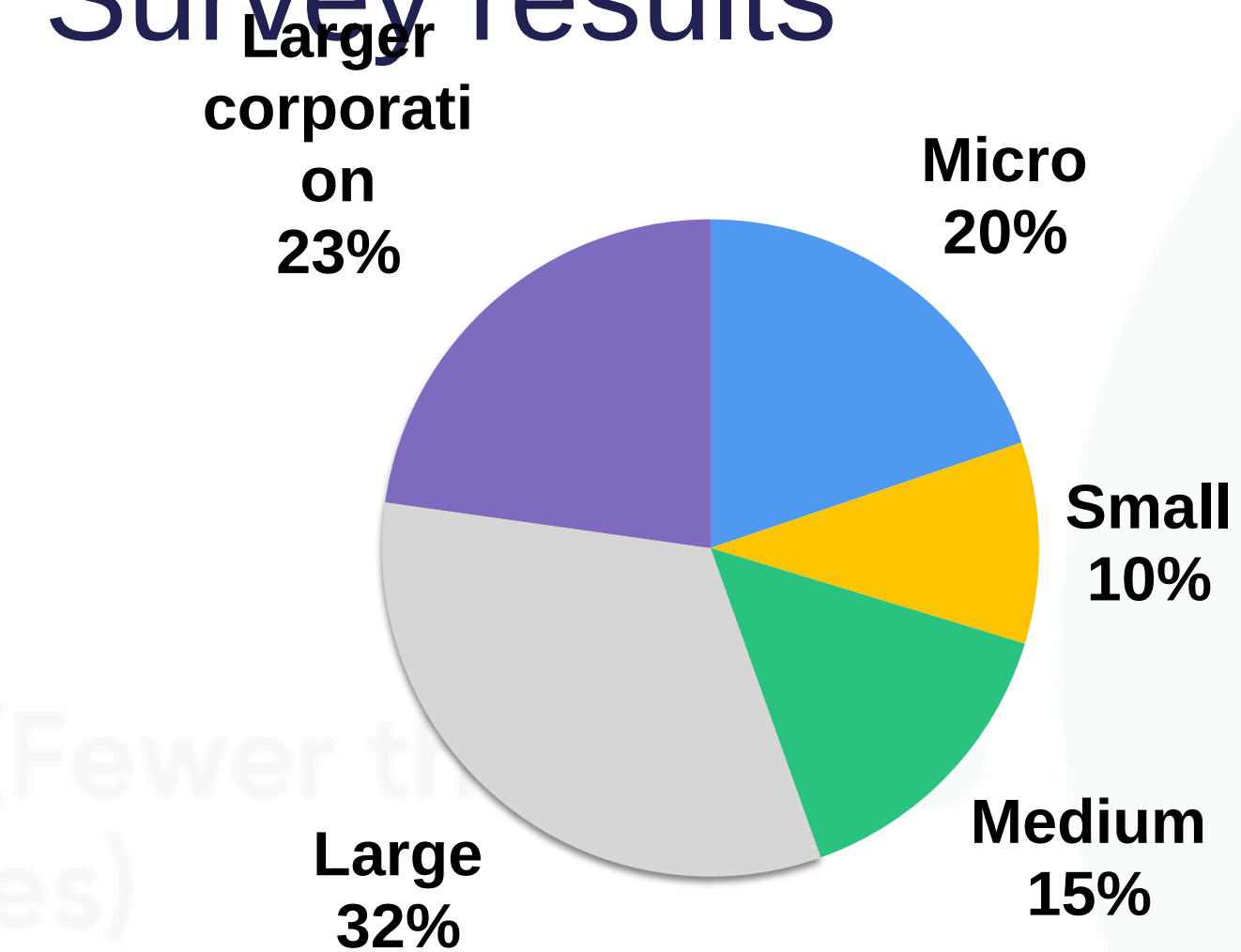
- If regulation is required
- If regulation and innovation can co-exist

The survey is conducted in collaboration with



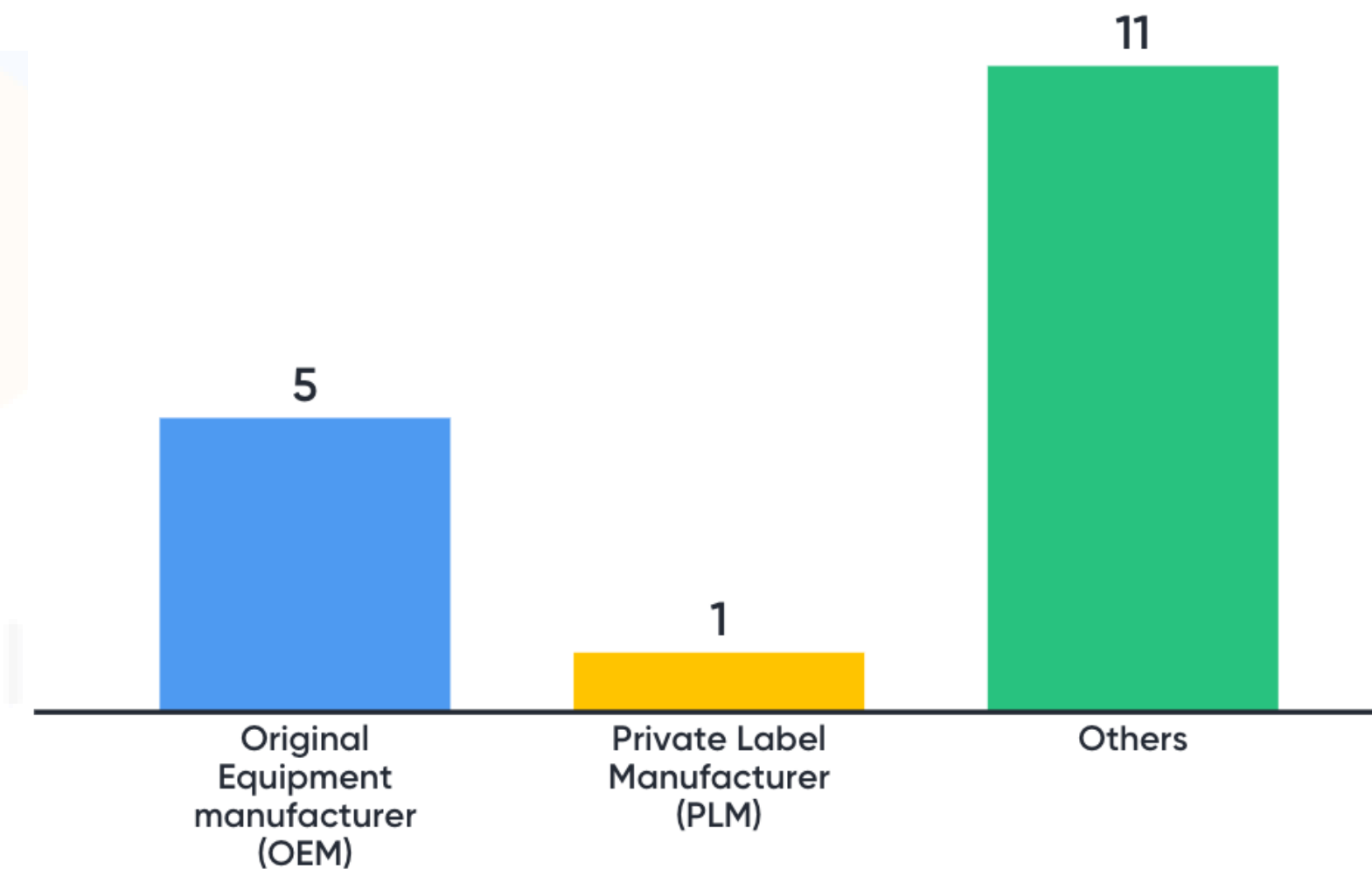
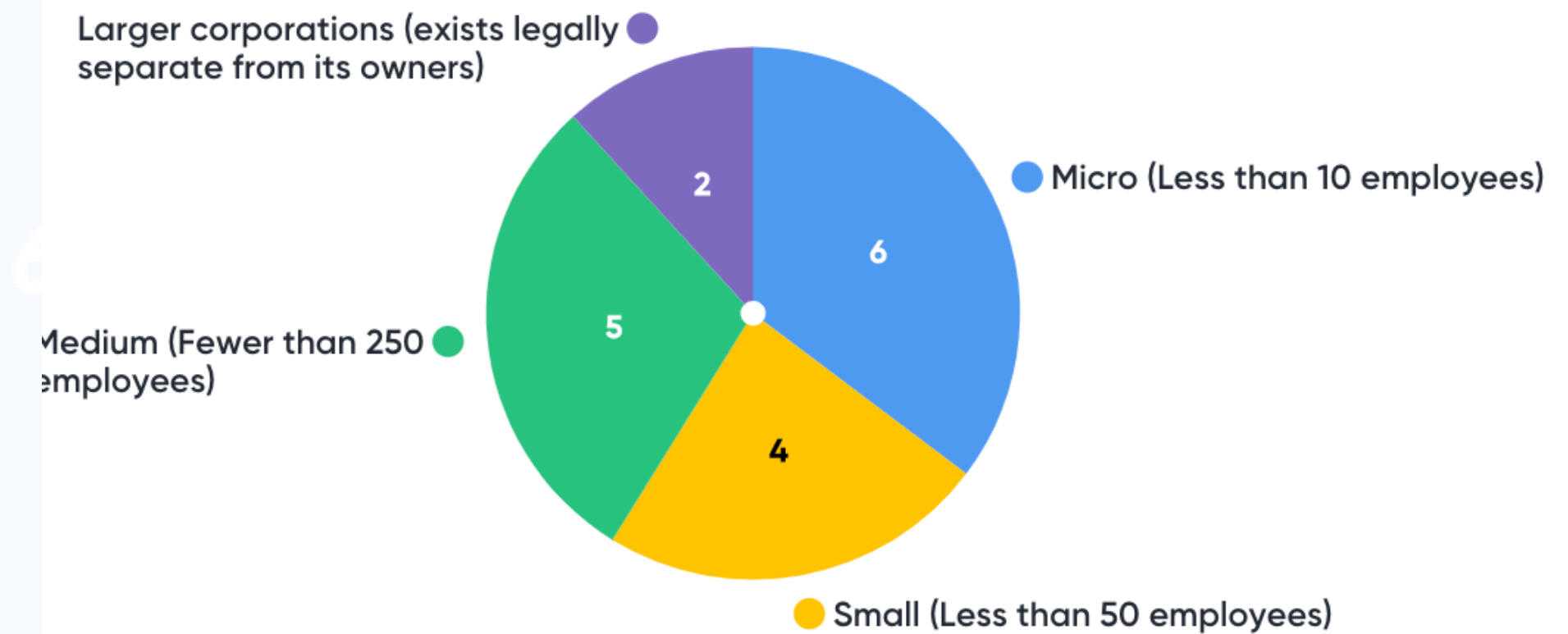
Response analysis – surveyed population

Survey results



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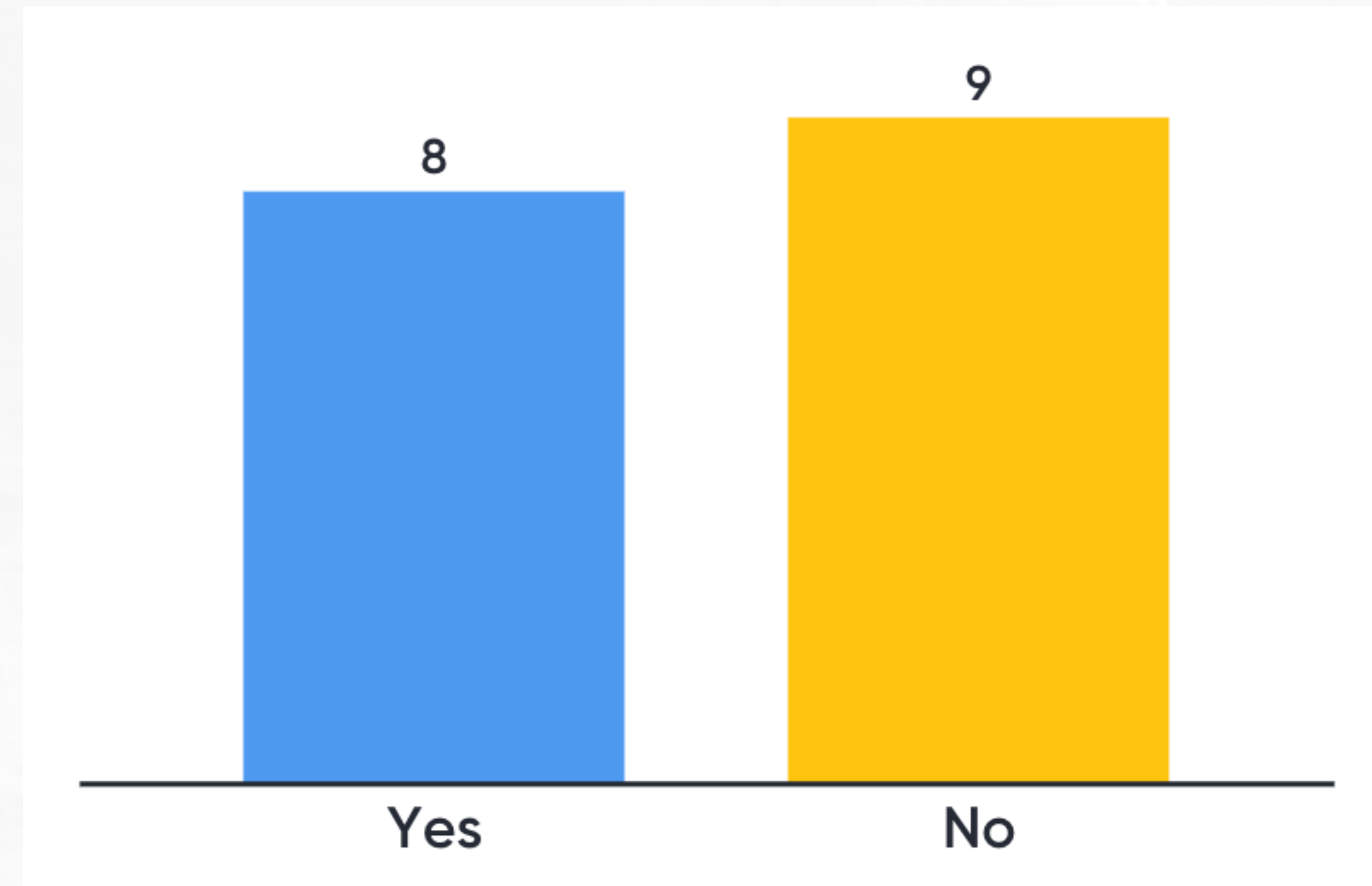
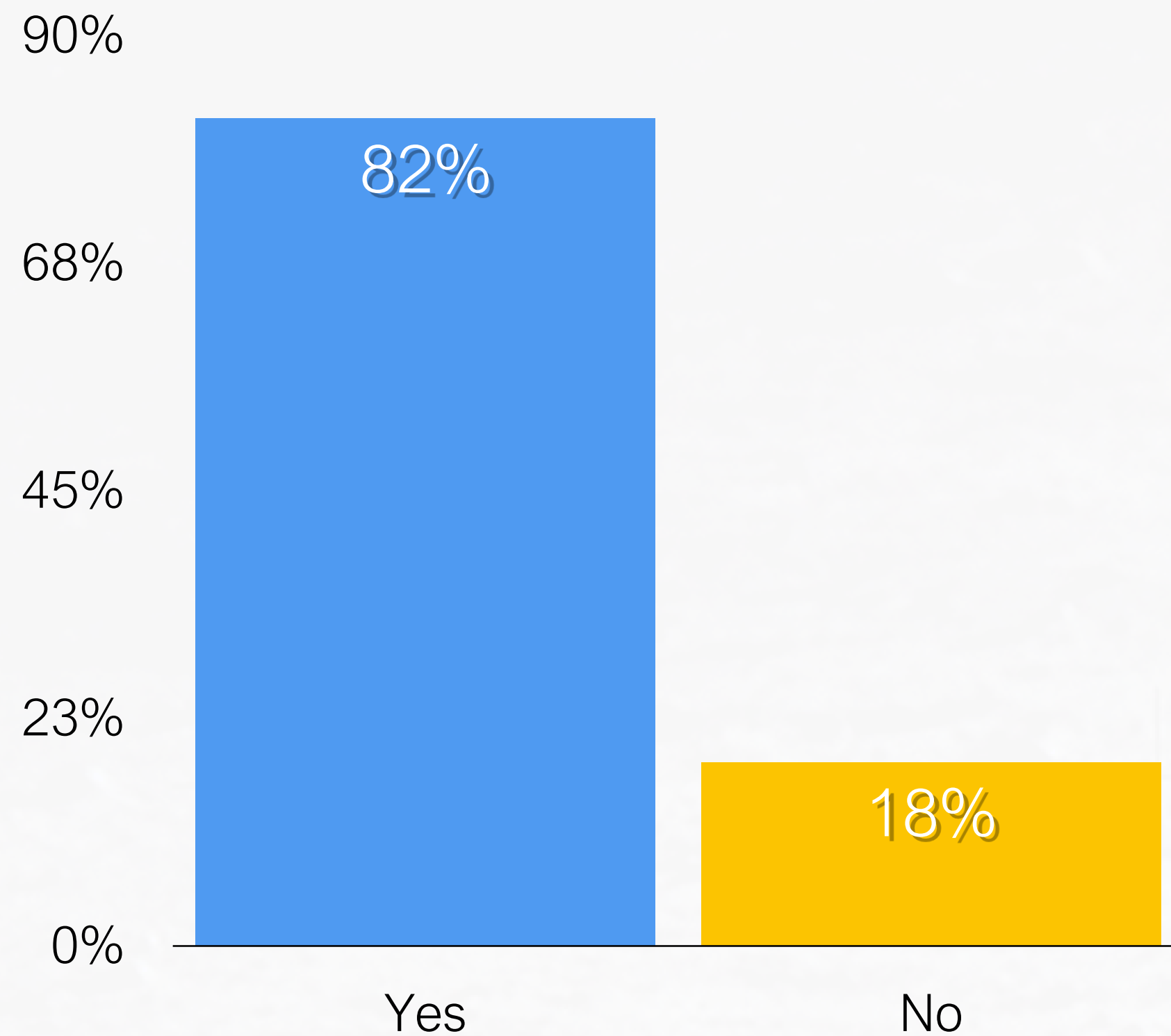
Today's results



Response analysis – Is there a dedicated research team?

Survey results

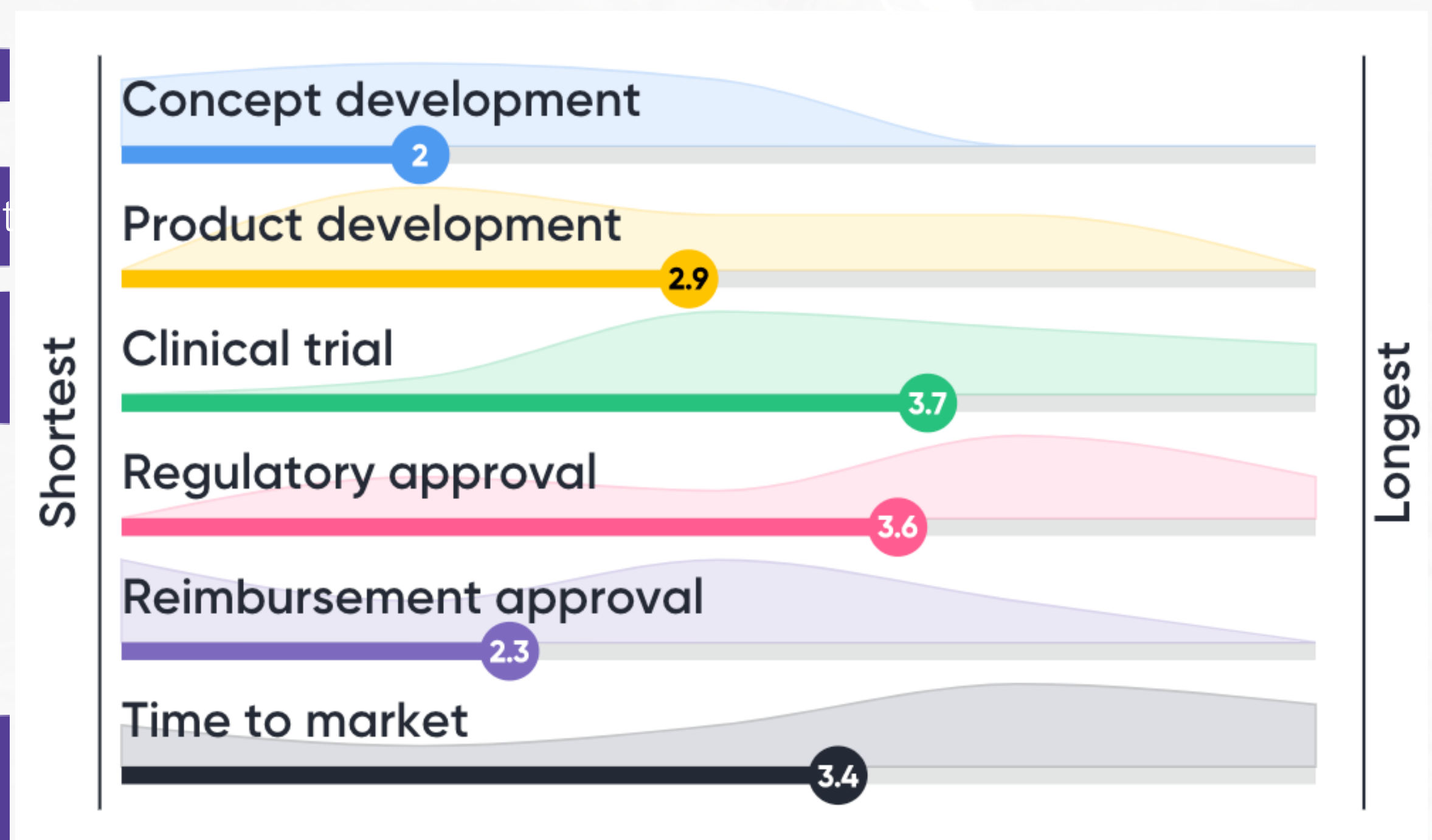
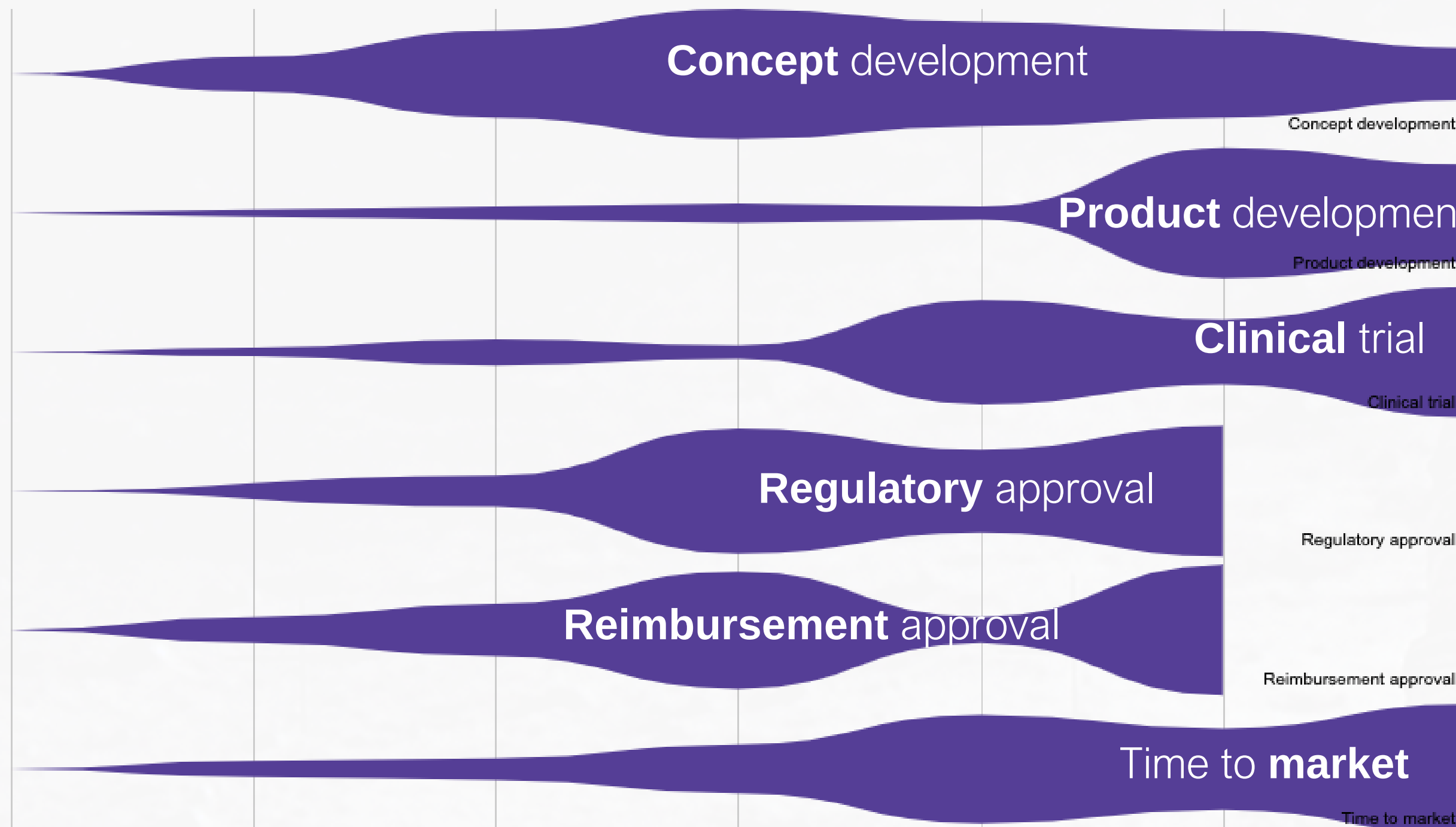
Today's results



Response analysis – What needs most time?

Survey results

Today's results



Shortest

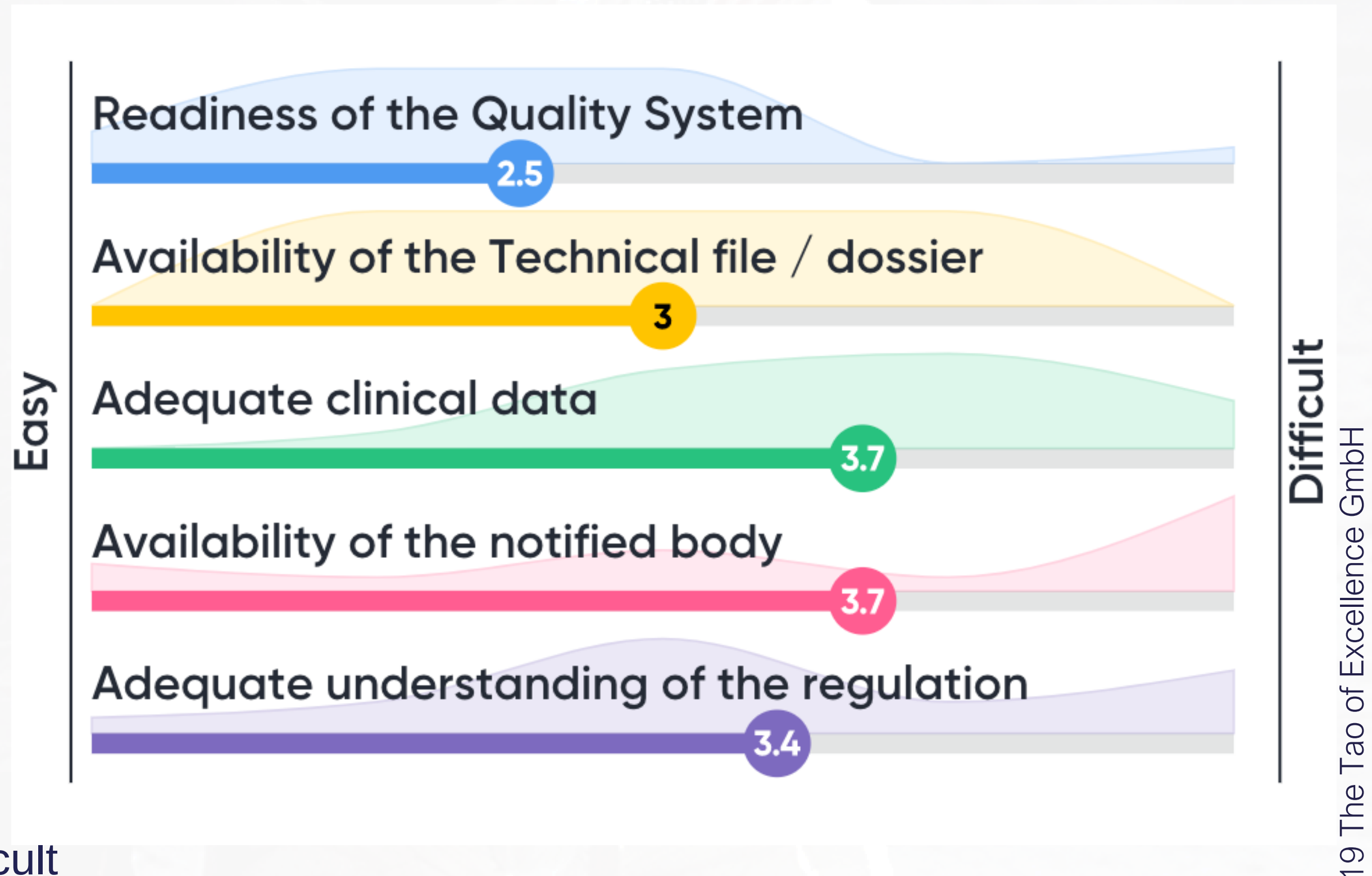
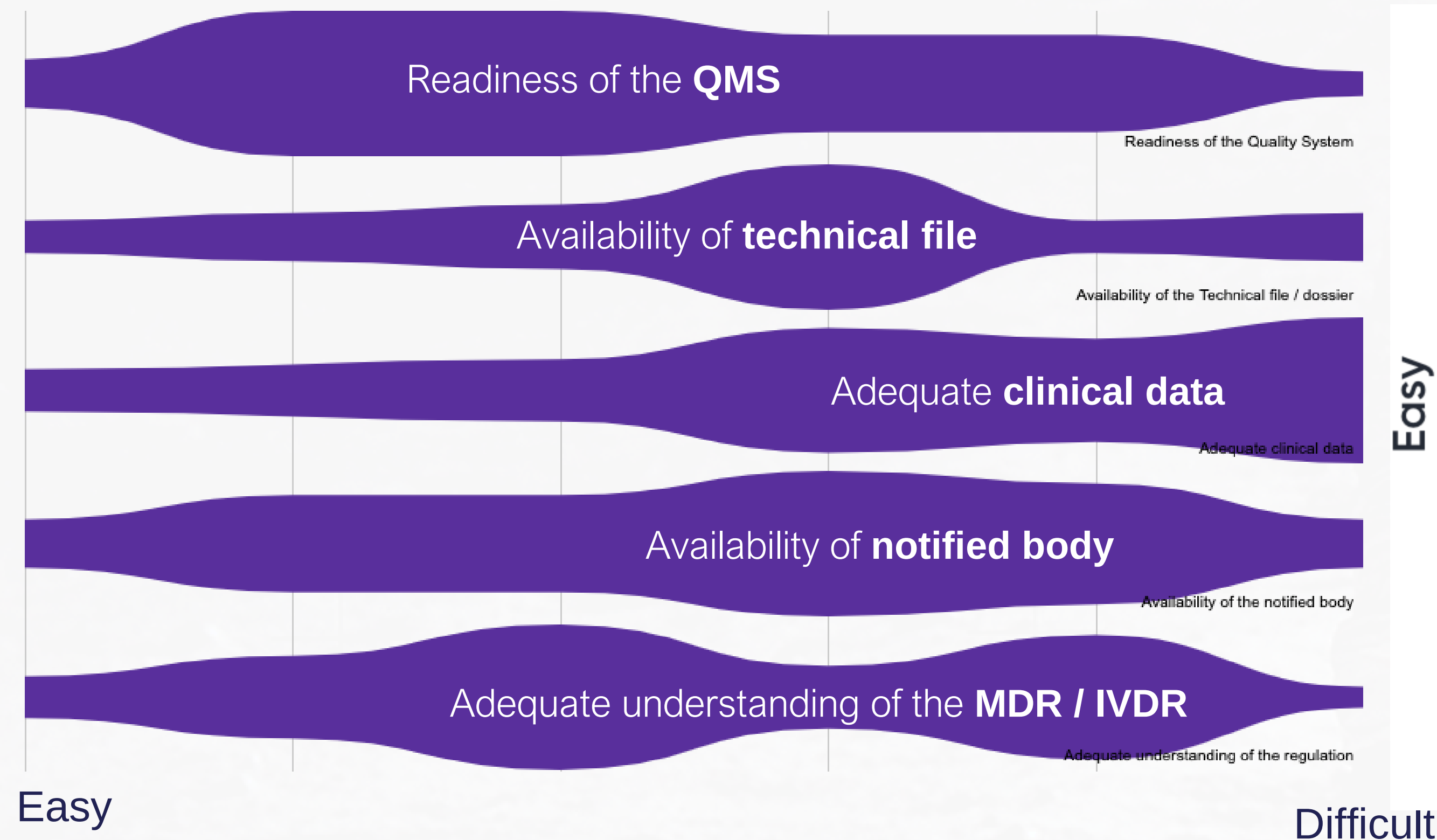
Longest

Longest

Response analysis – What is most difficult to comply to?

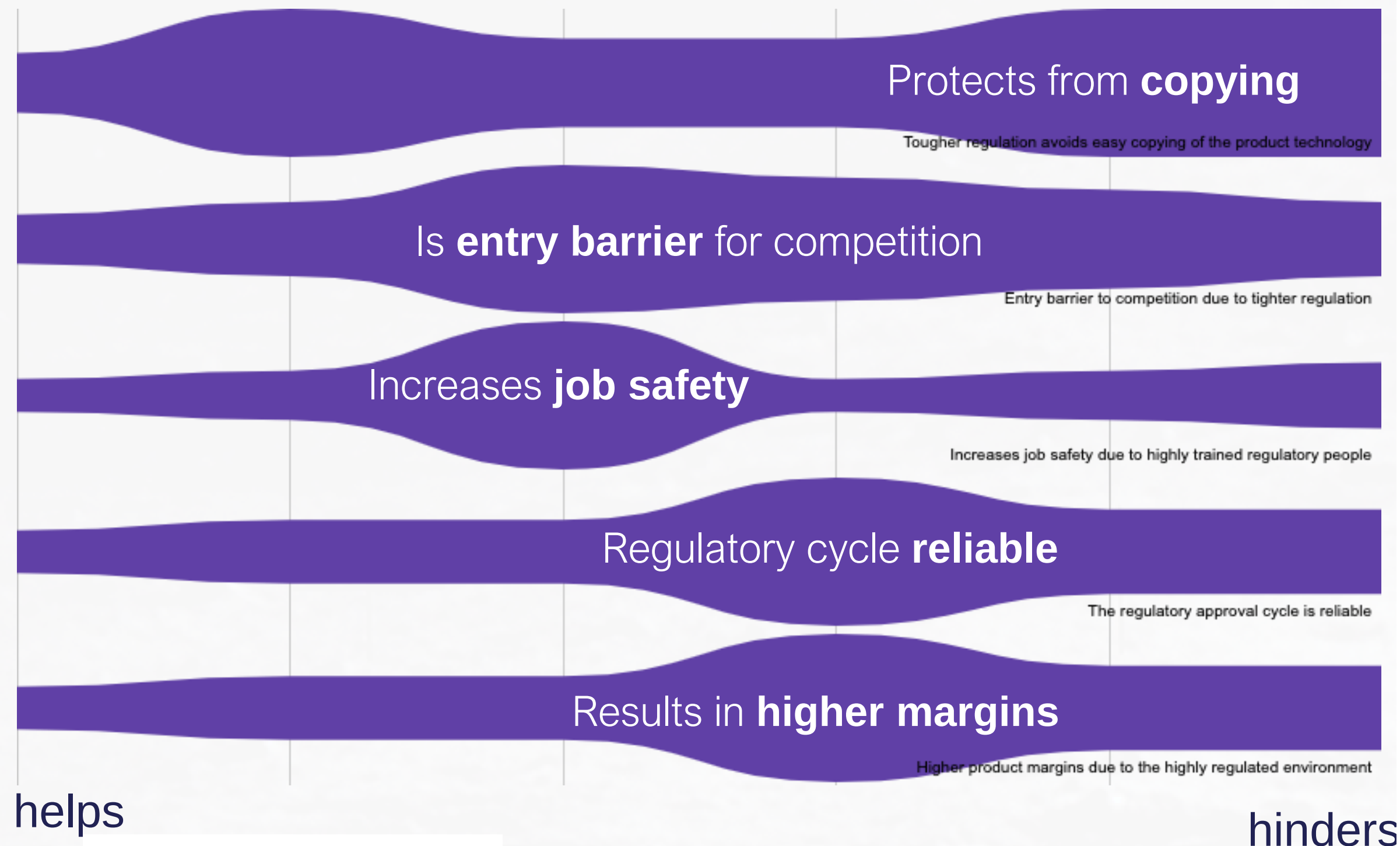
Survey results

Today's results

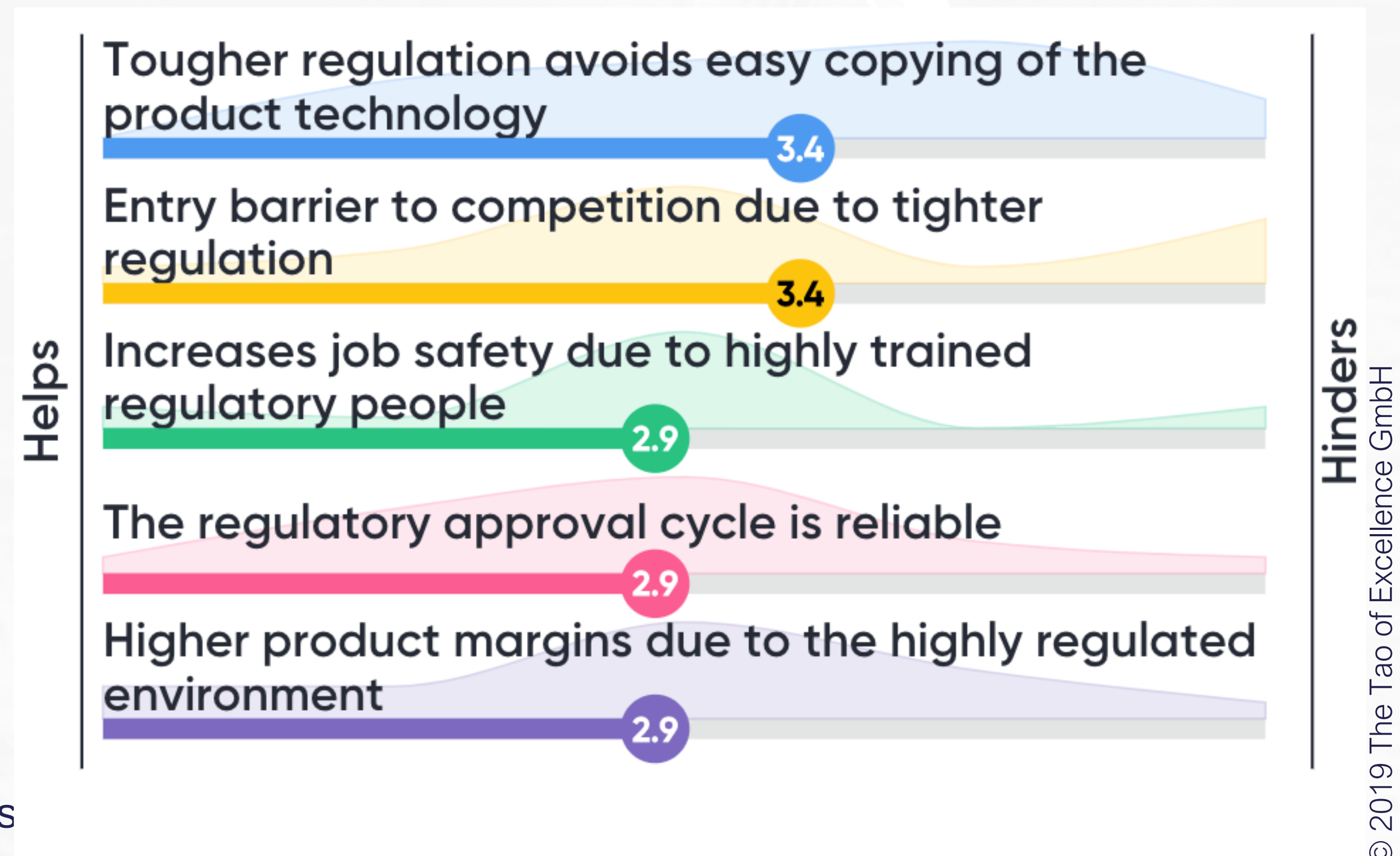


Response analysis – Does regulation help the business?

Survey results



Today's results



Conclusion of conducted survey

- 80% of the surveyed organisations have a **dedicated research team** focussing on innovation and spending a minimum of 5% of turnover on research.
- **Having adequate clinical data is considered to be the most difficult in complying to the regulation.**
- 60% of the surveyed companies give credit to the clinical data helping **improve product** design.



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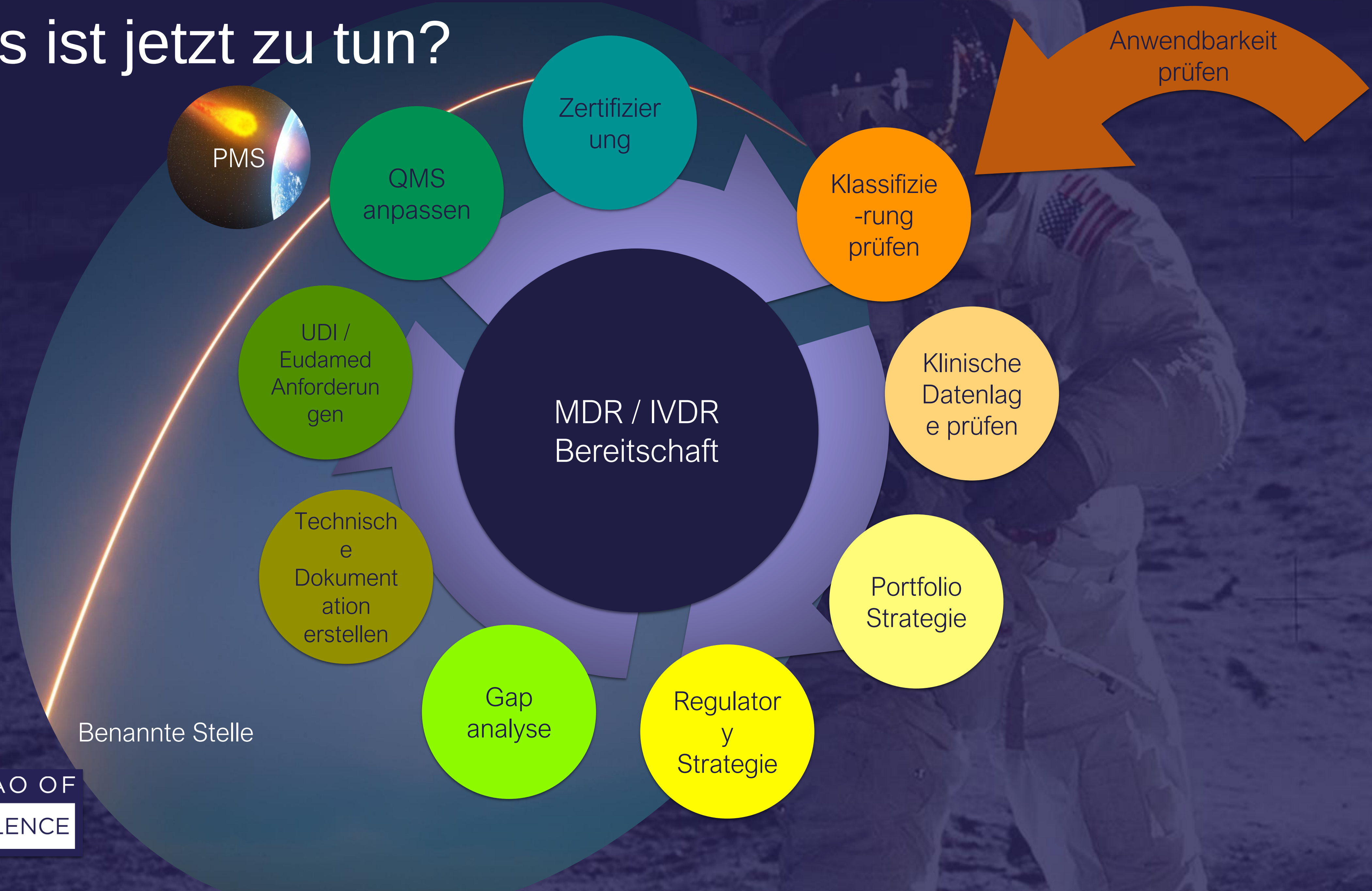
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Was ist jetzt zu tun?

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Was ist jetzt zu tun?

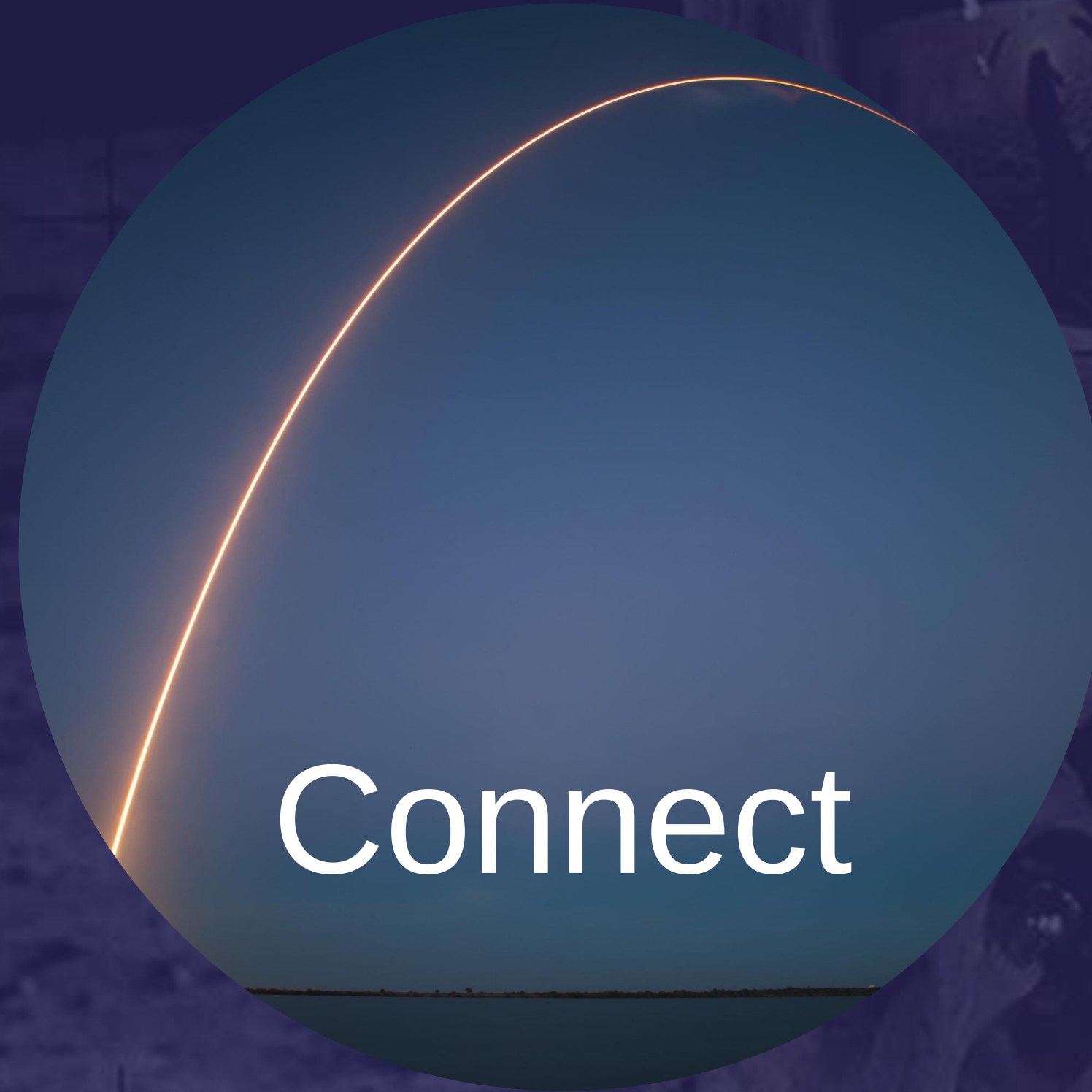


Workshop



Identify

● Wie finde ich den richtigen NB



Connect

● Wie komme ich zu einem NB



Collaborate

● Wie erstelle ich eine partnerschaftliche Zusammenarbeit