



Digital Transformation in Pharma Quality: where is the industry today?

Teresa Minero

Founder & CEO | LifeBee

International Board of Directors & Pharma 4.0™ SC | ISPE





Teresa Minero

Founder & CEO | LifeBee

International Board of Directors & Pharma 4.0™ SC | ISPE

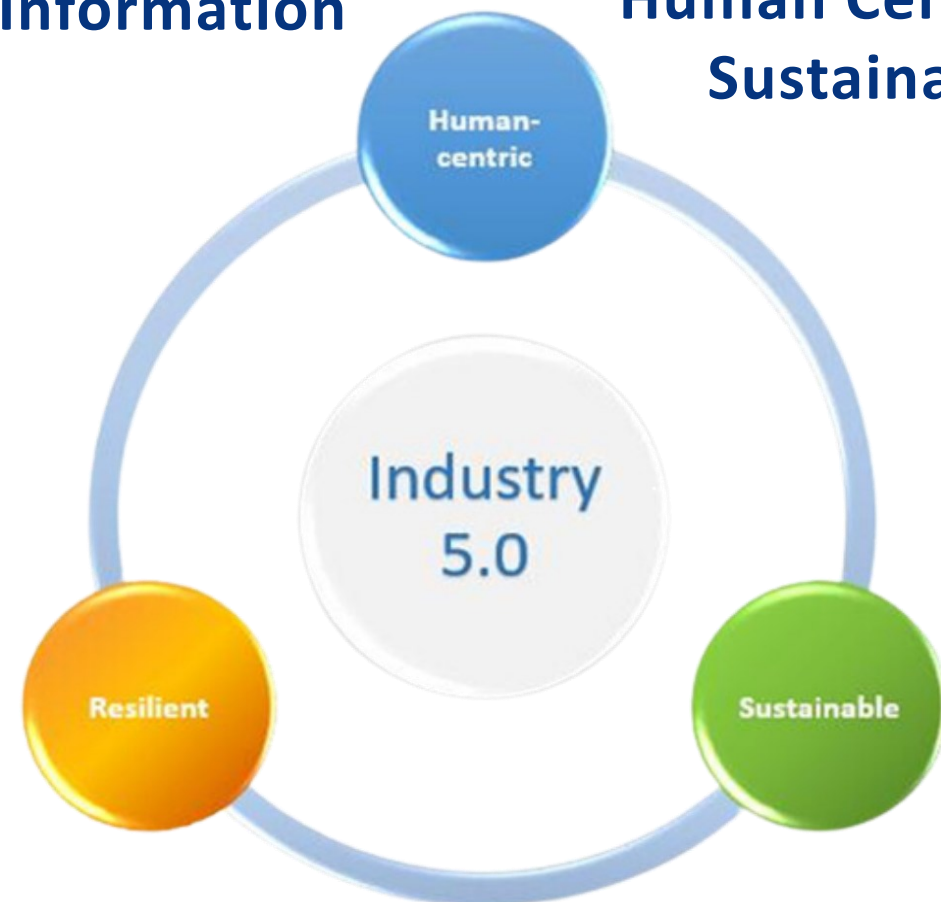
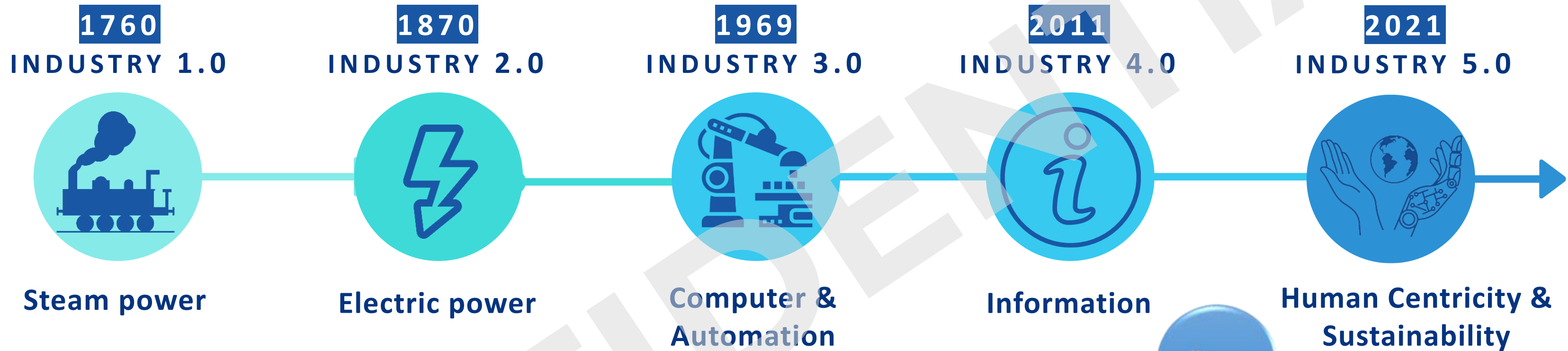
With a background in Computer Science, Teresa Minero is the Founder & CEO of LifeBee, a Consulting and Digital boutique dedicated to Life Sciences since 2004.

She holds 35+ years of experience in managing Innovation projects for Production, Logistics, Quality, Labs, Regulatory and R&D, mainly spent in Pharma.

For ISPE she is currently part of the ISPE International Board of Directors and part of the Foundation Board of Directors and involved in the Steering Committee of the Pharma 4.0™ Community of Practice and in many other ISPE initiatives at global level.

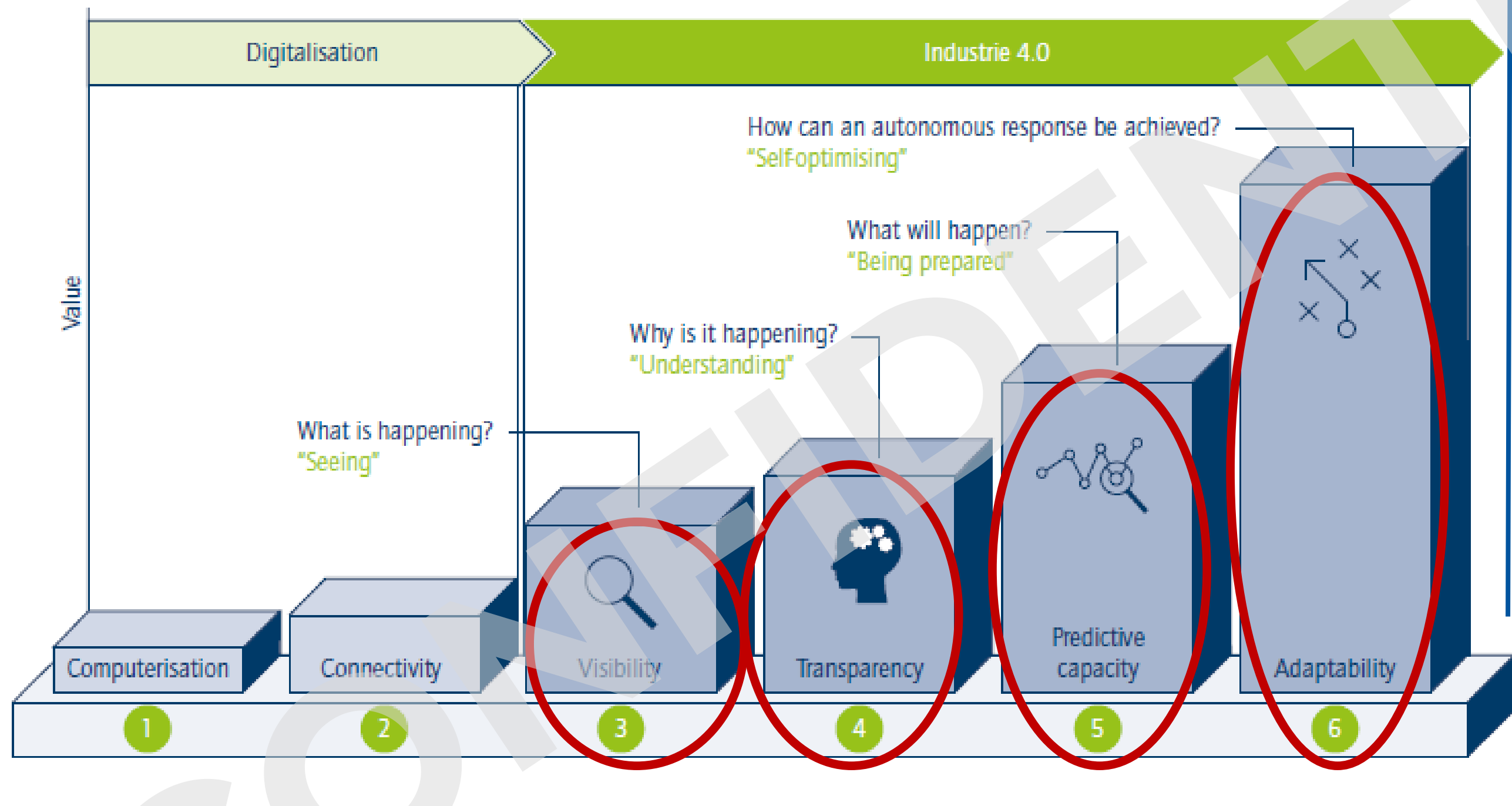
Author of the recently published ISPE Pharma 4.0™ Baseline Guide.

A PREMISE 1/4: ... to 4.0 and 5.0: it is been a very long journey!



Industry 5.0
Towards a sustainable, humancentric and resilient European industry - Jan 2021
European Commission Directorate - General for Research and Innovation

A PREMISE 2/4: Inside 4.0, it is a journey too: one of the many Digital Maturity Models*



3. What is happening?
= *Visibility*

4. Why is it happening?
= *Transparency*

5. What will happen?
= *Predictive*

6. How can an
autonomous response be
achieved?
= *Adaptability*

Figure 5: Stages in the Industrie 4.0 development path (source: FIR e. V. at RWTH Aachen University)

* ACATECH, 'German Academy of Science and Engineering', a key global opinion leader on 4.0

A PREMISE 3/4:

4.0 or 5.0: Digital Transformation in Pharma: the WHY*



WHY



- providing the **right information** at the right time and in the right place
- supporting decisions, increasingly in a **predictive manner**
- not only for **Managers**, but also for **Operators, Regulatory Agencies** on to ... **Patients**
- consistency in **full compliance**
- to **timely deliver innovative, quality, effective and safe drugs at fair costs**
- in a **sustainable environment**

The WHY of the WHY

* *One of the many definitions ...*

A PREMISE 4/4i:



ISPE Connecting Pharmaceutical Knowledge

ISPE – the International Society for Pharmaceutical Engineering – is the largest global non-profit Life Science professional association

Mission: "Shape the Future of Pharma"™

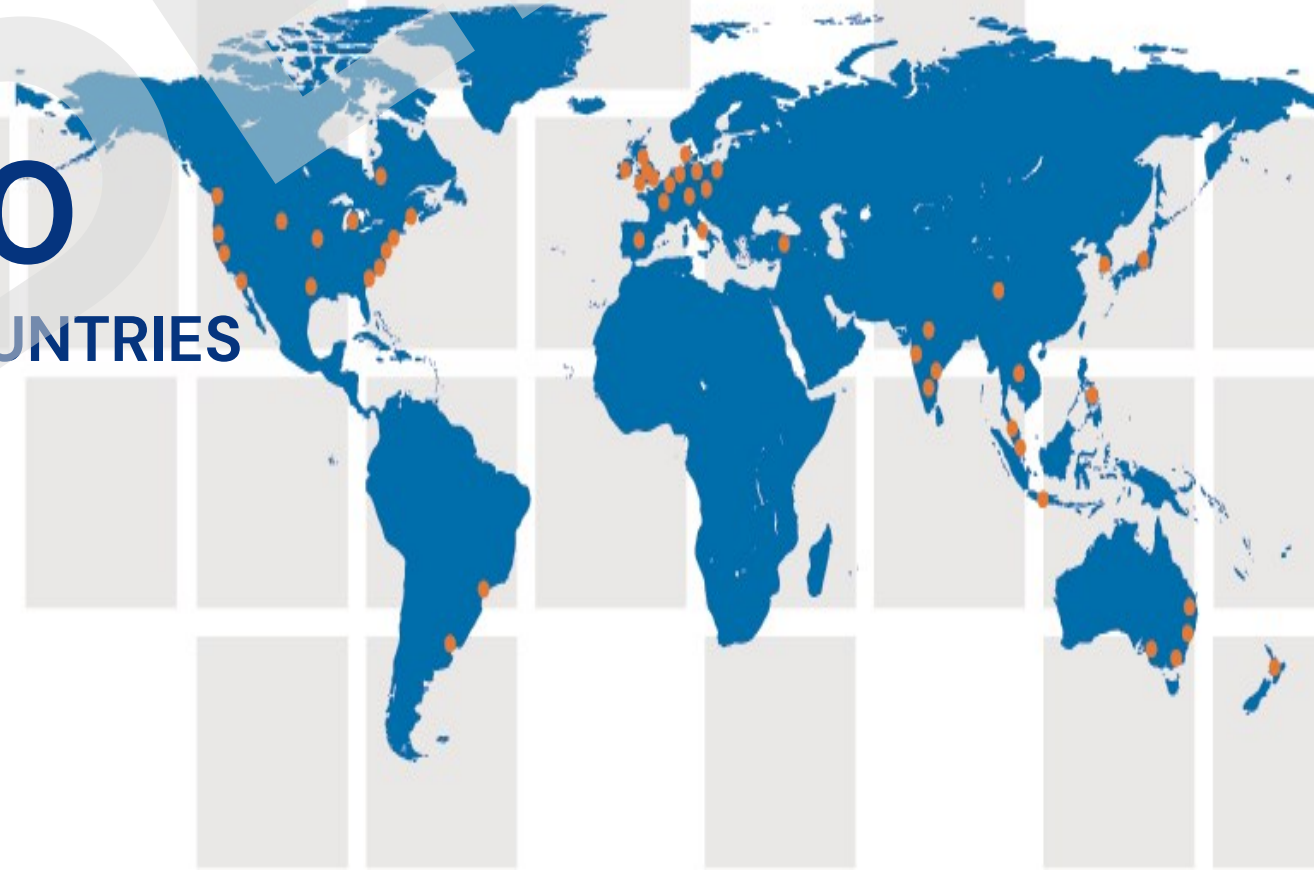
22.000

MEMBERS, of which **6.000** in Europe

varying from Clinical Operations & Supply to Development, Engineering, Commissioning & Qualification, Production, Labs, Quality Assurance, Logistics, Digitalization, Validation, Regulatory, etc.

90

COUNTRIES



A PREMISE 4/4ii:



ISPE Pharma 4.0™ Community of Practice



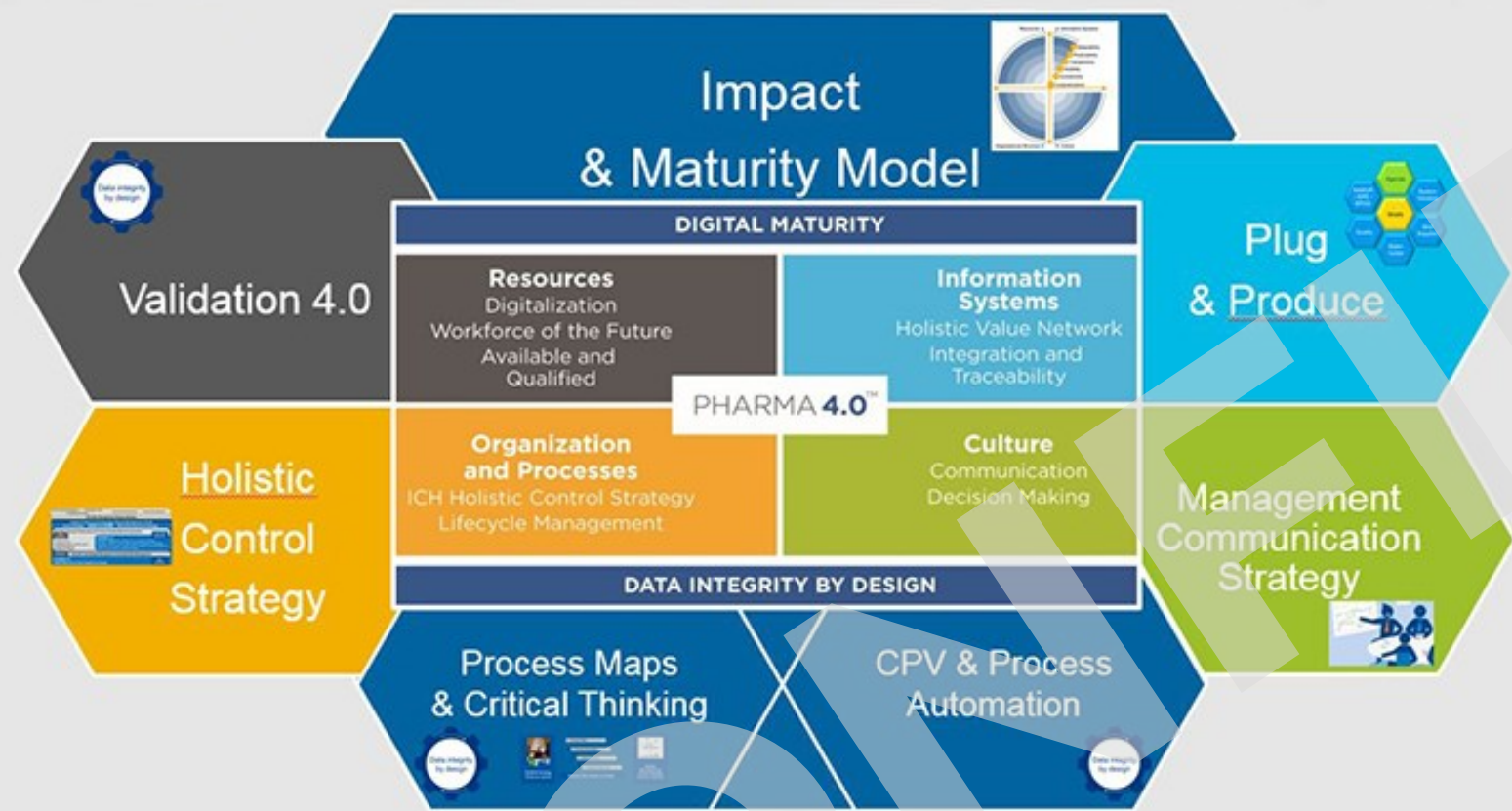
Pharma 4.0™ Community of Practice adopts the mission to provide practical guidance with:

- Guidelines
- Articles
- Case Studies
- Surveys
- Presentations
- Workshops and Webinars
- Local and Global Working Groups

The Baseline Guide on Pharma 4.0™ has been published in December 2023

embedding regulatory best practices to accelerate Pharma 4.0™ transformations.

The objective is to enable organizations involved in the Life Science product lifecycle to leverage the full potential of digitalization to provide faster innovations for the benefit of Patients.





Charting Pharma's Digital Journey – Insights from the 7th Pharma 4.0™ Study

Teresa Minero
LifeBee | A ProductLifeGroup Company

2024 ISPE EUROPE ANNUAL CONFERENCE 16 – 18 April 2024 – LISBON, PORTUGAL



The Pharma 4.0™ survey initiative



large datasets with
~400 participants and
10 questions per
survey



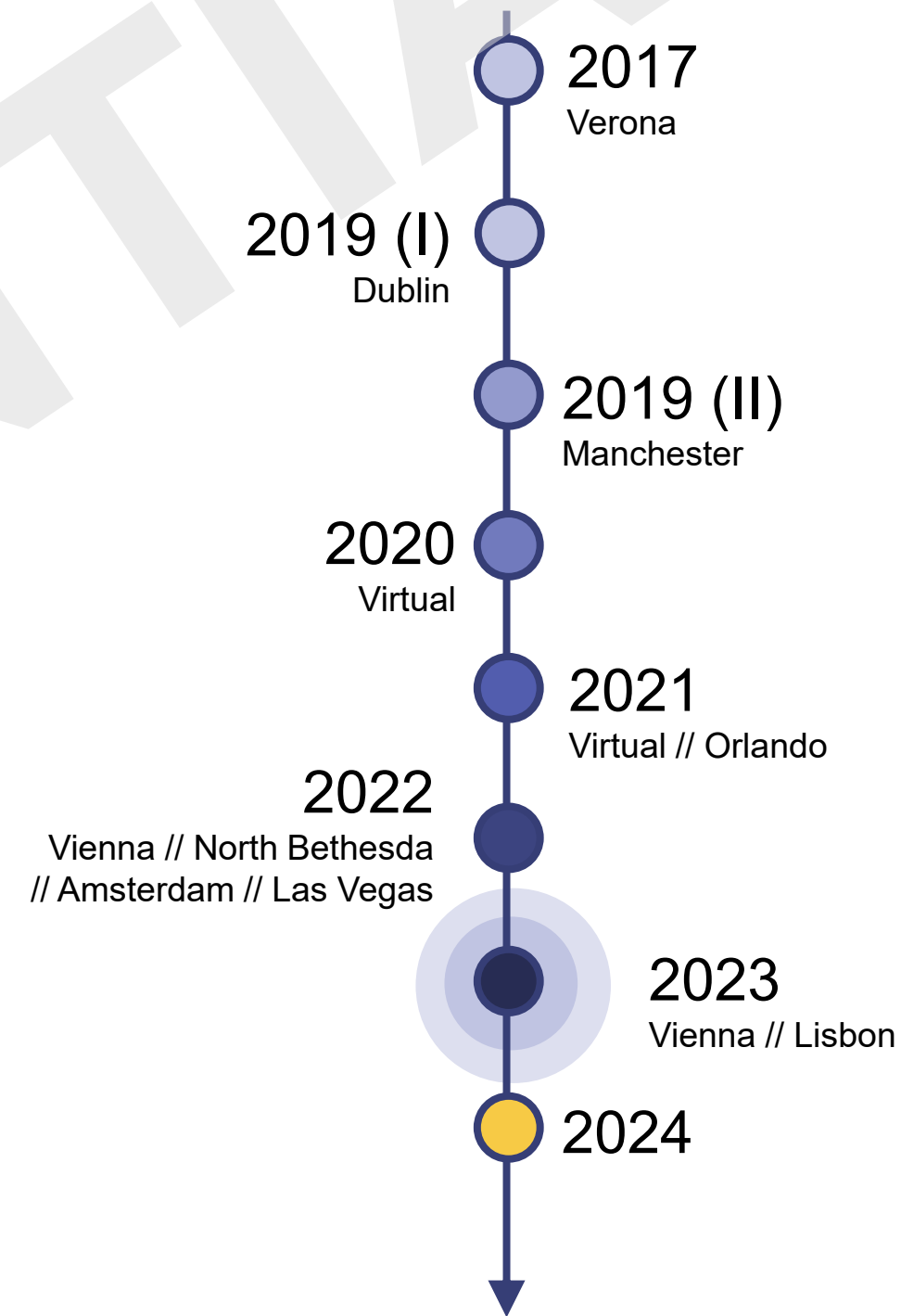
Extensive, exploratory
evaluation of the
datasets – conducted
by ISPE



Presentation of the
results at 12 ISPE
conferences
around the globe



Seven surveys
over seven years




We aim to support ISPE members with data-driven decision-making observing the development of Pharma 4.0™ trends, initiatives, and maturity

The Pharma 4.0™ survey - Questions



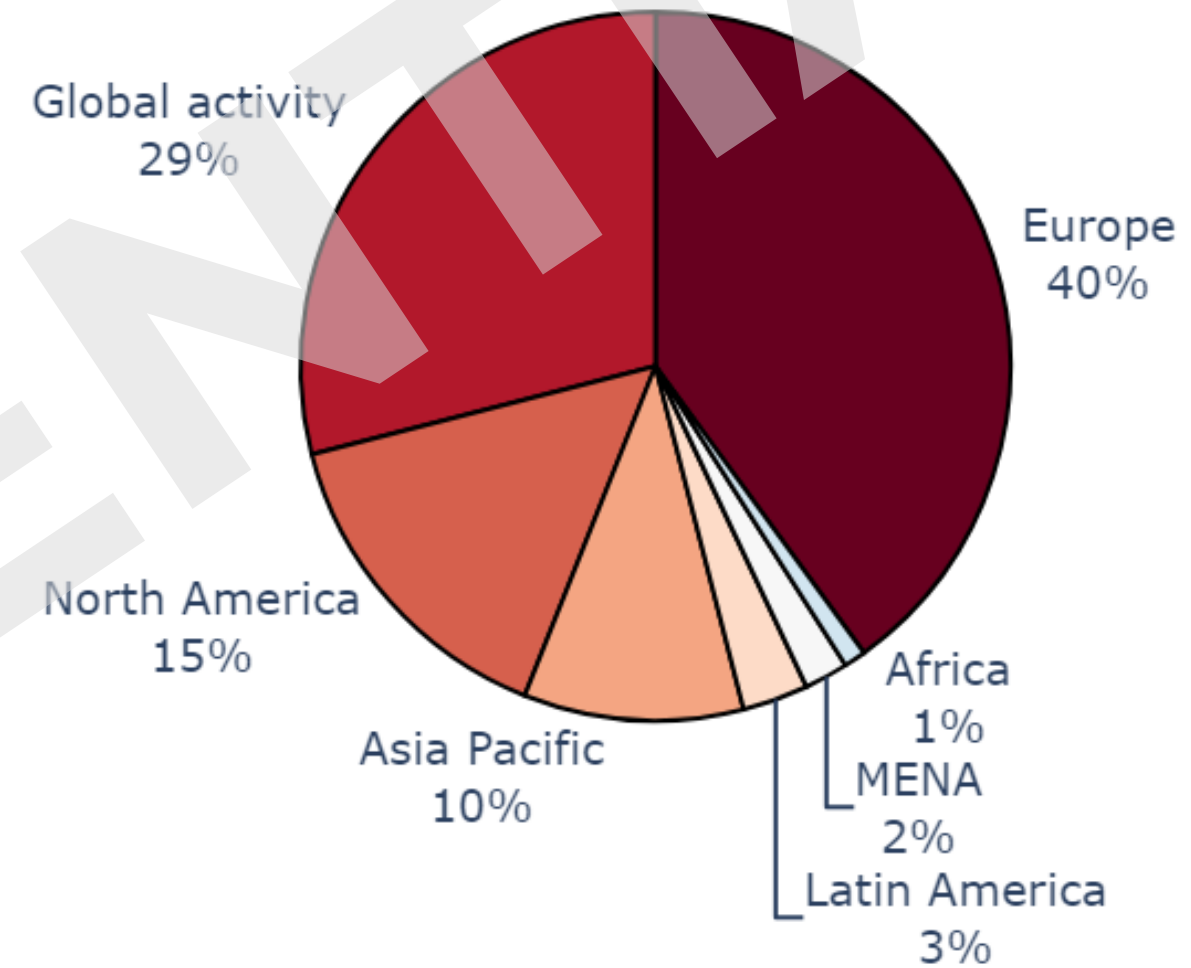
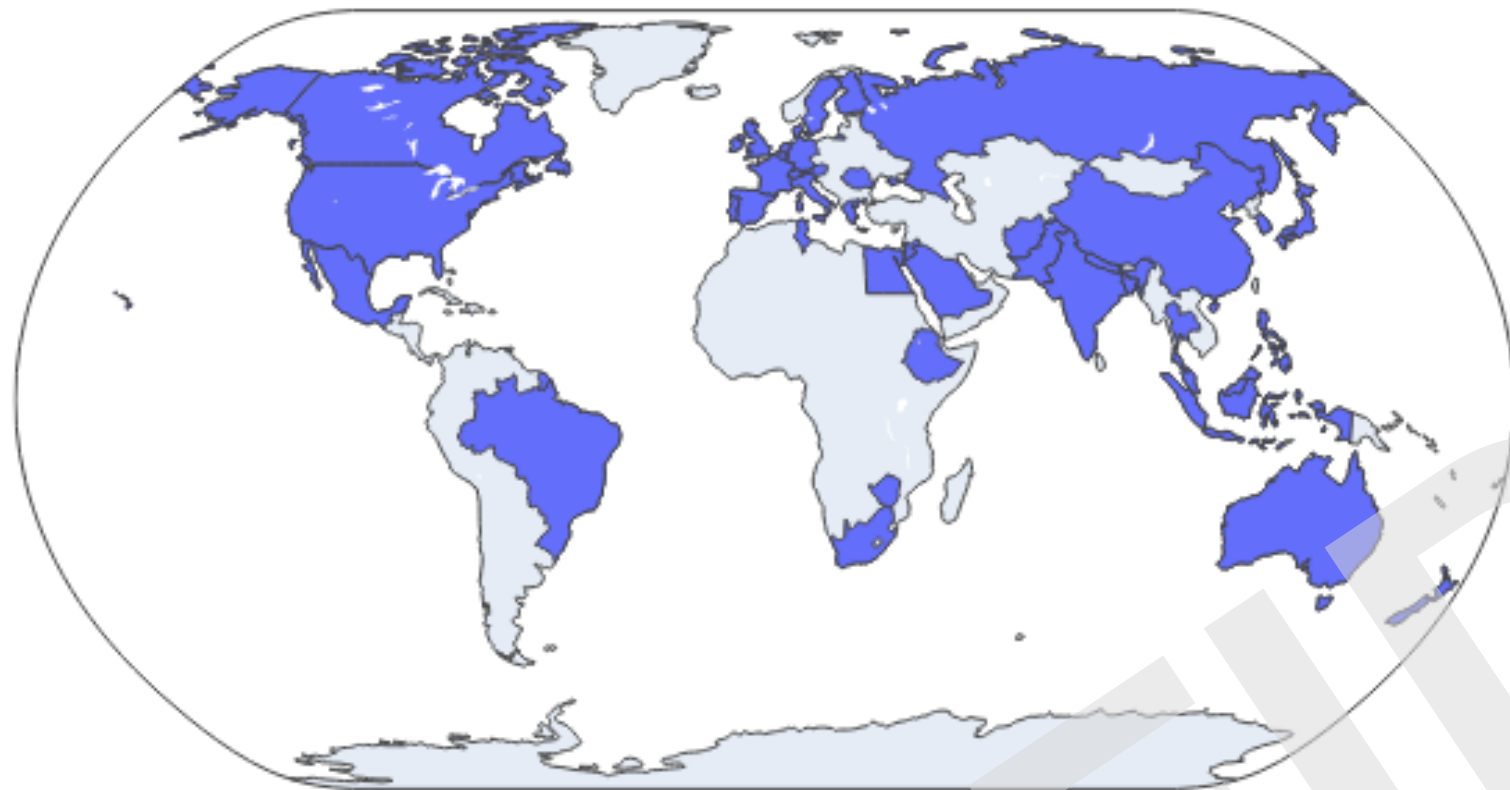
1. **Demographics:** Country, end/non-end-user, area of activity, company size, product type
2. What **Pharma 4.0™ maturity** in terms of implementation level do you find in your organization?
3. Which **enabling technologies** are the focus of adoption in your company?
4. Which are the **top benefits** that are driving and supporting your Pharma 4.0™ programs?
5. Which are the **two key challenges** on your Pharma 4.0™ programs?
6. Taking into account the **main dimensions of data management**, what are the respective **maturity** levels at your site?
7. Which are the main **data management benefits** anticipated for your site? (max. 2)
8. **What's next?** Briefly specify and describe the projects you are planning to implement the next two years.
9. Any **other comments** or suggestions?

 New focus questions in the 7th edition



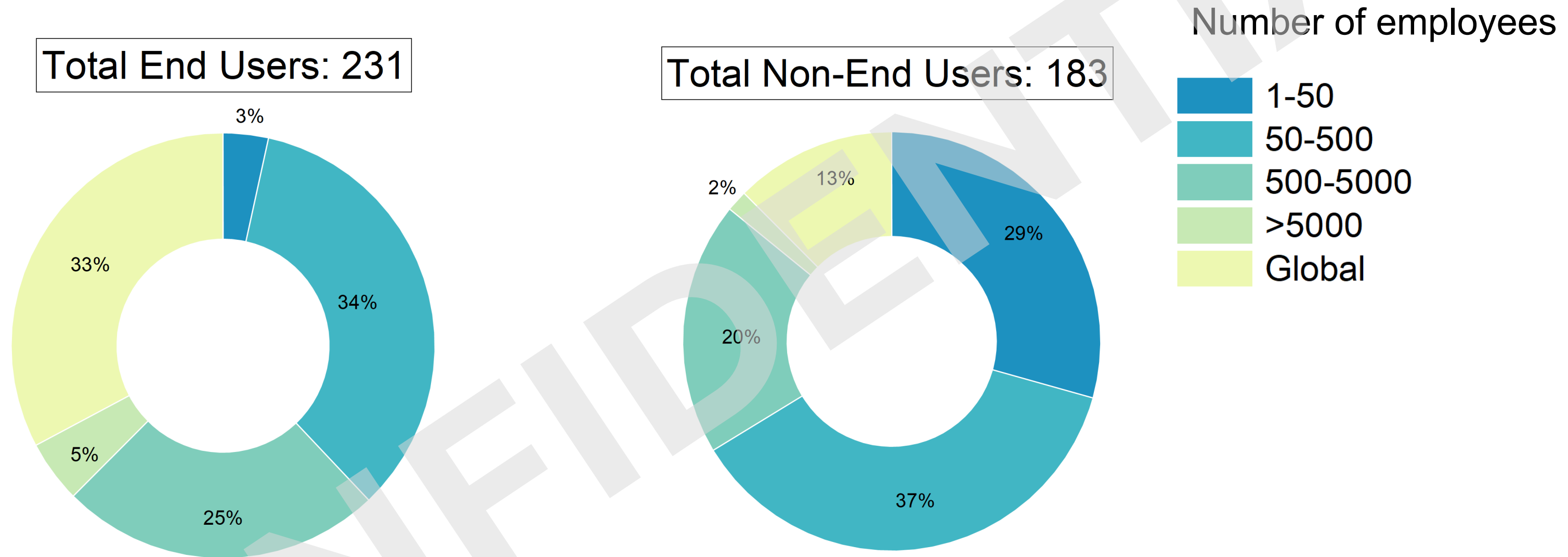
1. Demographics

1.1 Survey sample has a good outreach regarding geographical territories



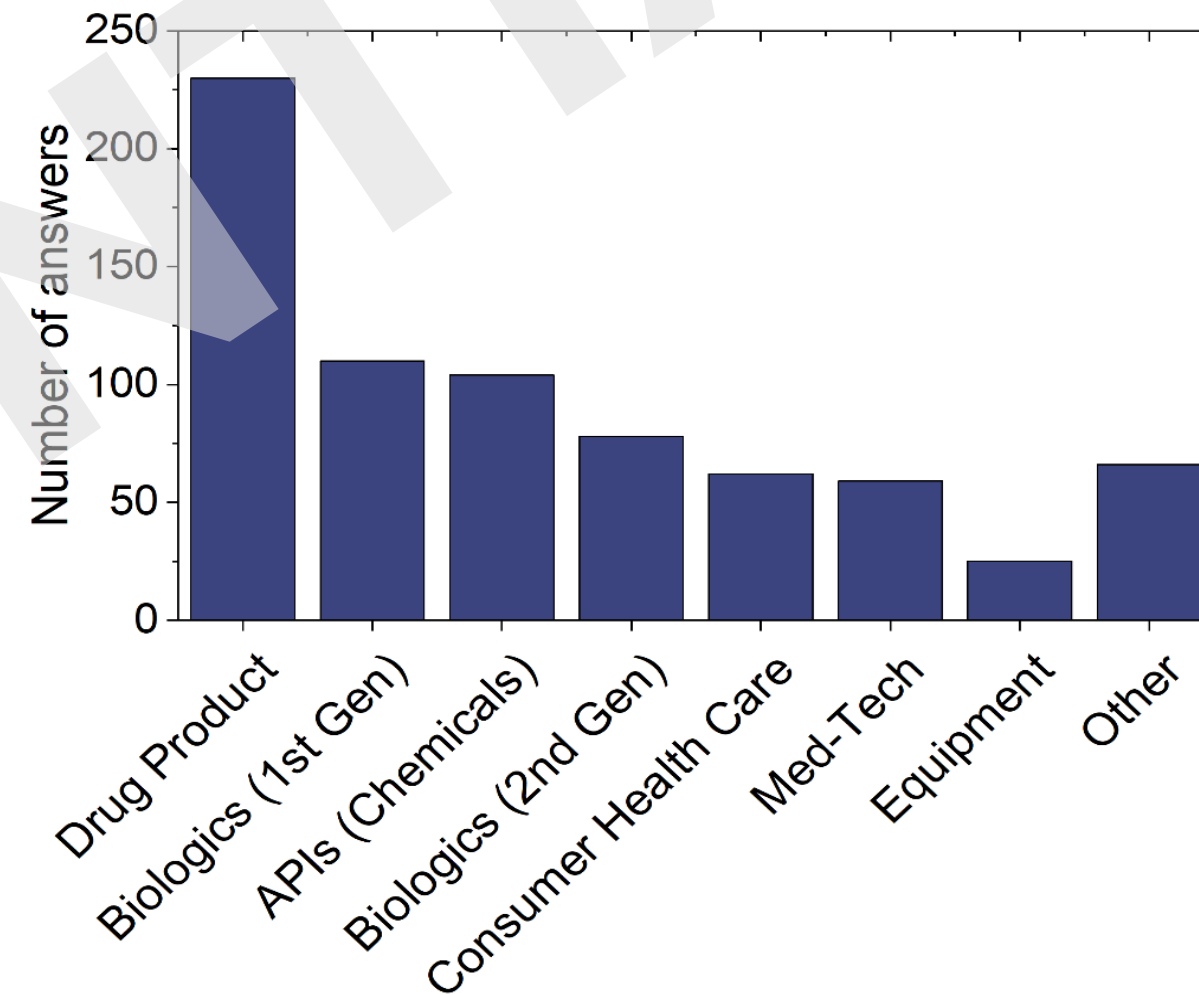
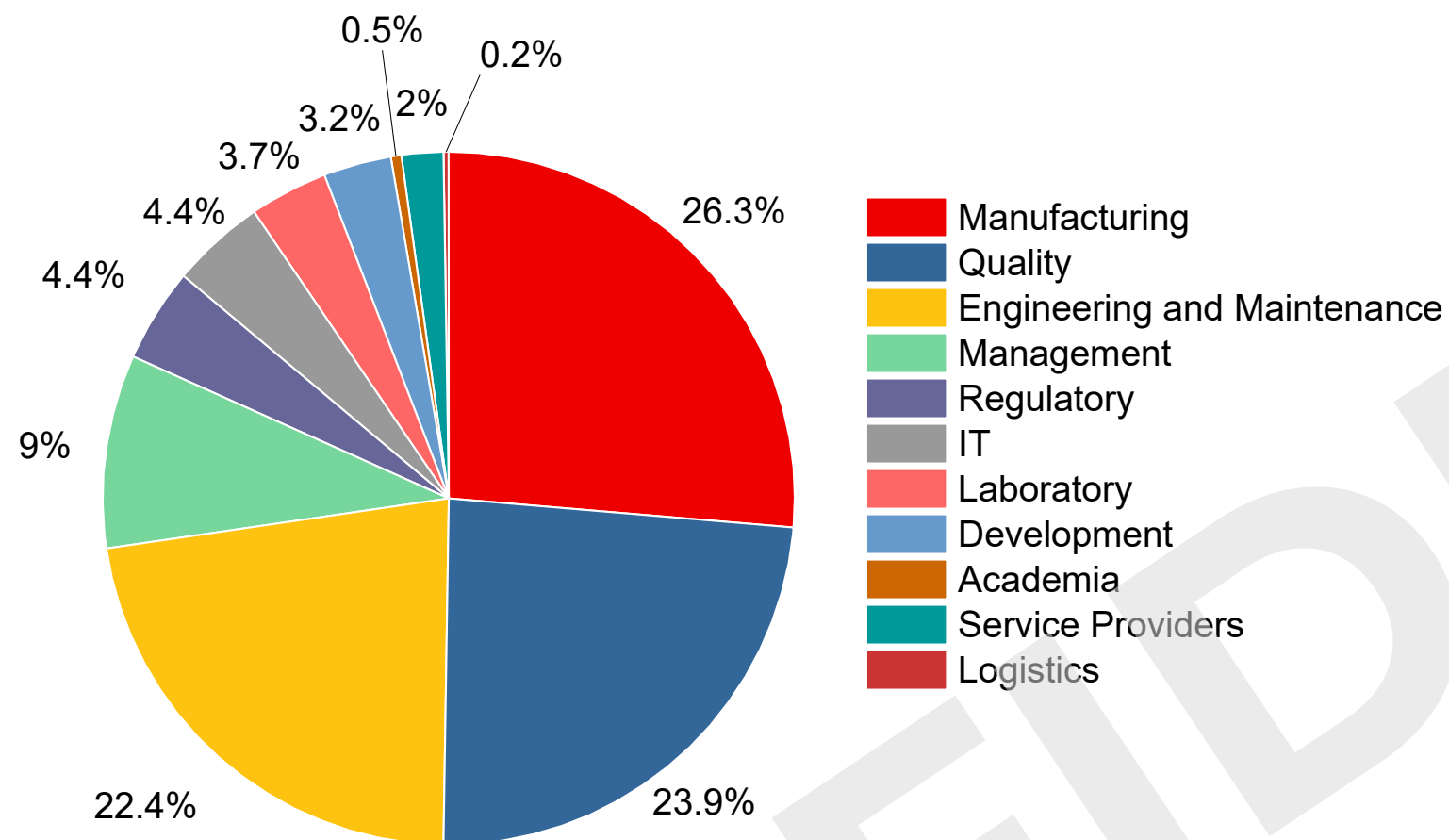
- We continue to have a **global outreach with good representation**, although we seek to get more respondents from african, LATAM, and MENA states.
- Sample is still dominated by Europe and North America.

1.2 Survey sample is well-balanced between user types and site dimensions



▪ **Good balance** between end-users and non-end users **across all site dimensions.**

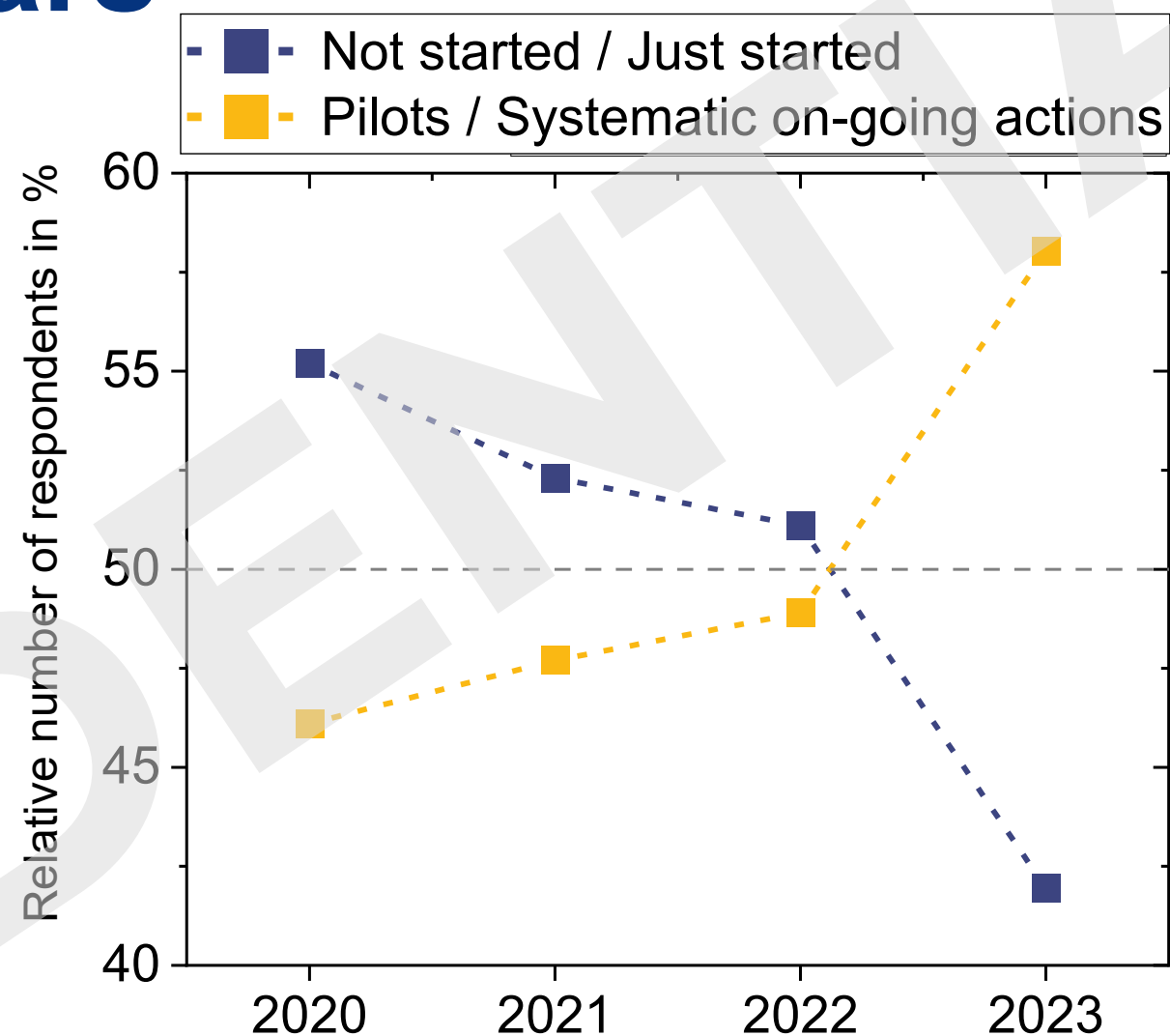
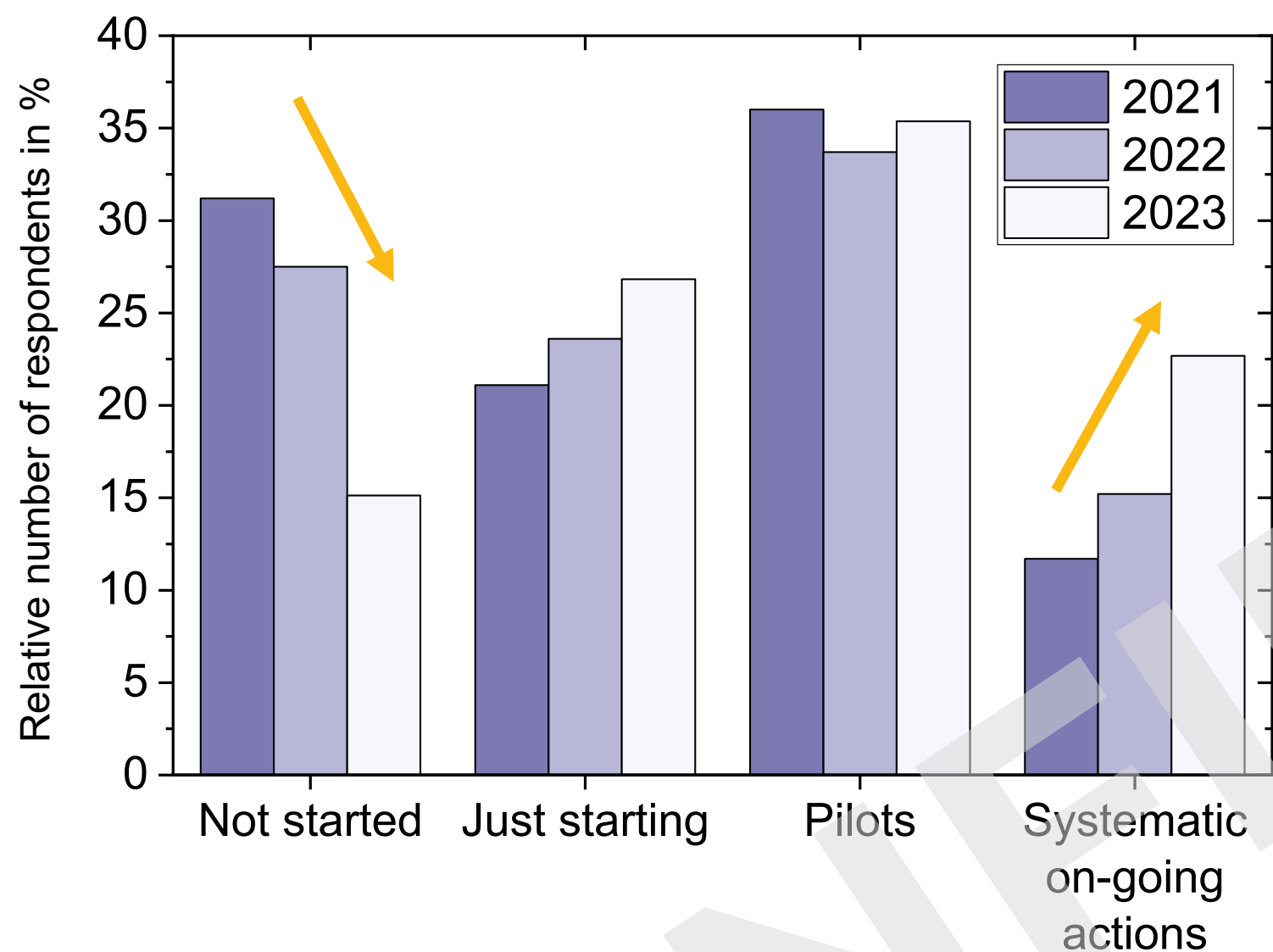
1.3 Diverse activity area backgrounds and product types, with dominance from Manuf & Quality & Eng.



- **Manufacturing, quality and engineering** together make up roughly 75% of respondents.
- Growing input from **regulatory** representatives (only 2.3 % in 2022).
- Approximately 10 % of respondents are from **management**.

2. Pharma 4.0™ maturity level

2.1 General movement toward higher maturity levels over the last three years



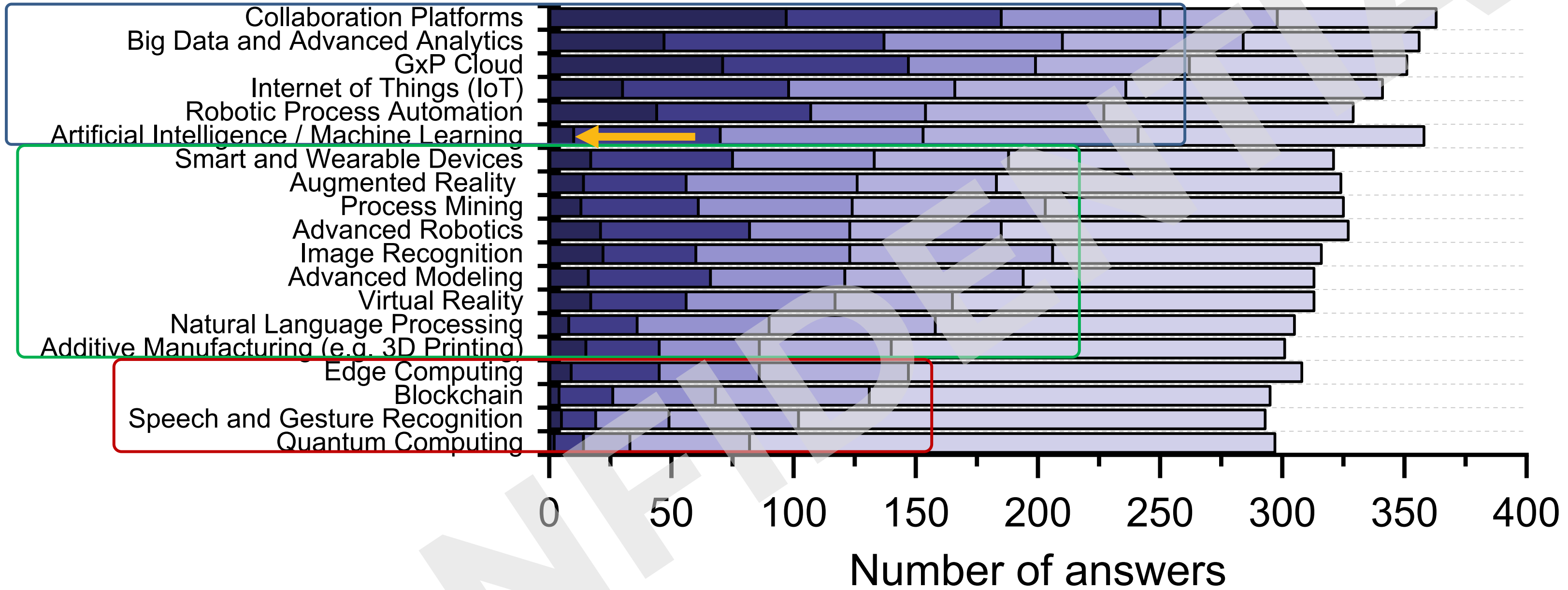
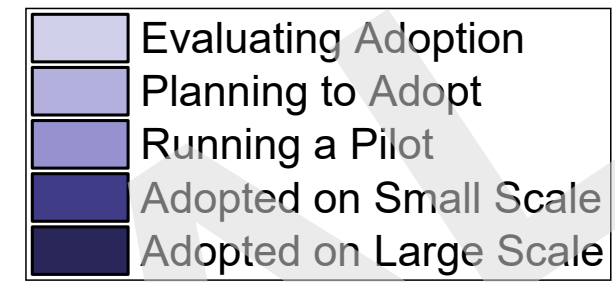
DEFINITIONS:

- 1. Not started:** no live projects; also none under evaluation
- 2. Just starting:** There is a plan or a team to assess, but, no “live” implementation projects
- 3. Pilots:** There are at least one/two projects already “live”, even in small areas, already started
- 4. Systematic on-going actions:** Pharma 4.0™ is adopted in a larger scale with several completed projects

- Confirmation of trends observed through the last years: **movement toward higher maturity.**
- First time occurrence of **pilots/systematic on-going actions exceeding starting phase.**

3. Enabling technologies adoption

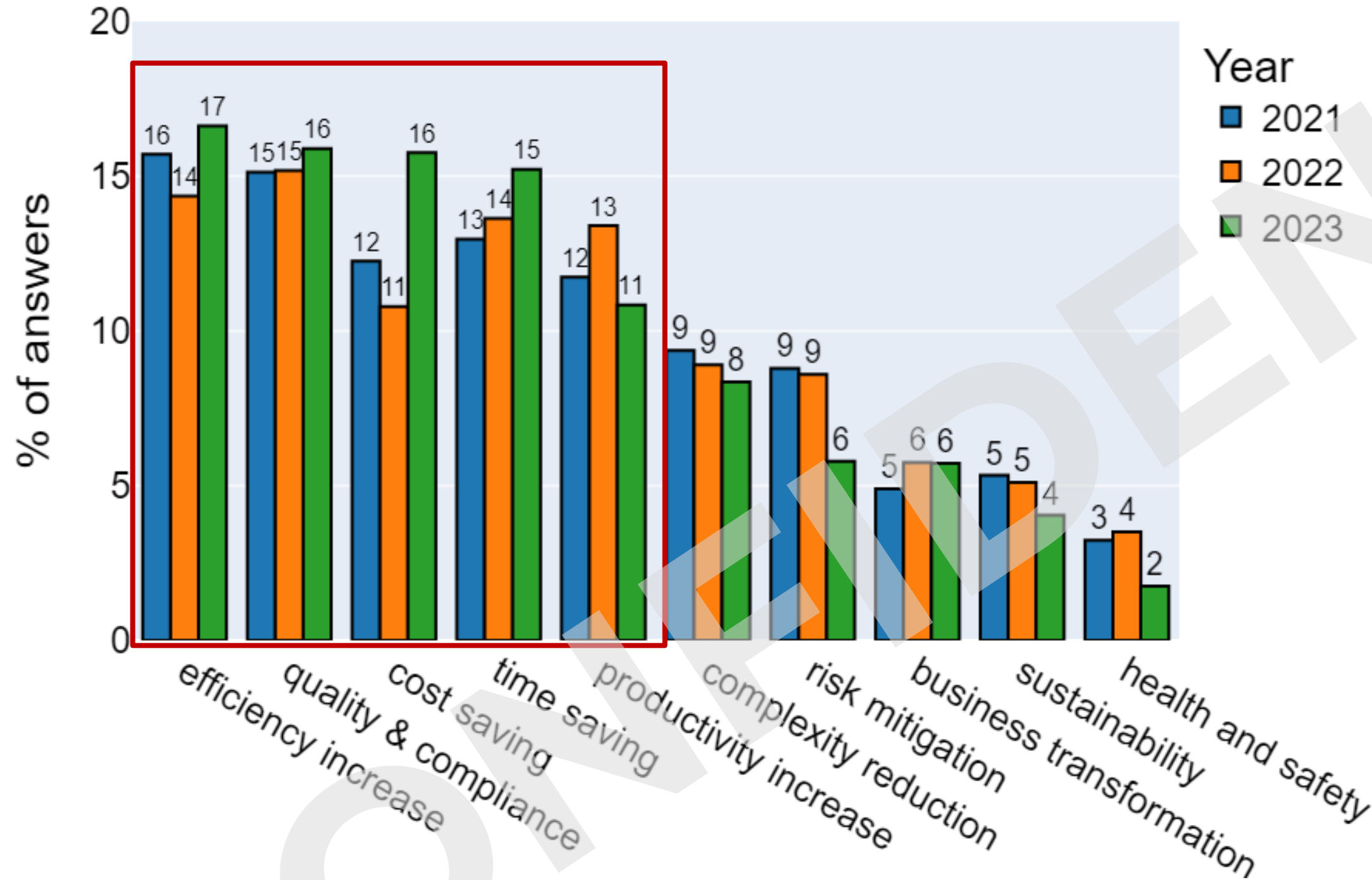
3.1 Which Pharma 4.0™ enabling technologies are in focus for adoption?



✓ Blue = well adopted, green = pilots and small scale, red = less adopted
 ✓ some technologies (e.g. AI/ML) seem to be hard to adopt on a large scale

3. Enabling technologies adoption

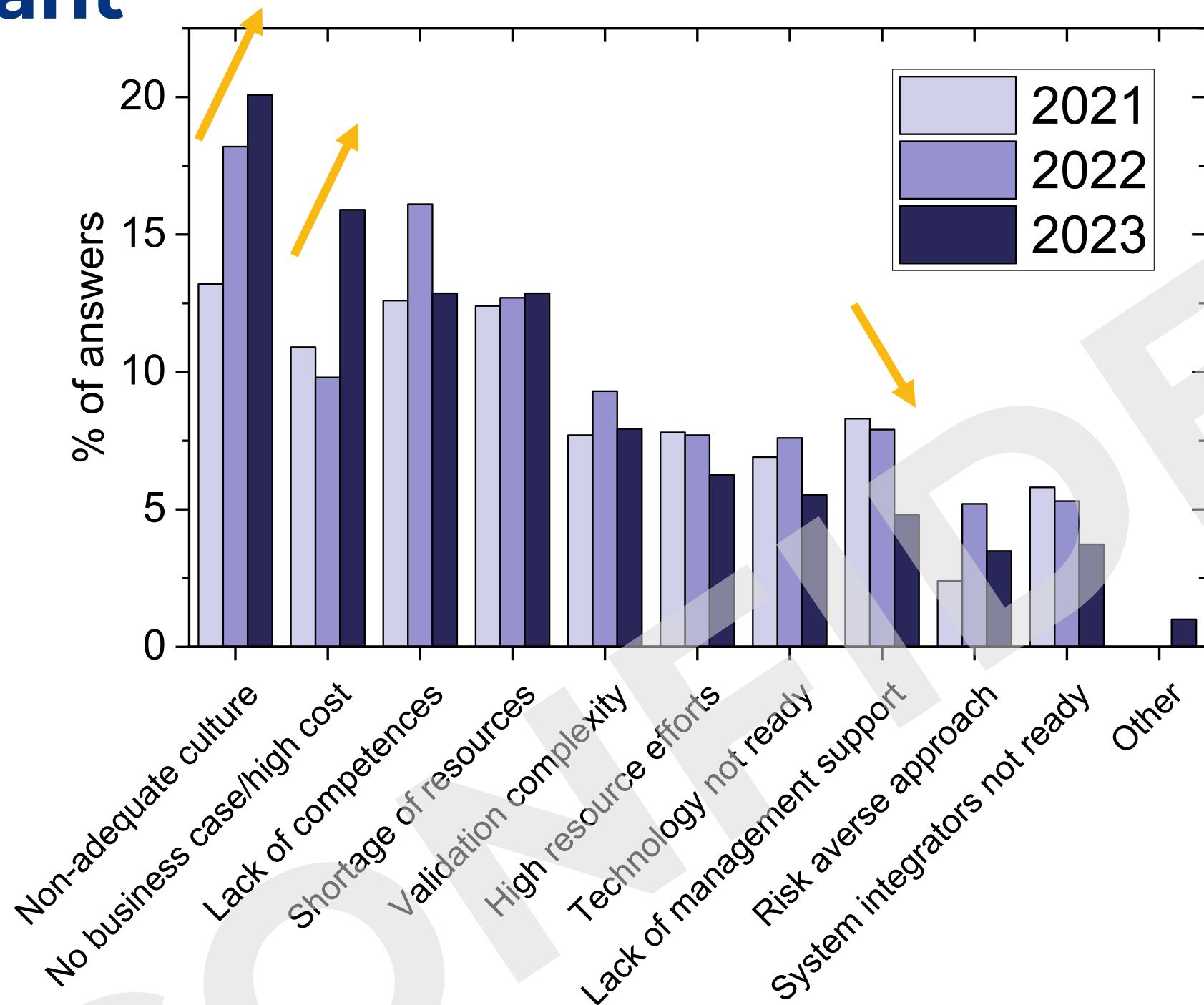
4.1 Economic benefits are the main drivers, but quality & compliance among top 3



- **Quality & Compliance remains among top 3** along with economic benefits
- More or less static across the last 3 years
- Increased awareness of **cost saving**

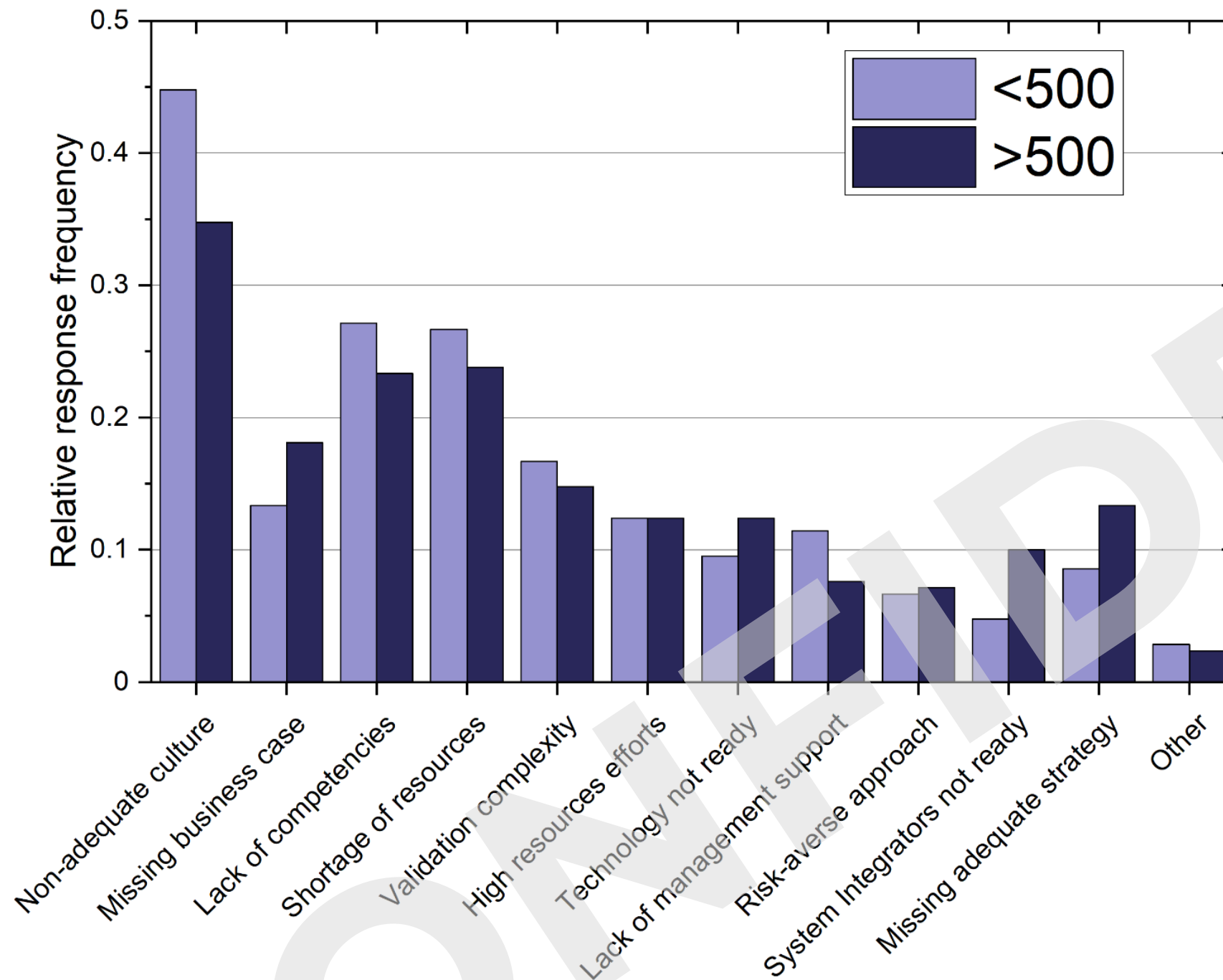
5. Challenges faced with digital transformation

5.1 Challenges related to culture further increase in impact, but lack of management support becomes less relevant



- Further increasing share of **organisation/culture-related challenges**
- >15% of answers imply **missing business cases**
- **decreasing lack of top management support**

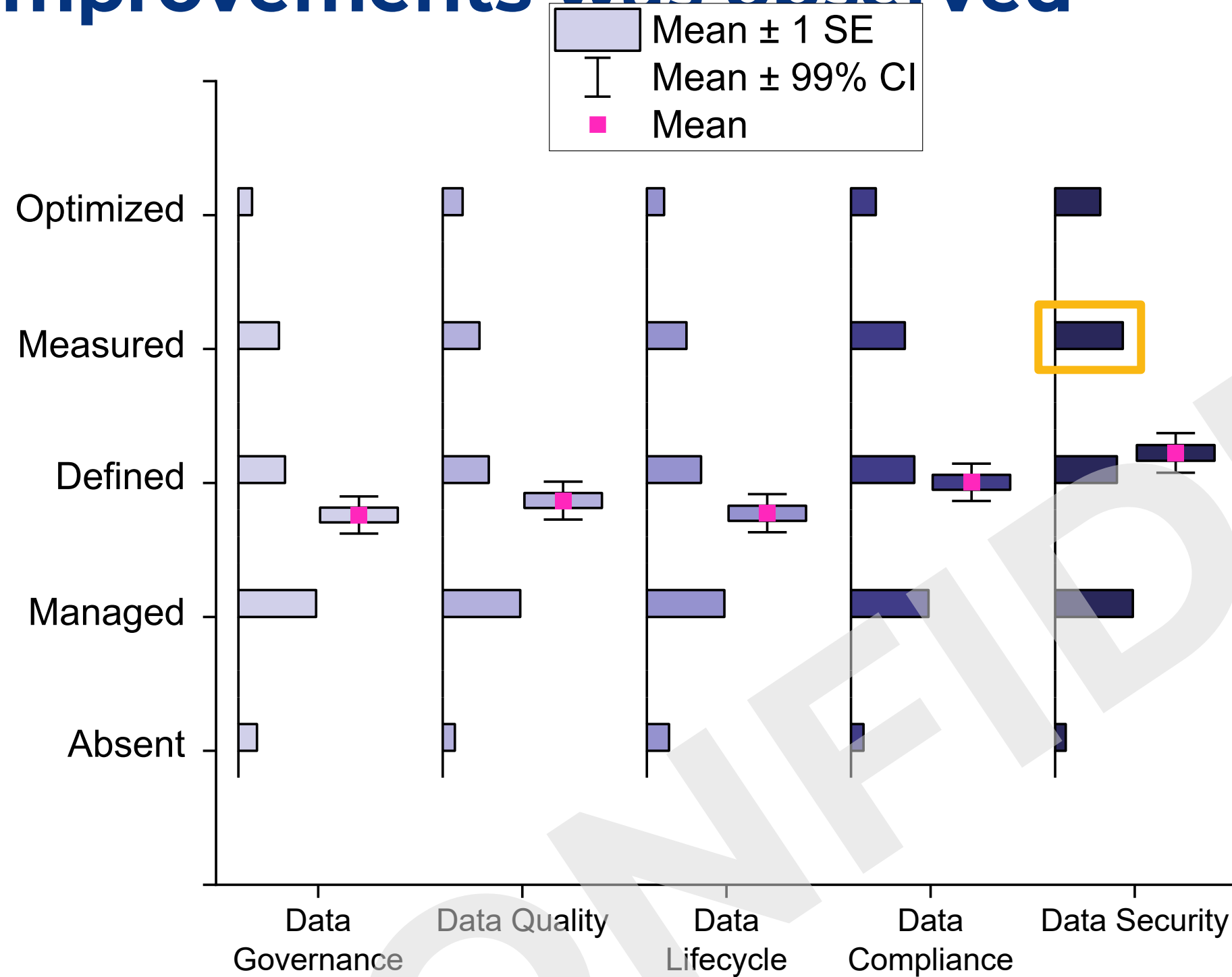
5.2 Smaller sites experience challenges with inadequate culture even more frequently



- **Smaller sites** rather struggle with **inadequate culture** and **lack of top management support**
- **Larger sites** miss an **adequate strategy** and sound **business cases** more frequently

6. Data management

6 & 7.1 Significant potential for data management improvements was observed

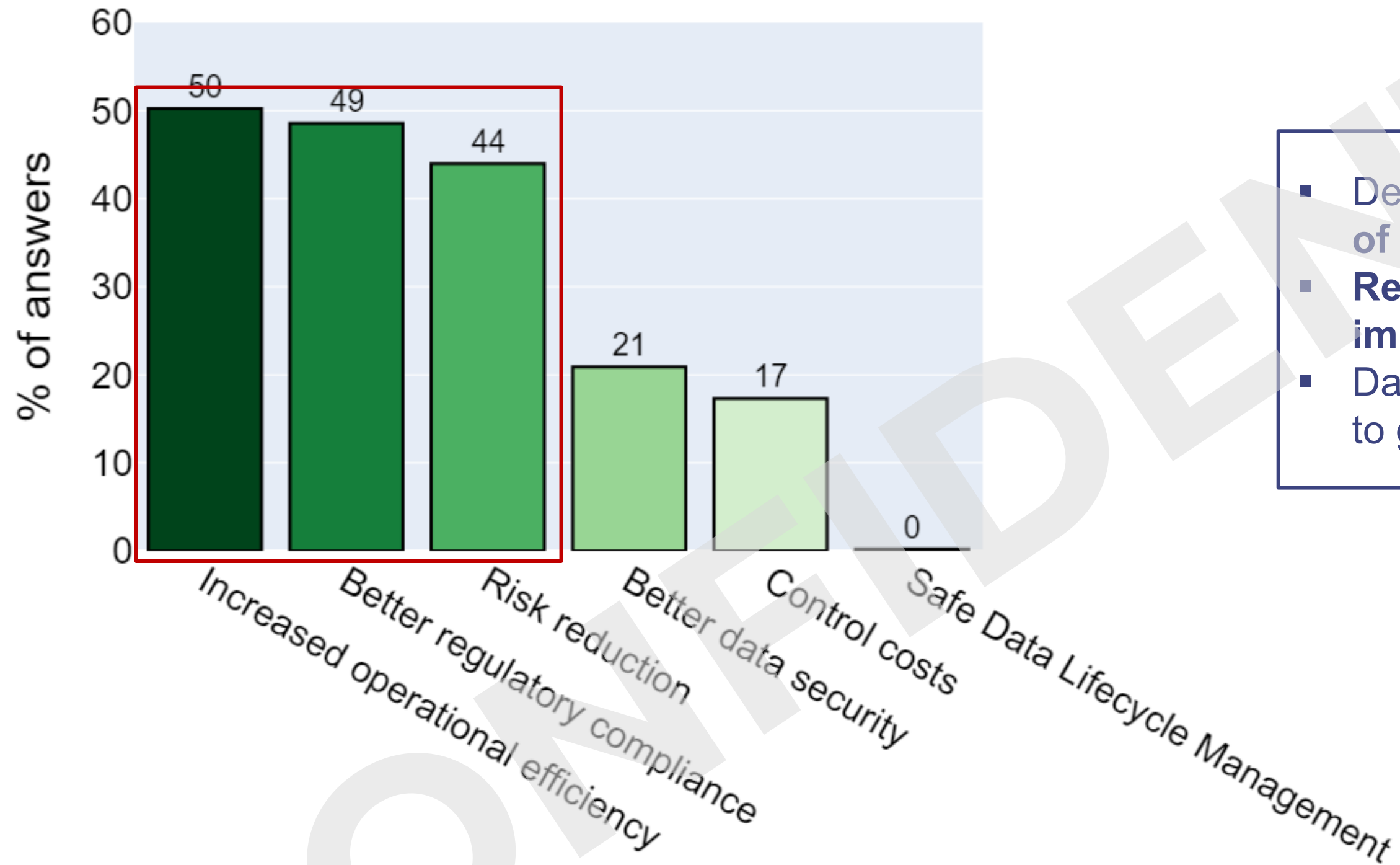


DEFINITIONS:

- **Optimized**
defined, documented, adopted using dedicated tools on enterprise level, and traceable with consistent measurement analytics
- **Measured**
defined, documented, and adopted using dedicated tools on enterprise level
- **Defined**
defined, documented, and consistently applied on data domain level
- **Managed**
defined and documented but performed at limited areas using an ad-hoc approach
- **Absent**
not defined nor adopted

- Each of the dimensions is **between „managed“ and „defined“**
- **Data Security: two groups**, either behind or in advance of „defined“

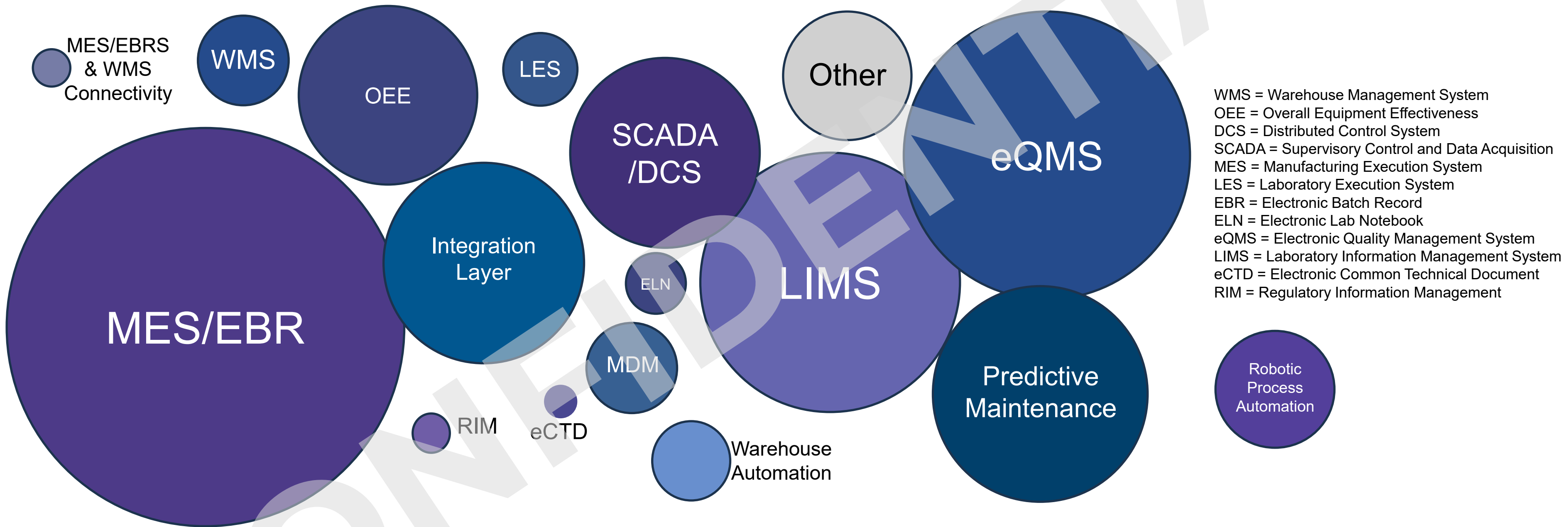
6 & 7 The benefits of high data management maturity are very similar to those of successful Pharma 4.0™ programs



- Demographics have shown a **low number of respondents from IT**
- **Regulatory compliance is a highly important benefit**
- Data management benefits are fairly similar to general Pharma 4.0™ program benefits

8. What's next?

Application areas of the upcoming Pharma 4.0™ projects



What is the conclusion of the 7th survey?

Our personal view concerning the main points:



- ✓ **Geographical Diversity:** Demonstrating the breadth of the ISPE network with a comprehensive coverage and diverse responses.
- ✓ **Progress Towards Higher Maturity:** Clear evidence of advancing towards higher maturity levels within the industry.
- ✓ **Data Management Dynamics:** Highlighting the spectrum between "defined" and "measured" dimensions in data management practices.
- ✓ **Top Benefits:** Quality and compliance improvements remain prominent alongside economic advantages as key benefits of adopting Pharma 4.0™.
- ✓ **Management Sponsorship:** Despite persisting cultural and resource challenges, there is a notable improvement in management sponsorship.
- ✓ **Specific Challenges:** Different geographies, site dimensions, and activity areas exhibit nuanced variations in benefits and challenges, not dictated by product type.
- ✓ **Future Directions:** While upcoming projects may not yet be transformative, they carry fundamental significance in shaping industry evolution.



Get involved in the 8th edition!



Be part of shaping the dialogue and knowledge of our next survey edition!

1

Prepare and communicate your proposed questions by June 7th, 2024.

Contact: t.minero@lifebee.it

Stay tuned for our call for responses from July to October

2



"A winner is a dreamer who never gives up" Nelson Mandela

Digital Transformation in Pharma Quality:

where is the industry today?

Teresa Minero

Founder & CEO | LifeBee

International Board of Directors & Pharma 4.0™ SC | ISPE

