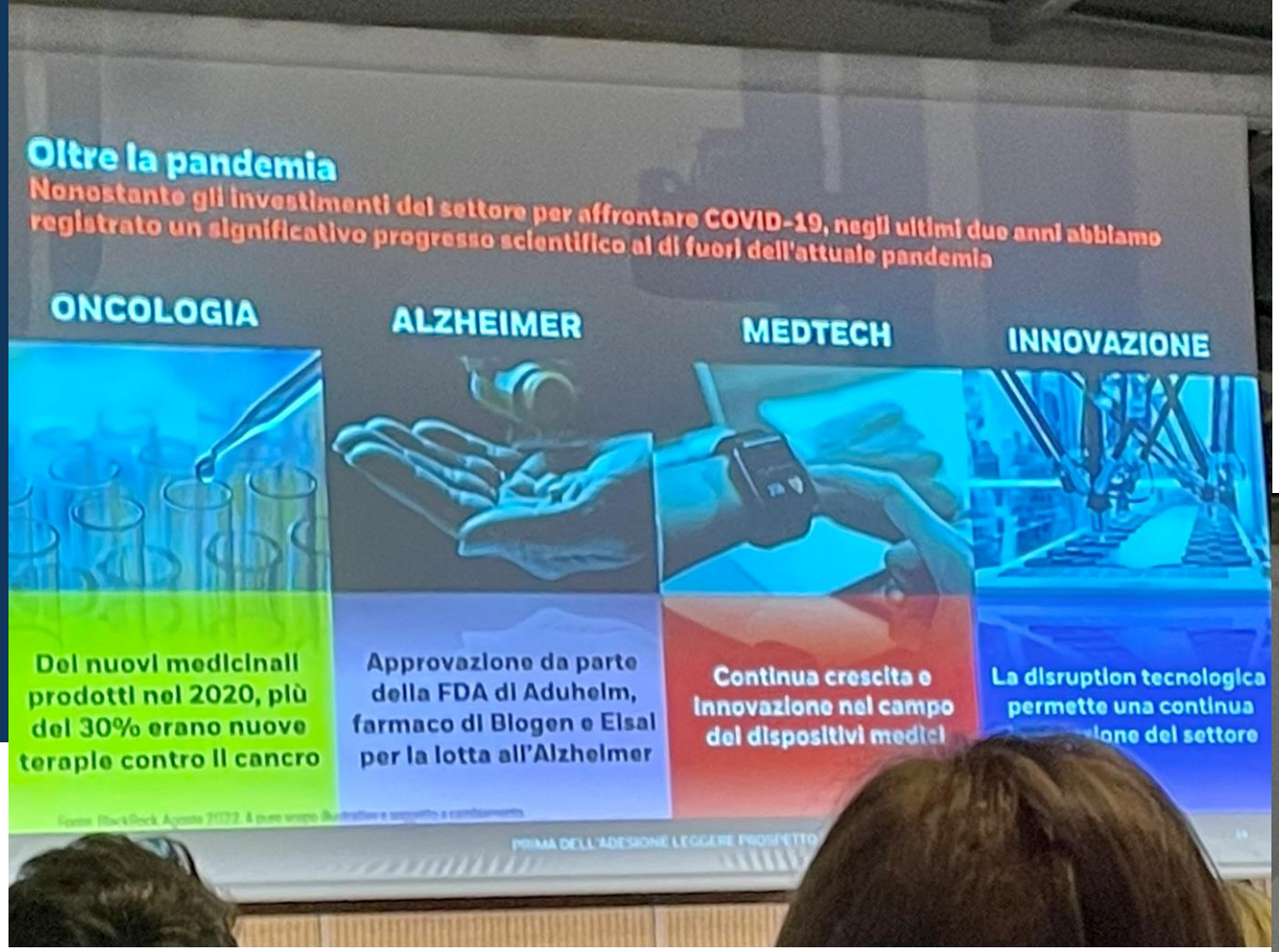
AICRO

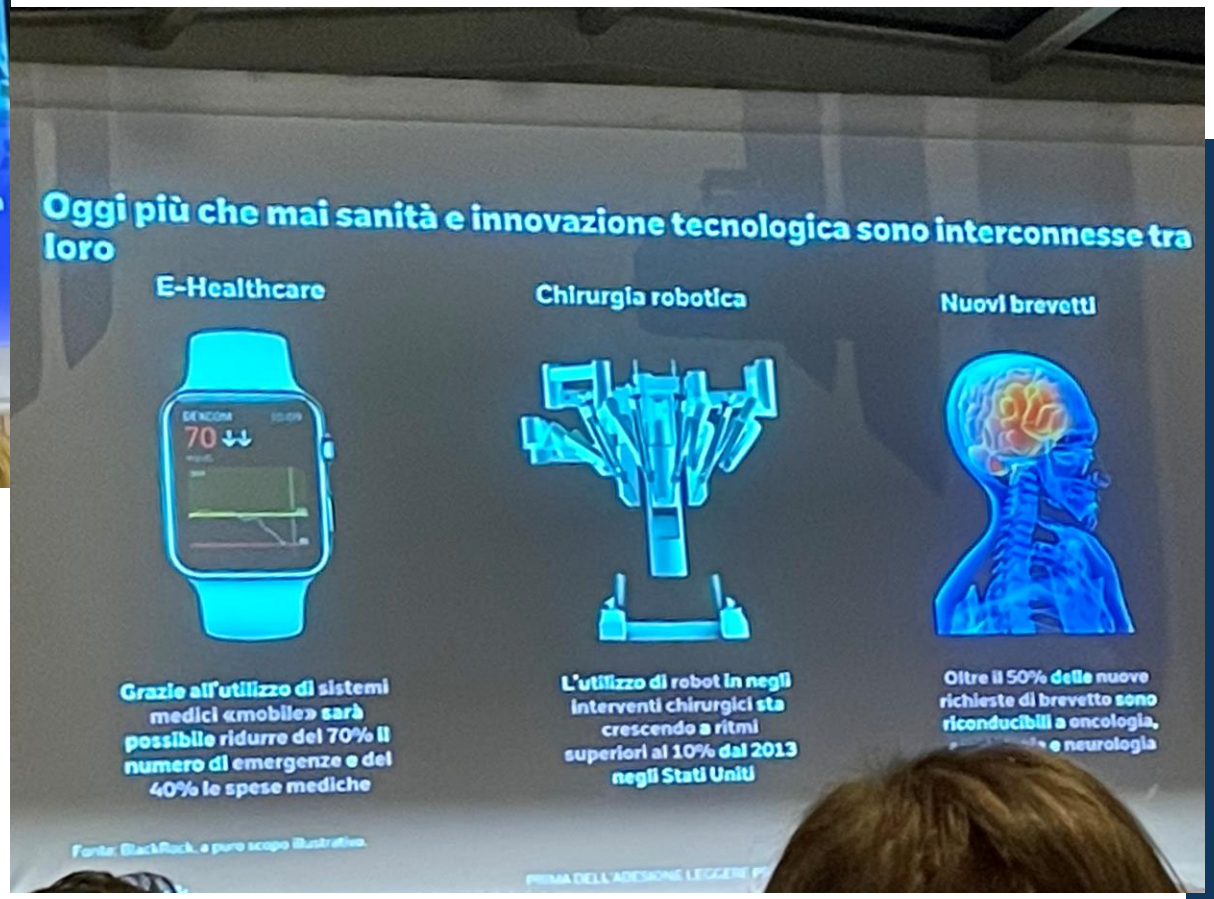
Associazione Italiana Contract Research Organization

La Ricerca Clinica tra imprenditoria e formazione. Cosa serve per avere successo?

Milano, 2 dicembre 2022

Fabrizio Forini, Presidente AICRO


Oltre la pandemia
Nonostante gli investimenti del settore per affrontare COVID-19, negli ultimi due anni abbiamo registrato un significativo progresso scientifico al di fuori dell'attuale pandemia
ONCOLOGIA
ALZHEIMER
MEDTECH
INNOVAZIONE
Dei nuovi medicinali prodotti nel 2020, più del 30% erano nuove terapie contro il cancro
Approvazione da parte della FDA di Aduhelm, farmaco di Biogen e Eisai per la lotta all'Alzheimer
Continua crescita e innovazione nel campo dei dispositivi medici
La disruption tecnologica permette una continua
PRIMA DELL'ADESIONE LEGGERE PROSPETTO


Oggi più che mai sanità e innovazione tecnologica sono interconnesse tra loro
E-Healthcare
Chirurgia robotica
Nuovi brevetti
Grazie all'utilizzo di sistemi medici «mobile» sarà possibile ridurre del 70% il numero di emergenze e del 40% le spese mediche
L'utilizzo di robot in negli interventi chirurgici sta crescendo a ritmi superiori al 10% dal 2013 negli Stati Uniti
Oltre il 50% delle nuove richieste di brevetto sono riconducibili a oncologia,
e neurologia
Fonte: BlackRock, a puro scopo illustrativo.

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“The 15 largest pharmaceutical companies invested a record $133 billion in 2021 in R&D expenditure, an increase of 44% since 2016”

“Venture capital deal activity and investment flows in the U.S. accelerated in the past two years as interest in life sciences intensified with more than 2,000 deals and $47 billion of deal value occurring in 2021”

Global Trends in R&D OVERVIEW THROUGH 2021 – IQVIA Institute for human data science

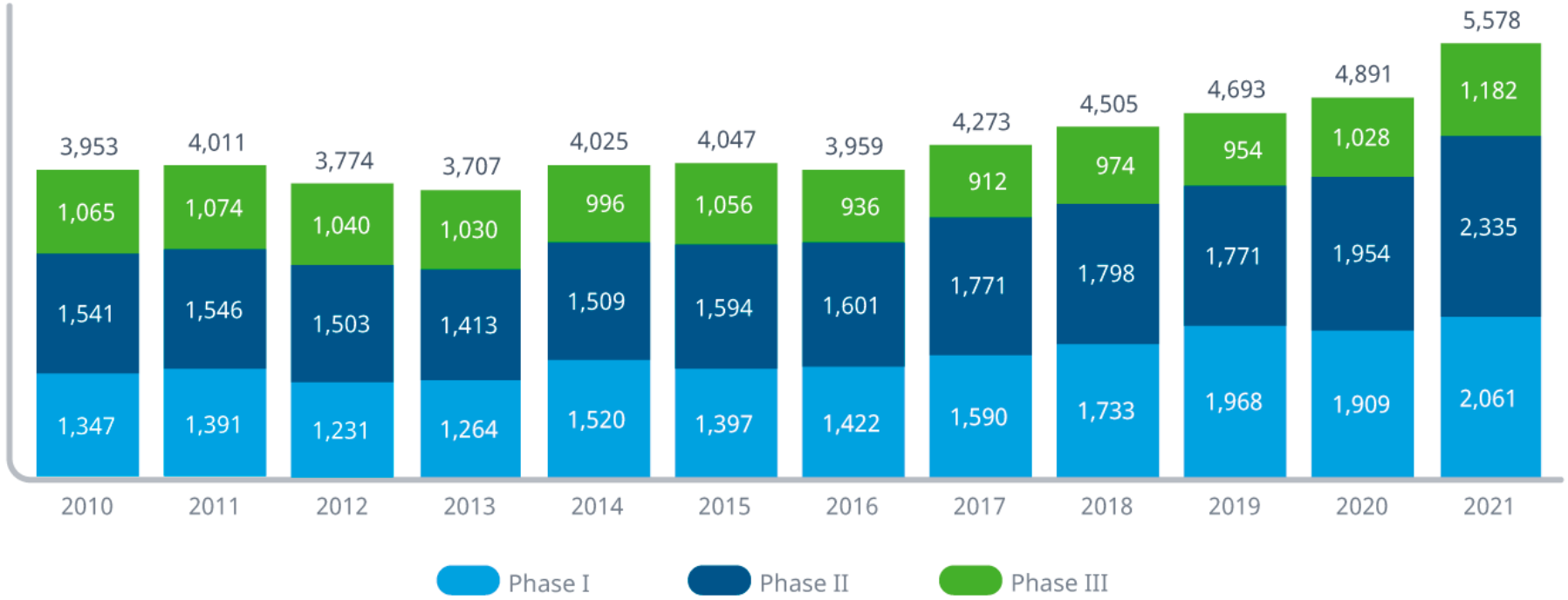

CONTRACT RESEARCH ORGANIZATION SERVICES MARKET
$62.75 Billion
2021
$73.38 Billion
2022
$163.48 Billion
2029
CAGR 12.1%
2022-2029


MARKET TRENDS
Growing Investment in R&D by Industries
MARKET DRIVERS
Rising Prevalence of Chronic Diseases
Strong Foundation for Biotechnology in Europe


BY SERVICE TYPE
Laboratory Services
Pre-Clinical
Discovery
Clinica
BY APPLICATION
Oncology 26.9%
CNS Disorder | Metabolic Disorder
Cardiology | nfectious Disease
Others
BY END-USER
Pharmaceutical & Biotech Companies | Medical Device Companies
Academic and Research institutes | Others

From the net…

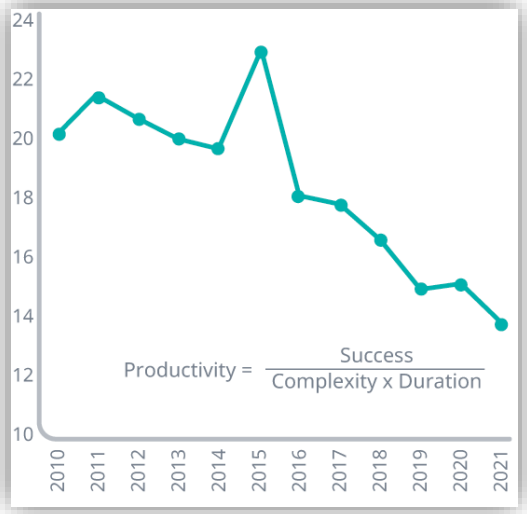
Total number of clinical trial starts by phase, 2010–2021



Source: Citeline Trialtrove, Jan 2022.

VOLUME

PRODUCTIVITY



Main decision drivers for country level

Prevalence pre-scoping: Data-driven assessment of patient population availability

Trial performance:
Speed and quality

Expertise network:
Knowledge and advocacy

Regulatory framework:
Value and innovation

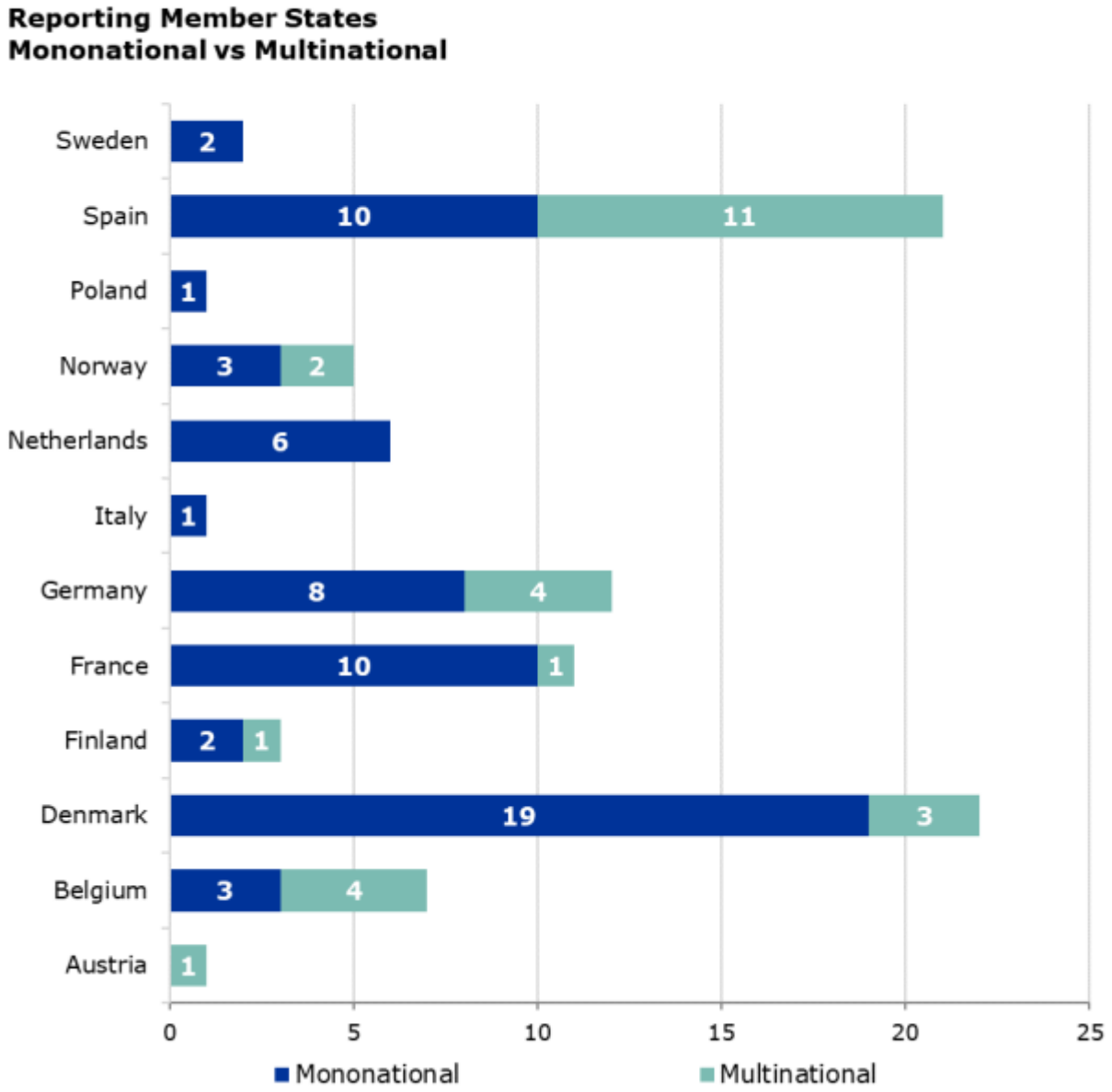
EU4 + UK

- In Jan. 2022 EMA launched Accelerating Clinical Trials (ACT EU) and MHRA launched consultation for optimisation of CT
- Low harmonisation of application assessment and approvals
- **Large disparities across local Ethics Committees can create long delays, specially in decentralised countries**

- **Stringent data protection regulations** as required by GDPR and no homogeneous data flow across member countries
- **Uncertainty for new regulations implementation and sense of potentially «making the process more complex»**
- Diversity and inclusion on agenda but not as advanced as FDA

Country archetype	Strategic goal	Actionable recommendations
"Cornerstone" countries	"Accelerate and collaborate"	• **Implementation of new local regulations (i.e. ACT EU, MHRA) with close follow up and co-creation with pharma co.s and associations** • **Digital investment to support novel clinical trial design (i.e. DHS, DCT), niche capabilities (e.g. omics) to support pioneering clinical breakthroughs** • Cross country agency collaboration to unlock optimisation of 60% of global CT

The graph below shows the distribution of appointment of Reporting Member State (RMS)[21], amongst the applicable Member States Concerned, for clinical trial applications on which a decision has been issued for mono- and multinational trials



A vote of confidence?

Source: EMA - key-performance-indicators-kpis-monitor-european-clinical-trials-environment-1-30-september-2022_en.pdf

Thank you

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