INSIDE INNOVATION

Corso di Biotecnologie applicate
A.A. 2025-2026

Milena Sinigaglia,
Alifax R&D
Trieste, 12th March 2026

1. Who we are?
2. What is an *In Vitro Diagnostic* device
3. Academy vs Company
4. Project management
5. In Vitro Diagnostic device development

ITALIAN EXCELLENCE IN INNOVATION

ALIFAX NUMBERS

120.000.000 ESR TESTS PERFORMED IN 2018

9.700 INSTRUMENTS

200 SCIENTIFIC PUBLICATIONS

160 PEOPLE WORKING IN ALIFAX

108 EXPORT COUNTRIES

50 COMPANIES REPRESENTED IN ITALY AND 20 EXCLUSIVE

40 SALES AGENTS

22 ACTIVE PATENTS

5 SUBSIDIARIES IN RUSSIA, CHINA, SPAIN, BRAZIL, GERMANY

Alifax was founded in 1988 in Padova by Paolo Galiano as a result of his valuable experience in the laboratory diagnostic market with special reference to hematology, microbiology, serology and autoimmunity fields.

INSIDE INNOVATION

BORN IN PADOVA, GROWN UP INTO THE WORLD

HEADQUARTERS **PADOVA**

OOO ALIFAX **MOSCOW**

ALIFAX SPA S.L. **BARCELONA**

ALIFAX DIAGNOSTICS CO., LTD SHANGAI **SHANGHAI**

ALIFAX BRASIL **SÃO PAULO**

ALIFAX DEUTSCHLAND GmbH **GÖPPINGEN**

Nowadays Alifax is present with 5 subsidiaries in Russia, Spain, China, Brazil and Germany.
A distribution network that includes more than 100 Countries around the world.

1	ALBANIA	28	EQUADOR	55	LIBERIA	82	REPUBBLICA DOMINICANA
2	ALGERIA	29	ESTERO	56	LIBIA	83	ROMANIA
3	ARABIA SAUDITA	30	ESTONIA	57	LIECHTENSTEIN	84	RUSSIA
4	ARGENTINA	31	ETIOPIA	58	LITUANIA	85	SERBIA
5	AUSTRALIA	32	FILIPPINE	59	LUSSEMBURGO	86	SINGAPORE
6	AUSTRIA	33	FINLANDIA	60	MACEDONIA	87	SIRIA
7	BAHRAIN	34	FRANCIA	61	MALESIA	88	SLOVACCHIA
8	BANGLADESH	35	GEORGIA	62	MALTA	89	SLOVENIA
9	BELGIO	36	GERMANIA	63	MAROCCO	90	SPAGNA
10	BIELORUSSIA	37	GIAPPONE	64	MAURITIUS	91	SRI LANKA
11	BOLIVIA	38	GIBILTERRA	65	MESSICO	92	STATI UNITI D'AMERICA
12	BOSNIA - HERZEGOVINA	39	GIORDANIA	66	NEPAL	93	SUD AFRICA
13	BRASILE	40	GRECIA	67	NICARAGUA	94	SUDAN
14	BULGARIA	41	GUATEMALA	68	NORVEGIA	95	SVEZIA
15	BURUNDI	42	HONG KONG	69	NUOVA CALEDONIA	96	SVIZZERA
16	CANADA	43	HONDURAS	70	NUOVA ZELANDA	97	TAILANDIA
17	CILE	44	INDIA	71	OLANDA	98	TAIWAN
18	CINA	45	INDONESIA	72	OMAN	99	TRINIDAD E TOBAGO
19	CIPRO	46	IRAN	73	PAKISTAN	100	TUNISIA
20	COLOMBIA	47	IRAQ	74	PANAMA	101	TURCHIA
21	COREA DEL SUD	48	IRLANDA	75	PERU	102	TURKMENISTAN
22	COSTA RICA	49	ISRAELE	76	POLONIA	103	UCRAINA
23	CROAZIA	50	KAZAKISTAN	77	PORTO RICO	104	UNGHERIA
24	DANIMARCA	51	KENYA	78	PORTOGALLO	105	URUGUAY
25	EGITTO	52	KUWAIT	79	QATAR	106	UZBEKISTAN
26	EL SALVADOR	53	LETTONIA	80	REGNO UNITO	107	VENEZUELA
27	EMIRATI ARABI UNITI	54	LIBANO	81	REPUBBLICA CECA	108	VIETNAM

BORN IN PADOVA
GROWN UP INTO THE WORLD

1988 foundation

1992 Uro-quick market launch

1997 Test1 market launch

1998 Sire Analytical Systems acquisition

2005 Alfred60 and ESR quality Controls market launch

2006 Opening of the new facilities in Polverara, Padova

2007 First publication about ESR Latex controls (Piva, Clin Biochem)

2009 First publication about Human Biological Liquid culture (Fontana, Med Sci Monit)

2012 US market introduction

2012 Opening of the new R&D and production site in Nimis, Udin

2013 Sidecar market launch

2015 2015 Opening of 3 subsidiaries in Moscow, Shanghai, Barcelona

2017 Inauguration of the new building in Polverara

2017 Opening of the new Alifax R&D in Area Science Park, Trieste

2018 ALIFAX BRASIL

2018 30th anniversary celebration

2019 New Logo

2020 Opening of the new subsidiary in Germany

Research, design and production: we internally manage the creation of each instrument

ISO 9001:2015

UNI CEN EN ISO 13485:2016

MDSAP

The entire production process is realised in Italy.

Alifax is directly involved in all the instrument and reagent-related design and production phases. The staff - comprising engineers, mechanics, biologists, chemists and software engineers – work in synergy on every aspect regarding the development of new diagnostic methodologies and solutions.

Alifax: an efficient service, whatever the situation.

We love to build lasting relationships with the companies that choose us; as a result, we are able to offer a **well-organised, efficient service** that meets the customers' needs, and provide a prompt and fully-operational after-sales support service, thanks to our team of highly qualified specialists.

Italian soul, international vocation

Alifax instruments are distributed in more than **130 countries** worldwide, through **5 international subsidiaries** and via **distribution trade agreements** with the industry largest multinational companies such as Sysmex, Siemens, Abbott Beckman for ESR line, and Antech USA for veterinary test with HBL on urine application

We exploit the exclusivity of our products manufactured by Alifax and we introduce new tests from our import activity by different dealers.

We take care of the future involving prestigious University and Hospitals to develop and validate our products, solving the problems related to registrations thanks to our Regulatory team of 6 people.

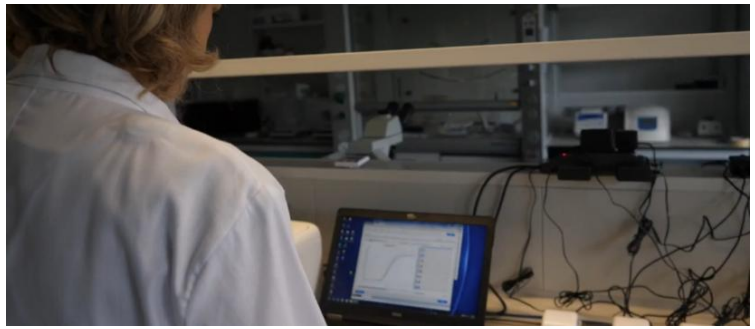
ALIFAX R&D AND PRODUCTION

Alifax has a large facility in Nimis (UD) dedicated to the research, development and production of health products and service

ALIFAX R&D

MOLECULAR BIOLOGY R&D IN TRIESTE

Alifax has an R&D site within Area Science Park of Trieste, one of the most important research site in Italy



INSIDE INNOVATION

Alifax R&D: Protein Science

Research and development of monoclonal antibody and recombinant protein

Alifax Research & Development, Trieste

has acquired a fully equipped facility already present in Area Science Park, and a team of extremely skilled people with the expertise to follow the whole process of **selection/screening of monoclonal antibodies** and **production/characterization of recombinant proteins**.

Alifax R&D Protein science – APPLICATION

Alifax R&D is addressing the need of **fast**, **affordable**, **accurate**, **precise** and **easy-to-use** tests to complete the phenotypic panel of Alifax through cutting edge systems in diagnostic and prognostic field.
The protein science team allows the **design, development**, **production** and **deep characterization** of protein of **high quality** and **low cost** to improve Alifax core business in the market of diagnostic tools with a focus in microbiology.

Fields of application:

- Rapid tests (diagnostic/prognostic)
- ELISA kit

MOLECULAR MOUSE SYSTEM

MicroWell
All necessary reagents are lyophilized in each 5 µL microwell for multiplex reactions

RFID tag
stores product and test information used by the software to perform the analysis

MODULAR CONFIGURATION

Up to 6 instruments can be managed independently with one software session

Scan qr-code
DISCOVER MORE

INSIDE INNOVATION

MOLECULAR MOUSE SEPSIS PANEL

POSITIVE BLOOD CULTURE

GRAM-STAINING

GRAM NEGATIVE AND RESISTANCES

MM GRAM NEG ID
code SI 1701.0102/L

Acinetobacter baumannii
Enterobacteriaceae
Klebsiella aerogenes
Enterobacter cloacae
Escherichia coli/Shigella spp
Haemophilus influenzae
Klebsiella oxytoca
Klebsiella pneumoniae
Neisseria meningitidis
Proteus spp
Proteus mirabilis
Pseudomonas aeruginosa
Salmonella typhi
Serratia marcescens
Stenotrophomonas maltophilia

MM GRAM NEG RES
code SI 1701.0101/L

KPC
VIM
NDM
IMP
OXA-23-like
OXA-48-like
SHV
SHV ESBL
CTX-M-1/9 groups
CTX-M-2/8 groups
CMY-2
mcr-1
mcr-2

YEAST

MM YEAST BLOOD
code SI 1701.0105

Candida albicans
Candida glabrata
Candida krusei
Candida parapsilosis
Candida tropicalis
Candida auris
Candida lusitaniae
Candida dubliniensis
Candida guilliermondii

Each kit code is composed by 20 cartridges.

GRAM POSITIVE AND RESISTANCES

MM GRAM POS NO STAPH
code SI 1701.0104/L

Bacillus subtilis
Enterococcus spp
Enterococcus faecalis
Enterococcus faecium
Listeria monocytogenes
Streptococcus spp
Streptococcus agalactiae
Streptococcus anginosus
Streptococcus pneumoniae
Streptococcus pyogenes
vanA
vanB
vanC1
vanC2/3

MM GRAM POS STAPH
code SI 1701.0103/L

Staphylococcus spp
S. aureus
S. epidermidis
S. haemolyticus
S. lugdunensis
S. sciuri
S. hominis
S. simulans
S. saprophyticus
S. xylosus
mecA
mecC
SSCmec-orfX
vanA e vanB

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Question time!

Medicinal Products vs Devices: The Products

A. Pharmaceutical

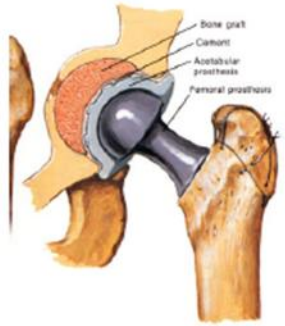
B. Medical Device

C. In Vitro diagnostic device

Medicinal Products vs Devices: The Products

- **Pharmaceuticals**
- Limited number of products ~ 20,000
- Development by trial and selection on the basis of quality, safety and efficacy
- Based on pharmacology, chemistry, biotechnology, and genetic engineering
- Biologically active and effective when absorbed by the body

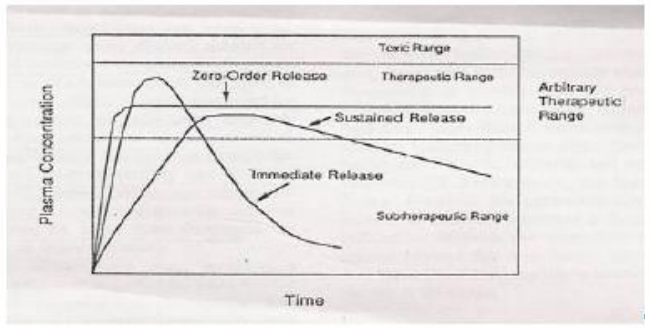
- **Medical Devices**
- More than 500,000 products (different sizes, models, etc.)
- Designed specifically to perform certain functions based on quality, safety and performance
- Based on mechanical, electrical and/or materials engineering
- Generally act by physical means



Source: Abbott

Medicinal Products vs Devices: Innovation

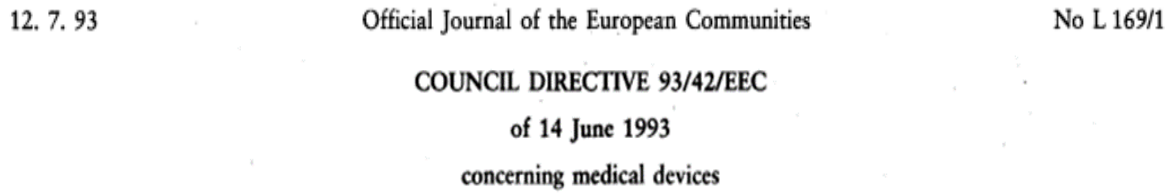
- **Pharmaceuticals**
  - Continuous innovation via delivery improvements based on new science and technology
  - Typically long product lifecycle
  - "Breakthrough drugs"



- **Medical Devices**
  - Continuous innovation based on new science, technology and available materials
  - Generally short product lifecycle due to frequent iterations
  - New devices bring added functions and clinical value based on incremental improvements

Source: Abbott

Medical Device: Definition



12. 7. 93 Official Journal of the European Communities No L 169/1

COUNCIL DIRECTIVE 93/42/EEC

of 14 June 1993

concerning medical devices

'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,

BUT

93/42/EEC Directive does not apply to in vitro diagnostic devices

CE – IVD In Vitro Diagnostic Device


Source: https://redcliffelabs.com/

In-Vitro diagnostic devices (IVDs) play a critical role in the **healthcare solution**. They allow healthcare providers and patients to **efficiently** and **accurately detect diseases, conditions, or infections**.

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 October 1998

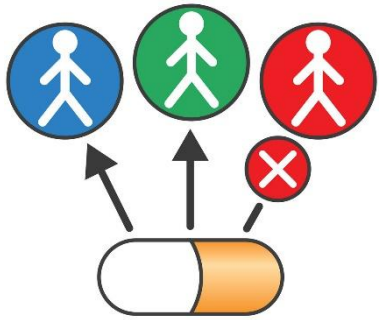
on *in vitro* diagnostic medical devices

"A **device**, whether used alone or in combination, intended by the manufacturer for the **in-vitro examination of specimens** derived from the human body solely or principally to provide information for **diagnostic, monitoring or compatibility purposes**. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles."

The **CE-**mark is a certification mark that indicates conformity with health, safety and environmental protection standard in the EU.

Each country has their own regulation.

Source: ttps://www.lifeloveandsugar.com



CE – IVD In Vitro Diagnostic Device:
Why are IVDs different from other medical devices?

- Run **tests on a sample** from the body in an artificial environment, most often a laboratory
- They rely on samples – such as blood, tissue or urine – to conduct diagnosis, predictive testing, screening, and monitor conditions.
- In some cases, **risk associated** with IVDs is linked to the possibility of **mis-diagnosis** (e.g. false positives or negatives…incorrect interpretation), not the device itself.

aid to diagnosis prognostic screening

diagnostic monitoring companion diagnostic

Let’s test out knowledge!

MOLECULAR SYSTEMS
CE-IVD/FDA/EUA*

ALL IN

Source: Genmark, Biofire, Diasorin

REAGENT KITS

Source: ROCHE, Seegene, Abbott

TOTAL AUTOMATION

Source:, Seegene, Beckman Coulter

***EUA= Emergency Use Authorization in extraordinary situation**

CE – IVD In Vitro Diagnostic Device:
Directives

7.12.98 EN Official Journal of the European Communities L 331/1

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 October 1998

on *in vitro* diagnostic medical devices

IVDD

Wish for increased transparency and accountability; involvement of medical professionals and patients

↓

Enhanced attention for the In Vitro Diagnostic sectors

↓

L 117/176 EN Official Journal of the European Union 5.5.2017

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

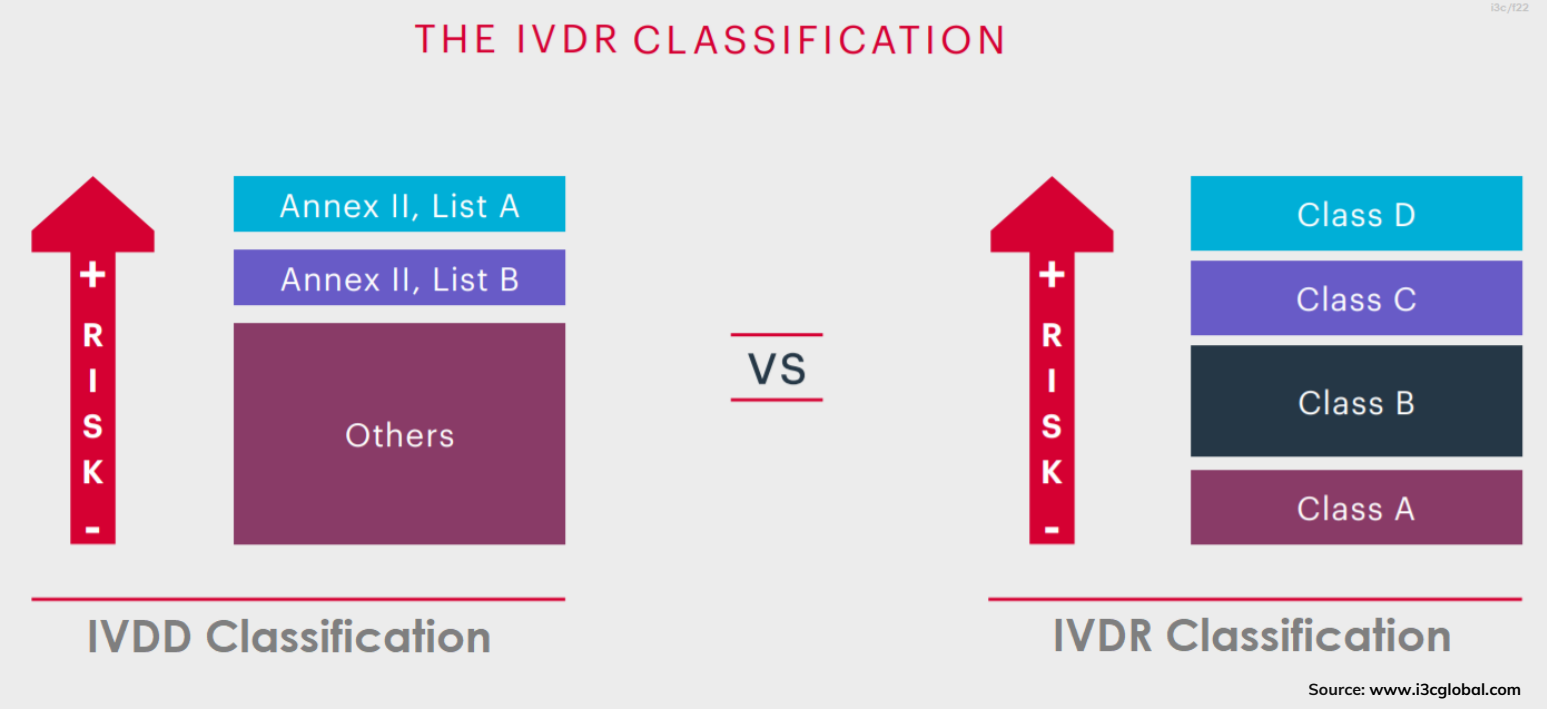
on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

(Text with EEA relevance)

IVDR

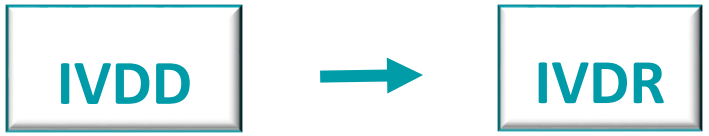
CE – IVD In Vitro Diagnostic Device:
Directives

IVDD → IVDR



One of the main changes in IVDR transition is the changes in '*in vitro diagnostic device*' classification

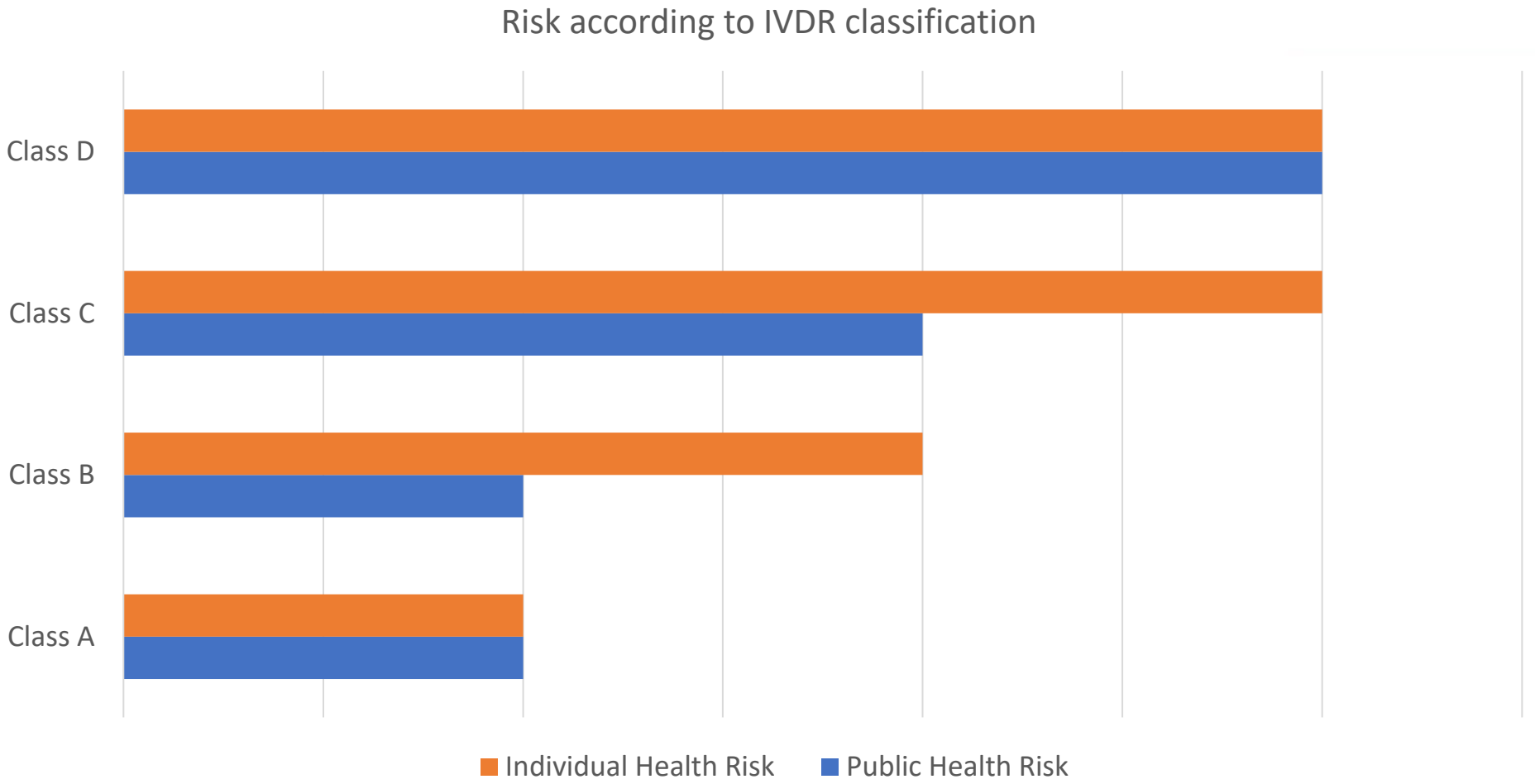
CE – IVD In Vitro Diagnostic Device:
Directives



Source: www.ceplus.eu

Many devices classified as ‘Others’ according to IVDD are classified as Class B, C and D according to IVDR

CE – IVD In Vitro Diagnostic Device: Directives



'*in vitro diagnostic device*' classification according to public and individual health risk in case of misdiagnosis

CLASSIFICATION OF IVDS ACCORDING TO IVDR 2017/746

CLASS A

LOW PERSONAL RISK, LOW PUBLIC HEALTH RISK

Examples

- Accessories
- Wash buffers
- Specimen receptacles
- Instruments
- Culture media

CLASS B

MODERATE TO LOW PERSONAL RISK, LOW PUBLIC HEALTH RISK

Examples

- Thyroid, kidney, liver function tests
- Infertility assays
- Clinical chemistry
- Hormones, enzymes, proteins • Inf ammatory markers
- Rheumatology markers
- Self-test devices that are not Class C: pregnancy, fertility, cholesterol and urine tests for glucose, erythrocytes, leucocytes and bacteria

CLASS C

HIGH PERSONAL RISK, MODERATE TO LOW PUBLIC HEALTH RISK

Examples

- Syphilis (diagnosis only)
- Neonatal screening for metabolic disorders e.g. PKU
- Rubella
- Cancer markers (screening and diagnosis)
- Genetic tests
- Companion diagnostics
- Blood glucose meters/strips
- Blood gas analysers
- Self tests
- Cardiac markers
- Tissue typing e.g. HLA

CLASS D

HIGH PUBLIC HEALTH RISK, HIGH PERSONAL RISK

Examples

- Blood donation screening e.g. Syphilis, CHAGAS, HTLV I/II
- Blood grouping ABO, Rhesus (including RHW1), Kell, Kidd and Duffy systems.
- Diagnostic test e.g. HIV 1/2

Medical Devices Regulatory Compliance
Your medical devices in a global market
mdro-consulting.com

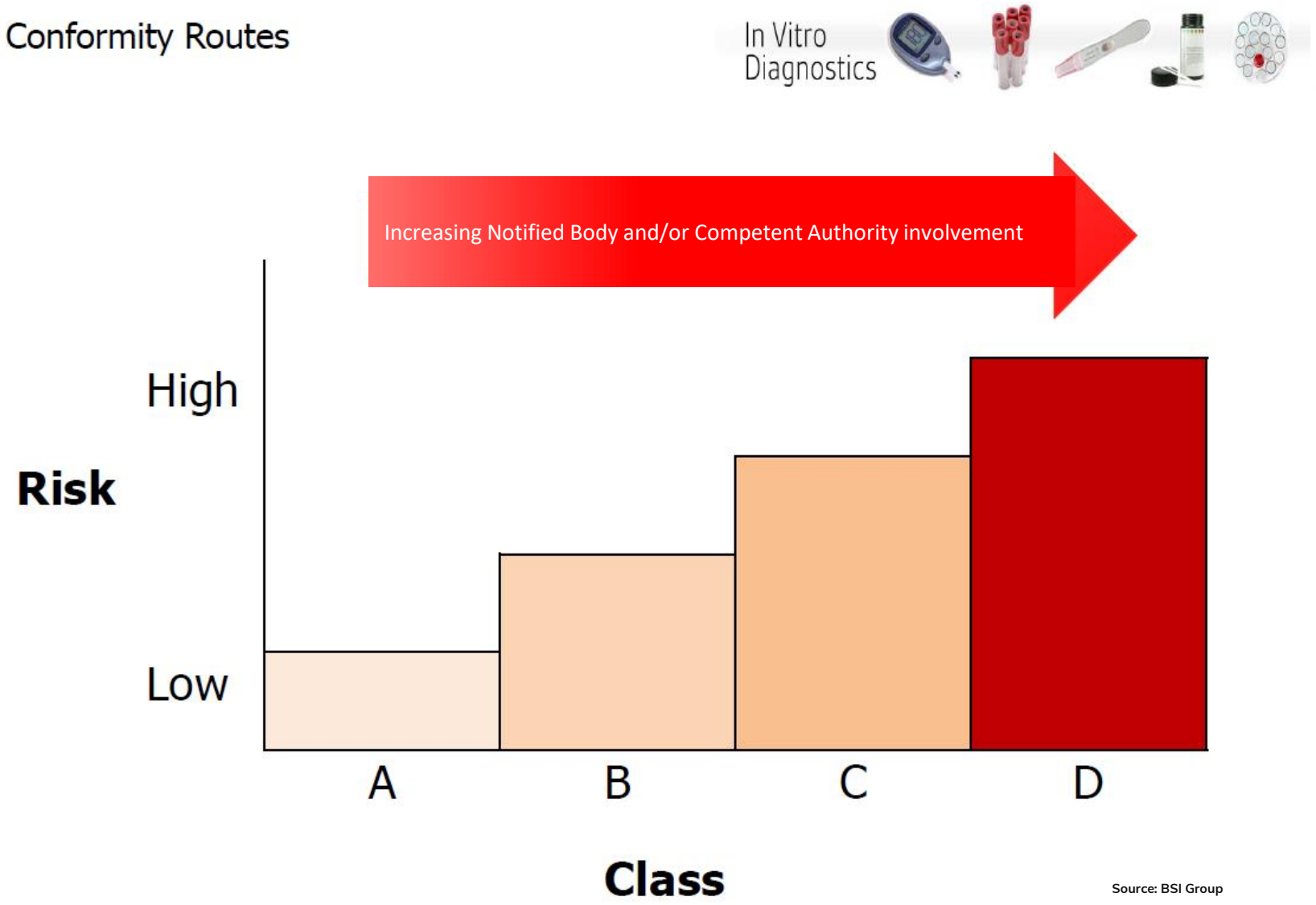
CE – IVD In Vitro Diagnostic Device:
Directives

A **Notified Body** is an organization that assesses the conformity of certain products before being placed on the EU market

Under 98/79/CE directive **10-15%** IVD's require Notified Body assessment

Under IVDR regulation 2017/46 directive **85-90%** IVD's require Notified Body assessment

IVDR classification



Source: BSI Group

IVDR
Dates of Application

26 May 2022 — All devices, except those covered by the transition period, must comply with the IVDR (e.g. class A non-sterile devices, new devices, devices with a significant change)

Only devices that are covered by a notified body certificate issued under the IVDD or that did not require the involvement of a notified body under the IVDD but do so under the IVDR can potentially benefit from the extended transition.

31 Dec 2027 — End of transition period for class D devices and for devices with a certificate issued by a notified body under the IVDD (e.g. devices for self-testing)

31 Dec 2028 — End of transition period for class C devices

31 Dec 2029 — End of transition period for class B devices and class A sterile devices

****Conditions to be fulfilled to benefit from extended transition period**

26 May 2025

Deadline to have an IVDR QMS in place

26 May 2025 | 2026 | 2027

Deadline to lodge an application for IVDR conformity assessment

26 Sep 2025 | 2026 | 2027

Deadline to sign a written agreement with an NB & transfer appropriate surveillance to an IVDR NB (where applicable)

Devices continue to comply with previously applicable EU legislation (IVDD)

No significant changes in design or intended purpose

Notified body certificate or declaration of conformity drawn up before 26 May 2022

Source: www.regulatoryglobe.com

In Vitro Diagnostic Device manufacturer

"Manufacturer is the natural or legal person with **responsibility for design and/or manufacture of a medical device with the intention of making the** medical **device available for use, under his name**; whether or not such a medical
device is designed and/or manufactured by that person himself or on his behalf by another person(s)"

Manufacturer has ultimate legal **responsibility** for ensuring **compliance with all applicable regulatory requirements** for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Each country has their own regulation.


INTERNATIONAL STANDARD

ISO 13485

Third edition
2016-03-01

Medical devices — Quality management systems — Requirements for regulatory purposes

Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires

In Vitro Diagnostic device's manufacturers are ISO 13485 certified

EN ISO 13485

ISO 13485 specifies **requirements for a quality management system (QMS)** where an organization needs to demonstrate its ability to provide medical devices and related services that consistently **meet customer and applicable regulatory requirements.** Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support).

ISO 13485 is **not mandatory**. You can create a QMS that suits your needs for your organization, so long as the processes of the QMS meet the legal and regulatory requirements for medical devices where you intend to manufacture and sell them. Even though ISO 13485 is not required for EU Medical Device Regulation (MDR) compliance, the EU MDR regulation requires that you have a QMS in place, and the **ISO 13485:2016 standard is the only QMS standard listed in the EU list of harmonized standards**, so most companies will use the ISO 13485 requirements to implement their QMS.

EN ISO 13485

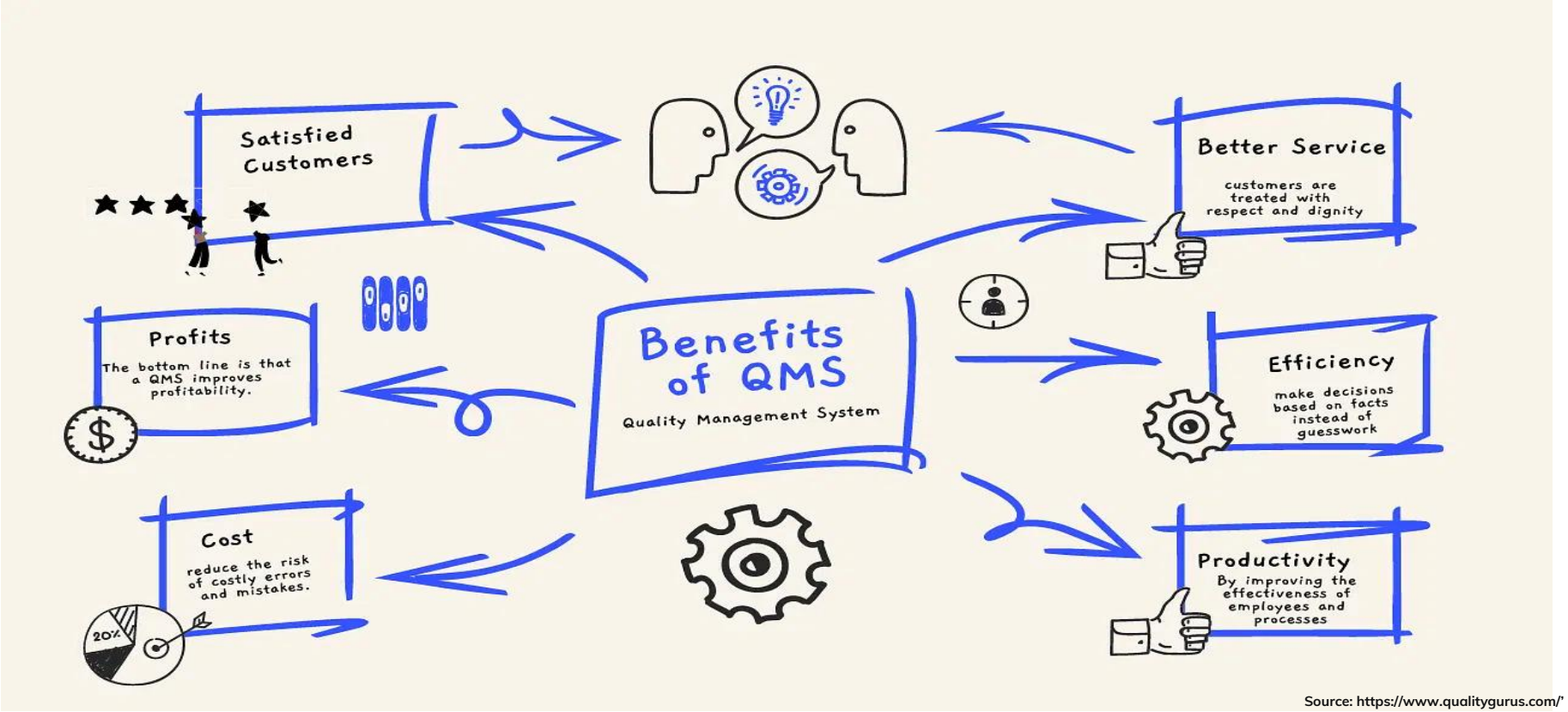
We often come across standards with the abbreviation “EN” e.g., EN ISO 13485:2016 or EN ISO 14971:2012. These are ISO standards that are **adopted by the European Commission** and **harmonized currently to the requirements of the European Directives** and thus, are called harmonized standards. With the introduction of the new regulations for medical devices, these standards are now being harmonized to the new regulations.

Others are:

- AFNOR:Association Française de Normalisation
- DIN: Deutsche Industrie Norm
- BS: British Standard

Quality Management System

"A quality management system (QMS) is **a set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organization** (i.e., areas that can impact the organization's ability to meet customer requirements)."



Source: https://www.qualitygurus.com/'

Quality Management System

Source: 'https://neurohealthchiro.com.au/

PROs

- Optimization of resources
- Increase efficiency
- Increase employee productivity
- Reduces Risk
- Deliver better products to customers
- Minimizes product and time waste
- Enhance brand image

CONs

- Requires substantial financial investment
- Can be difficult to implement without expertise
- Requires ongoing feedback and training
- Difficult to Understand
- Can take years to show results
- Assumption of increased 'burocracy'

It has to be done properly to maximize benefit!

QMS: an example

Source: https://about.ikea.com/

How to be ISO 13485 certified

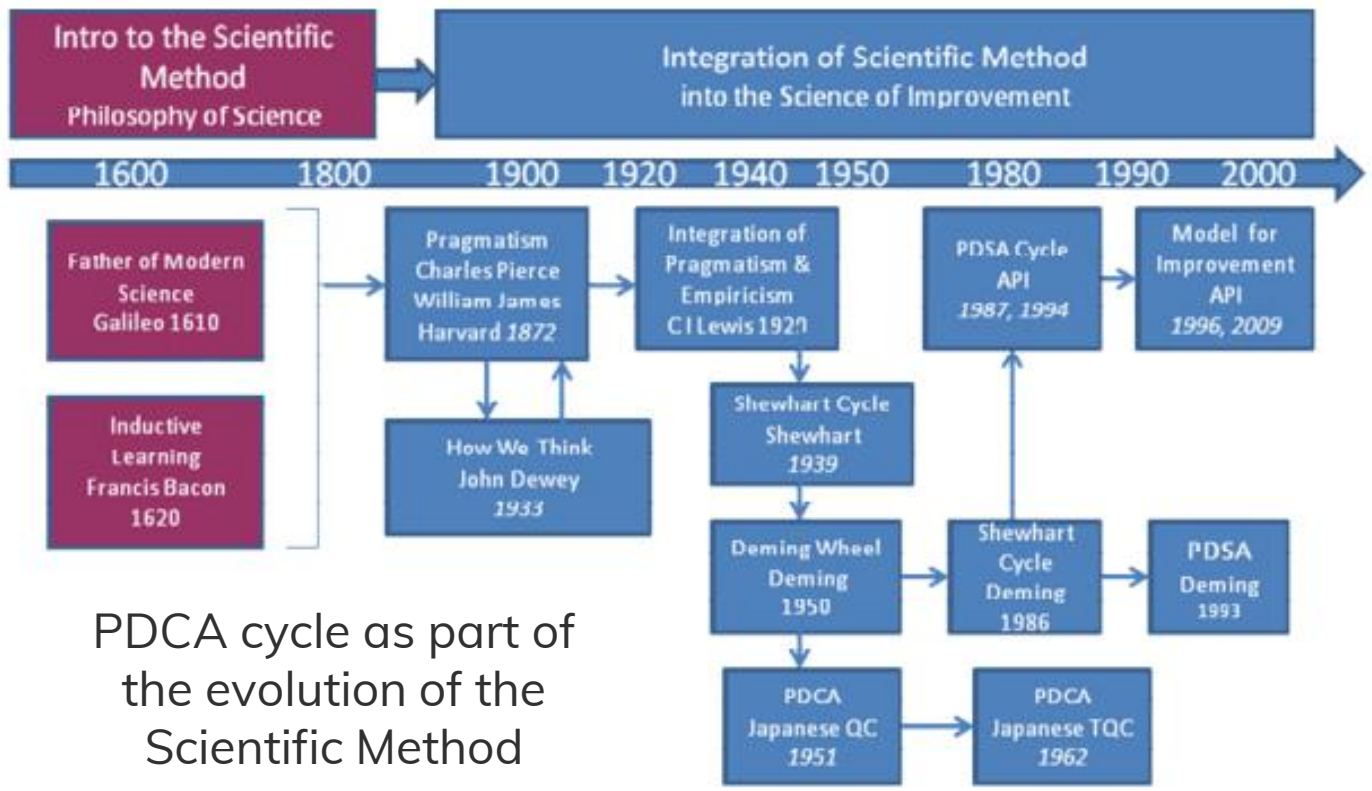
“The organization shall:

- document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements.
- establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements.
- document the role(s) undertaken by the organization under the applicable regulatory requirements.”

Source: ‘systemdocuments.wordpress.com

PDCA cycle

The PDCA cycle stays at the base of any quality management system and it is an extremely important approach useful to fully understand the **general structure of a quality system**, independent from the type of business or type of industry it is related to.



PDCA cycle as part of the evolution of the Scientific Method

Source: Moen, R., and Norman, C., "The History of the PDCA Cycle." In Proceedings of the 7th ANQ Congress, 2009

PDCA cycle

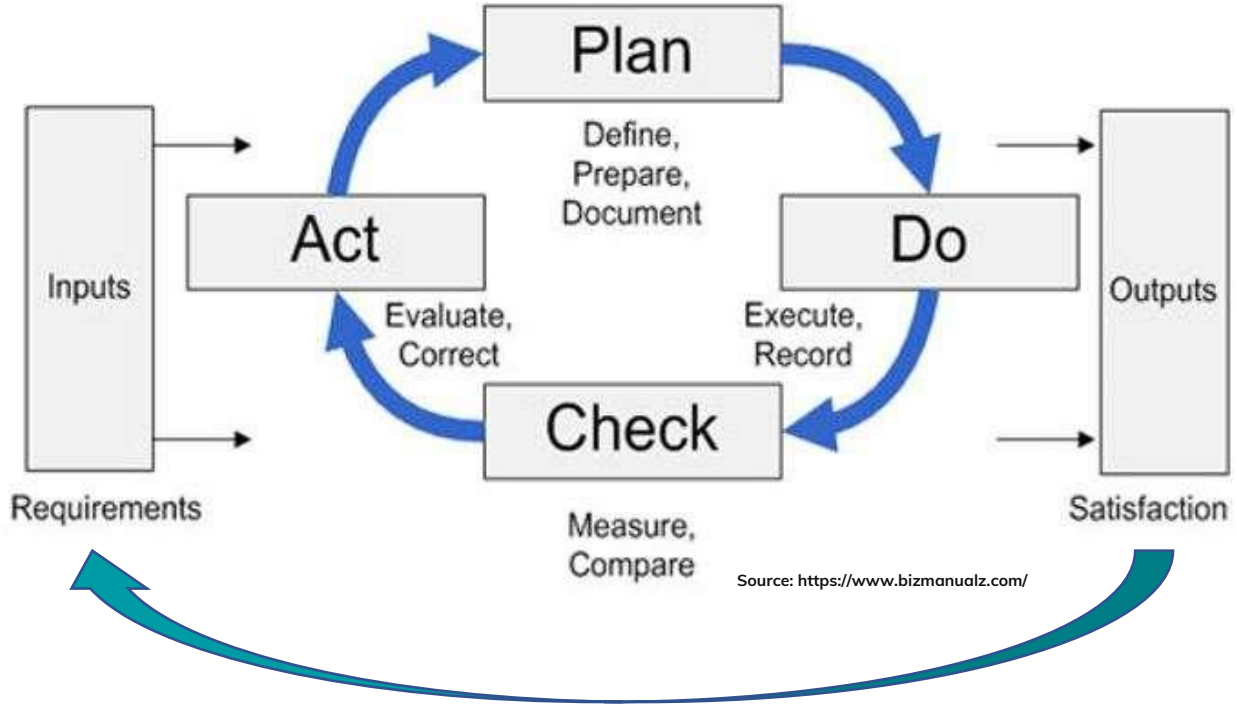
Originally created by Walter Shewhart in 1939 (one of the fathers of modern quality control), and later popularized by Edward Deming in 1950 (the other founding father). The premise is that **a cycle for implementing change, when followed and repeated, will result in successive improvements in the process to which it was applied.**

The PDCA can be summarized based on the following considerations:

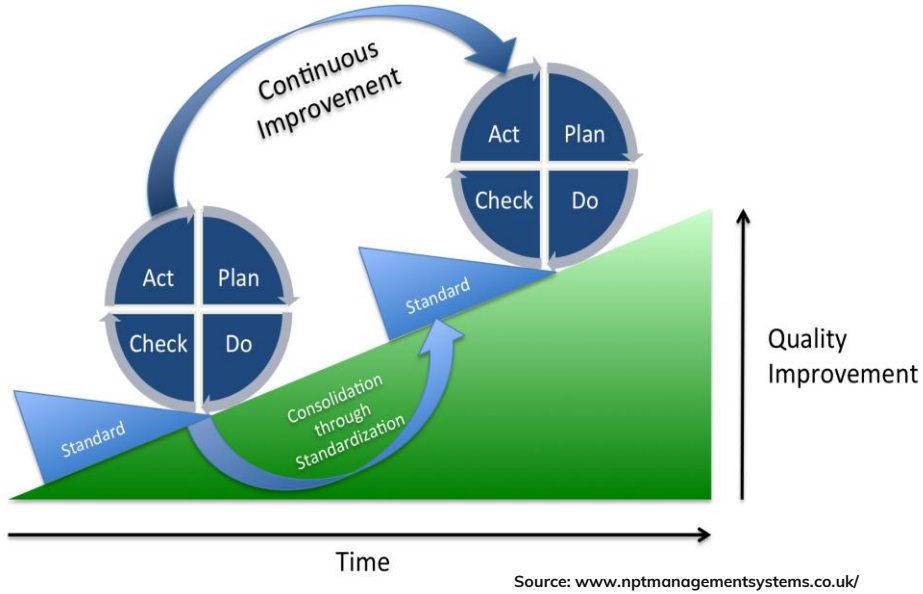
- **Plan**: planning phase. This consists in the establishment of the objectives of the system and its processes, based on customer requirements and internal organization policies.
- **Do**: implementation of the plan
- **Check**: monitoring activities need to be performed, in order to check if the implementation phase was successful and the plan has been fully implemented.
- **Act**: if during the monitoring phase, any actions to further improve performance/safety is identified, this needs to be implemented.

Source: Moen, R., and Norman, C., "The History of the PDCA Cycle." In Proceedings of the 7th ANQ Congress, 2009

PDCA cycle



Source: https://www.bizmanualz.com/



Source: www.nptmanagementsystems.co.uk/

Quality Management System: PDCA cycle as the basis for continuous improvement

How to be ISO 13485 certified

Audit
"Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled"

- External audit: A certification audit is the audit your selected registrar will conduct to verify conformance against the ISO 13485 standard before they issue your official ISO 13485 certificate. After certification, your registrar will check-up on your periodically using surveillance audits to verify you are still upholding your QMS and the ISO requirements
- Internal audit: performed by the organization and is a self-examination of your organization's Quality Management System, performed on-site. Internal audits have many benefits including preparing your organization for external audits

MDSAP

Medical Device Single Audit Program
conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program

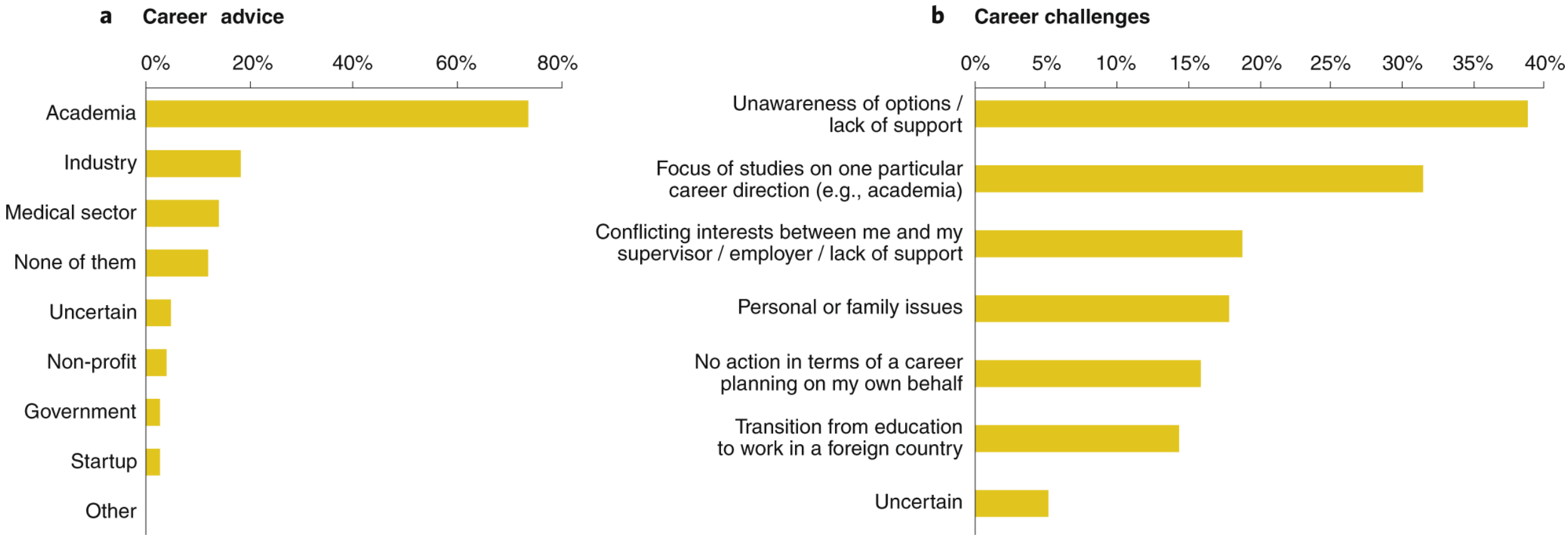
- **MDSAP Members**
  - Therapeutic Goods Administration of Australia
  - Brazil's Agência Nacional de Vigilância Sanitária
  - Health Canada
  - Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency
  - U.S. Food and Drug Administration

1. Who we are?
2. What is an *In Vitro Diagnostic* device
3. Academy vs Company
4. Project management
5. In Vitro Diagnostic device development

After graduation?

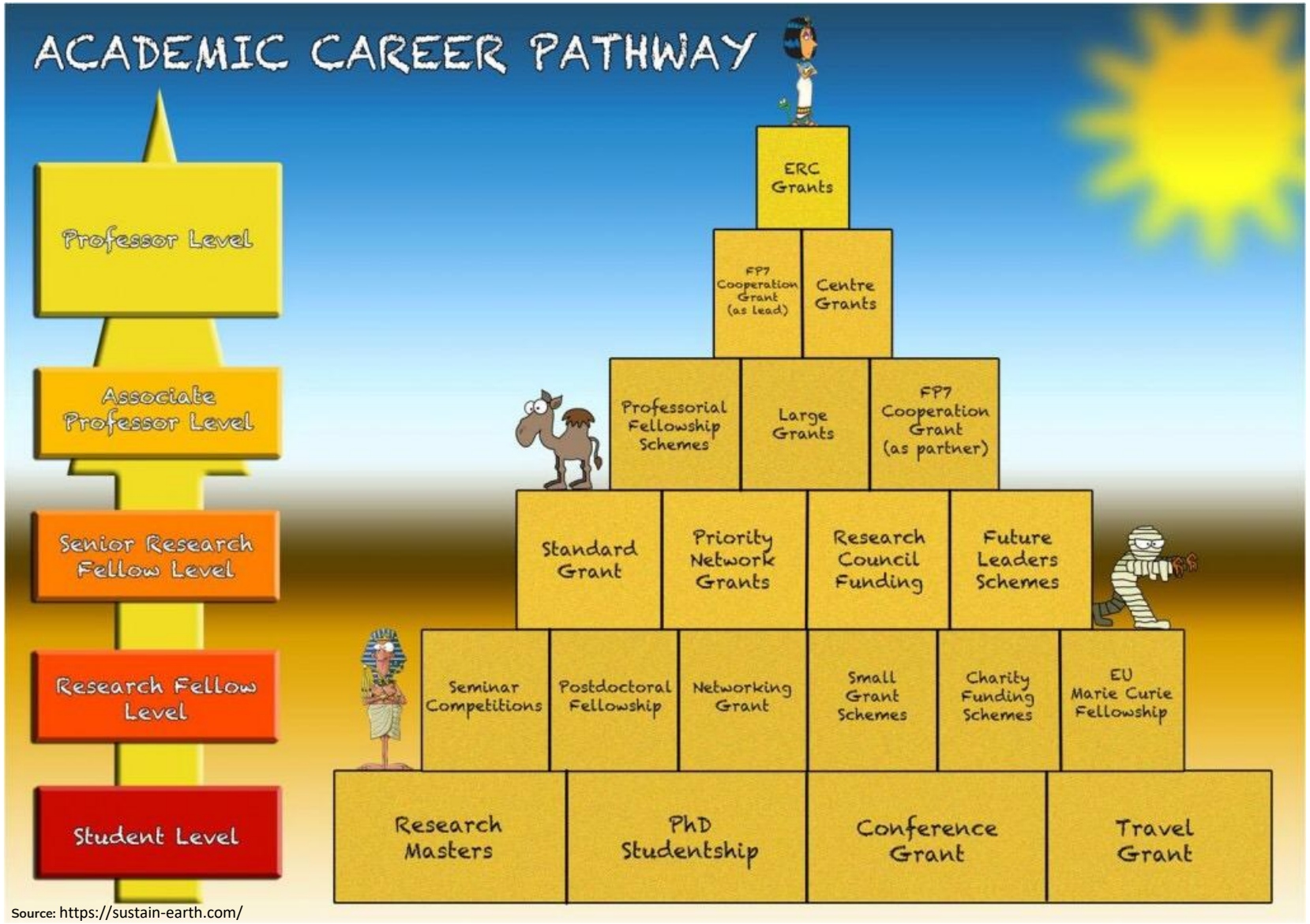
After graduation?

INSIDE INNOVATION



Survey of 300 graduate and postgraduate students in the United States and Europe.
a. Students received the most career advice about academic careers. b. A large proportion of students felt a lack of support and awareness of career options blunted their ability to reach their ideal careers.

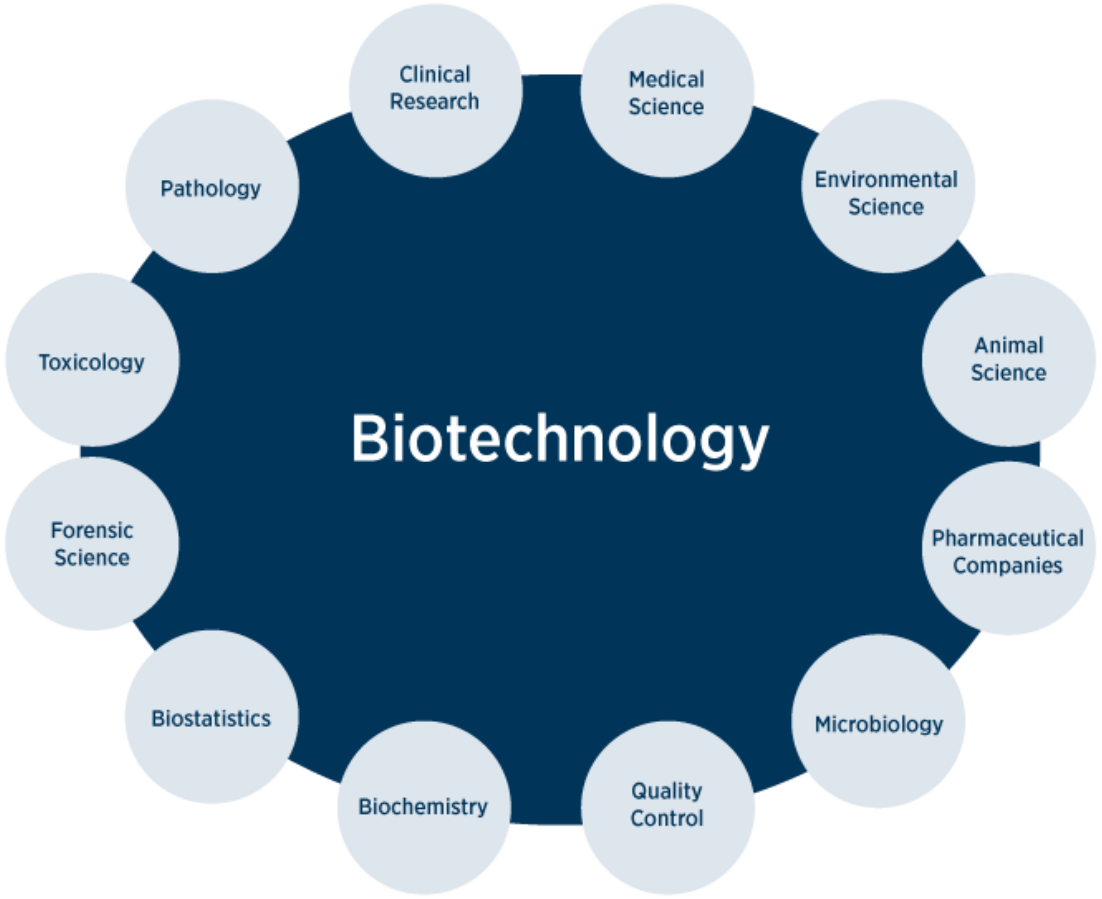
Academic career



Source: https://sustain-earth.com/

Industrial career

INSIDE INNOVATION



Source: www.careerguide.com/

Marketing

R&D

Production

Quality control

Scientific technical support

Administration

Product Specialist

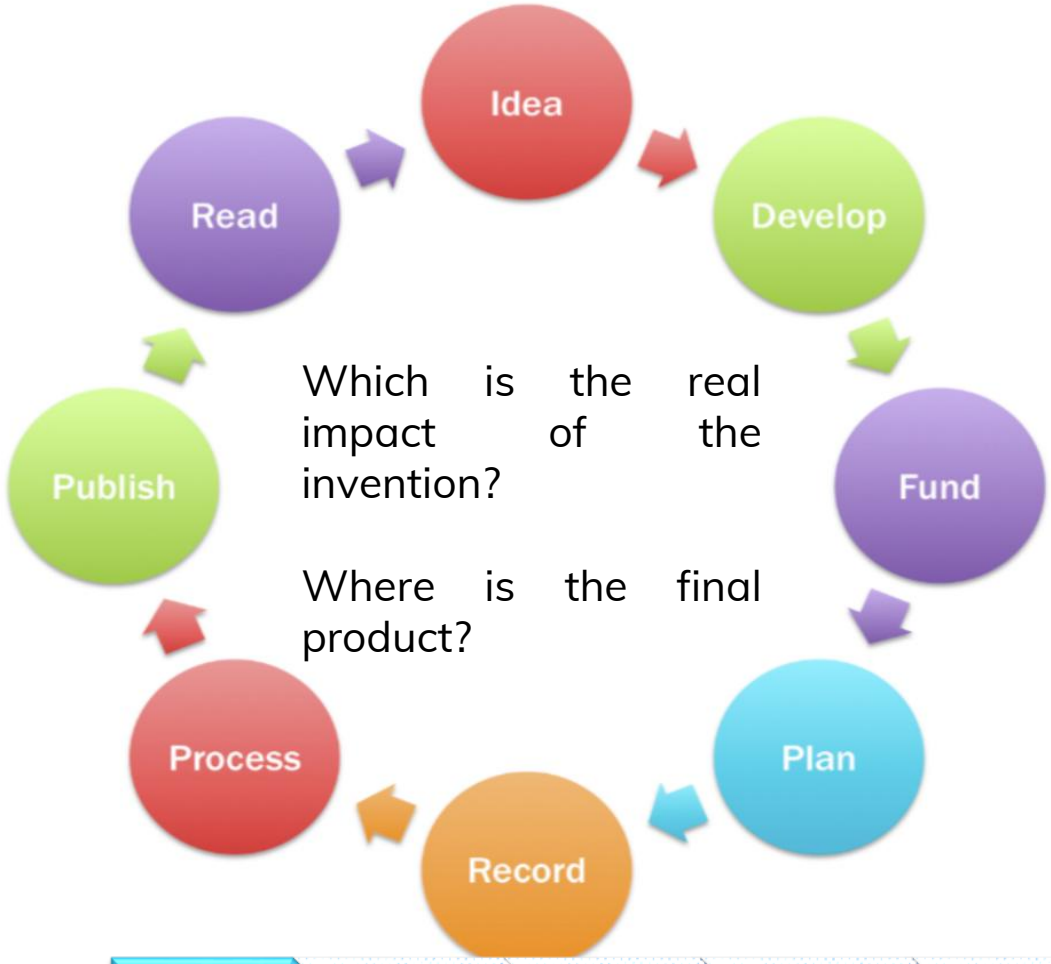
Manager

Sells

Technician

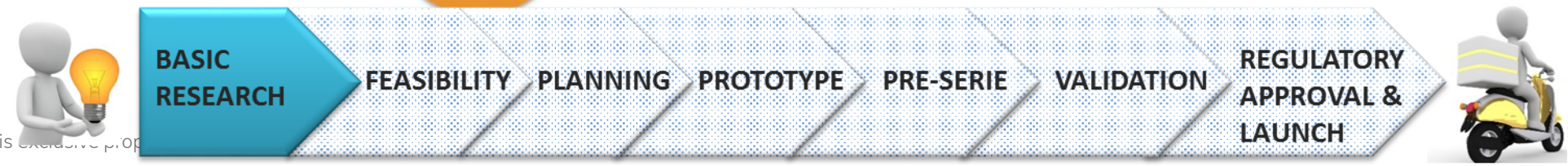
Basic research as a road toward a better life

INSIDE INNOVATION



The final aim of basic research is to increase knowledge to improve the quality of life.

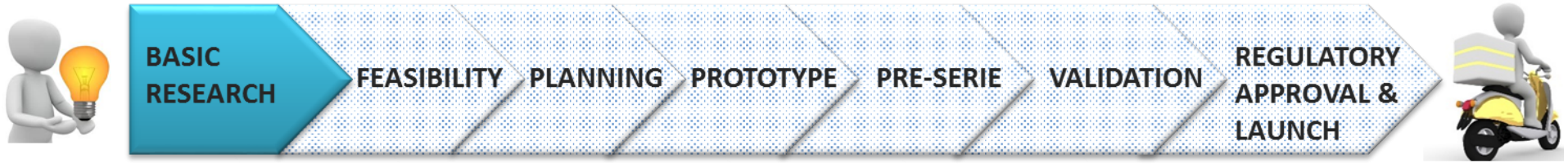
Sometimes useful R&D ideas can not be translated into a product due to feasibility issue



Basic research: different perspectives academia vs industry

- Idea
- Protocol
- Sample
- Disease
- Collaboration
- Impact Factor

- User needs
- Competitor / Patent
- Quality / Costs
- Prototype production, verification, validation
- Time to market



Basic vs Applied Research

Research

- *noun*: the systematic investigation into and study of materials and sources in order to establish facts and research new conclusions.
- *verb*: investigate systematically

Industrial research

The planned research or critical investigation aims at the acquisition of new knowledge and skills for developing new products, processes or services or for bringing about a significant improvement in existing products, processes or services. (source 'European Union')

Basic vs Applied Research

INSIDE INNOVATION

Basic Research

- To accumulate information, extending the base of knowledge ina discipline - why?
- Pure science (i.e. Bech scientist/ natural science)
- Identify functional relationships
- May not have immediate relevance
- Critical to the survival of applied research

Applied Research

- To find immediate solution to an existing problem-what is the goal?
- Clinical science (i.e. Practice settings)
- Development of new products, processes or services or for bringing about a significant improvement in existing products, processes or services
- Aimed to solve problems
- Based on basic research

Basic vs Applied Research

Academic Research

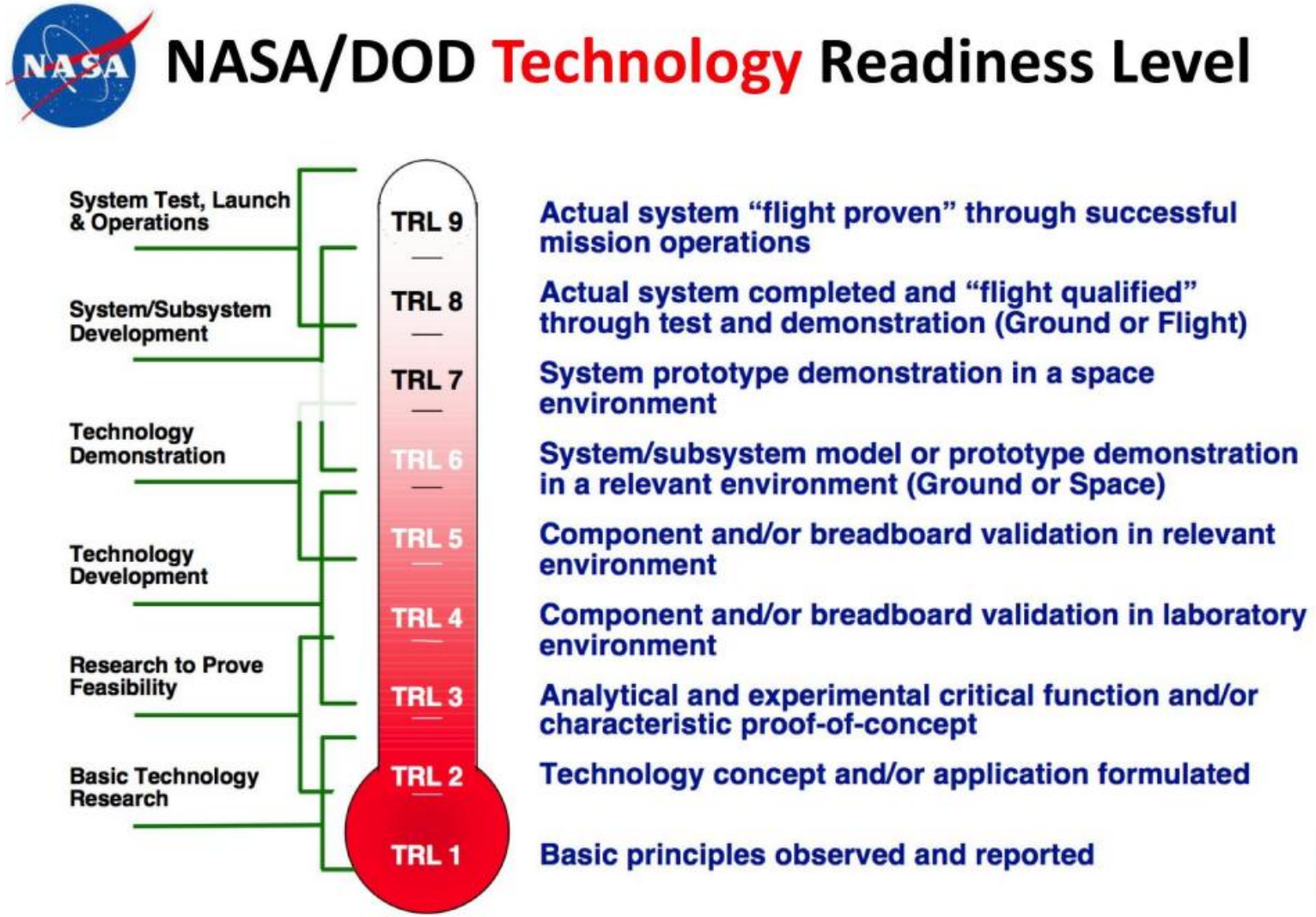
Both positive and negative outcomes are equally valid and important contributions to the body of knowledge that the world shares

Industrial research
industrial research success is new knowledge that leads to new products, processes or services. Due diligence needed to invest only in feasible projects.

Industrial research is similar to, but distinct from, academic research. Both fields share the **same rigour**, although their **goals** are **different**. Within the academic world success can be defined as discovering new knowledge. There is a subtle but important difference which affects the type of research and hence work that industrial research teams undertake to reach the market and improve disease management.

Technology Readiness Level

NASA developed it during 1974 in respect of planning the Jupiter Orbiter design team. The original definition of TRL involved seven levels of development stages, but the current one, which has been adopted by NASA and European Union, now has nine levels.



Source https://www.researchgate.net/

Technology Readiness Level

TRL 0: **Idea**. Unproven concept, no testing has been performed.

TRL 1: **Basic research.** Principles postulated and observed but no experimental proof available.

TRL 2: **Technology formulation**. Concept and application have been formulated.

TRL 3: **Applied research**. First laboratory tests completed; proof of concept.

TRL 4: **Small scale prototype** built in a laboratory environment ("ugly" prototype).

TRL 5: **Large scale prototype** tested in intended environment.

TRL 6: **Prototype system** tested in intended environment close to expected performance.

TRL 7: **Demonstration system** operating in operational environment at pre-commercial scale.

TRL 8: **First of a kind commercial system**. Manufacturing issues solved.

TRL 9: **Full commercial application**, technology available for consumers.

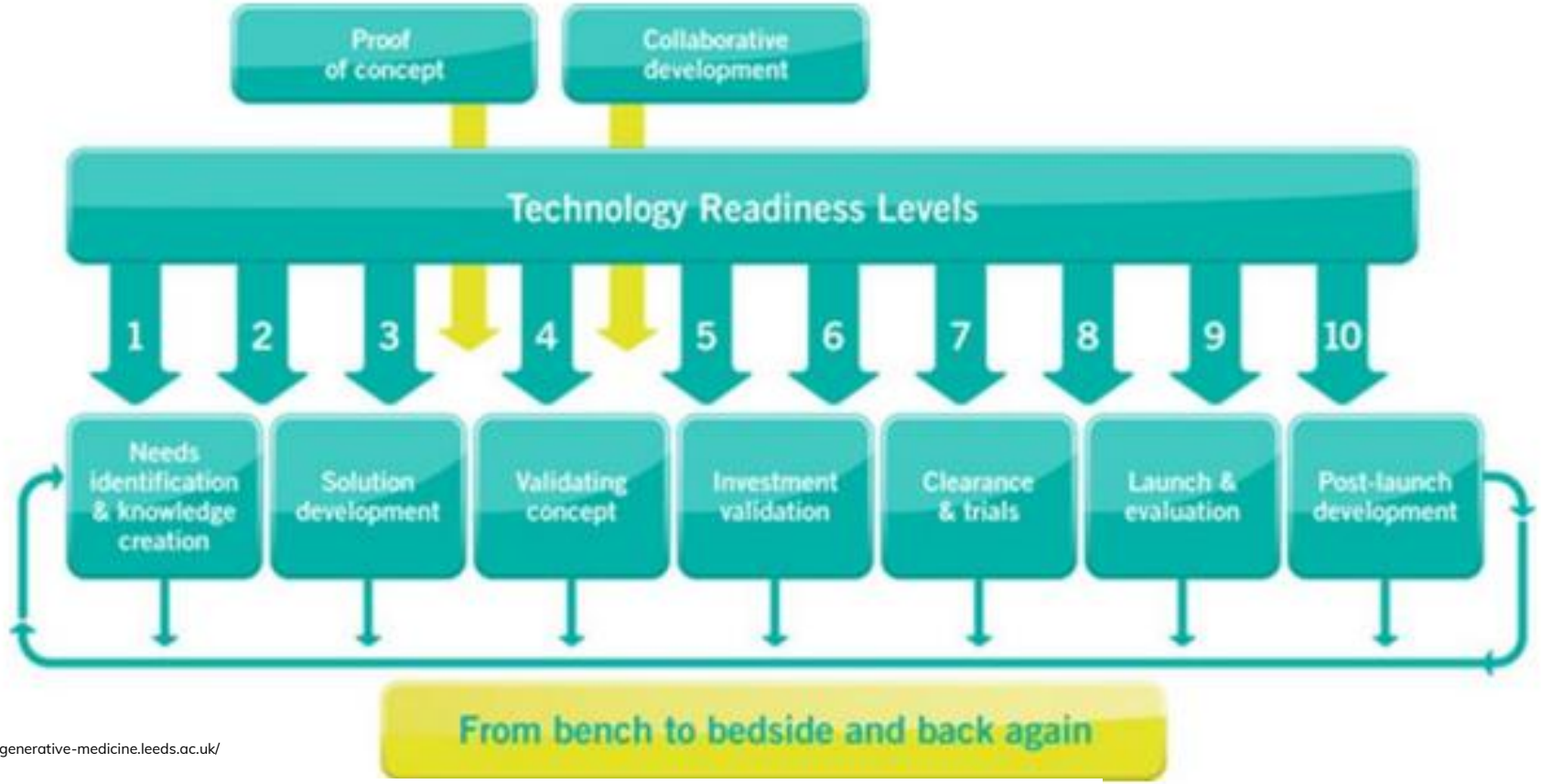
Source: European Commission

TRL evaluation applied to several applications

Technology Readiness Level

TRL 1	TRL 2	TRL 3	TRL 4	TRL 5	TRL 6	TRL 7	TRL 8	TRL 9	TRL 10
Basic Research	Preclinical Research / Proof of Concept	Manufacturing Validation / Late Preclinical	Clinical Phase	Regulatory Clearance & market preparation	Post-Launch				

Example of Technology Readiness Levels (TRL) using in medical device development



Source: https://regenerative-medicine.leeds.ac.uk/

Technology Readiness Level

INSIDE INNOVATION

Technology Readiness Level (TRL)						
1-2	3	4	5-6	7-8	9	10
Clinical need defined & knowledge created	Solution Generation	Investment Validation	Development & Validation	Clearance & Clinical	Outputs / Outcomes	Post Launch Market Support
Define clinical need/relevance Develop/refine solution IP	Generation of Prototypes IP Preliminary Value Proposition Risk Assessment	Market Research FTO searches Pilot Studies	Design Control Regulatory Capability	Market support data Supply Chain Reimbursement considerations Capability Clinical	Regulatory Approval Closure & Evaluation Metrics Feedback / Launch SOP	Product Support data White Paper Product Recall Support

T1 T2

IP: Intellectual Property
FTO: Freedom to Operate (commercially 'safe' for you to make / sell your product)
SOP: Standard Operating Procedures

First gap (T1): "…translating ideas from basic and clinical research into the development of new products and approaches to diagnosis/prognosis/treatment of disease and illness"

Second gap (T2): "…implementing those new products and approaches into clinical practice" – ie disconnect between the development and the implementation of new interventions"

Source:A review of UK health research funding. London: HM Treasury, 2006/

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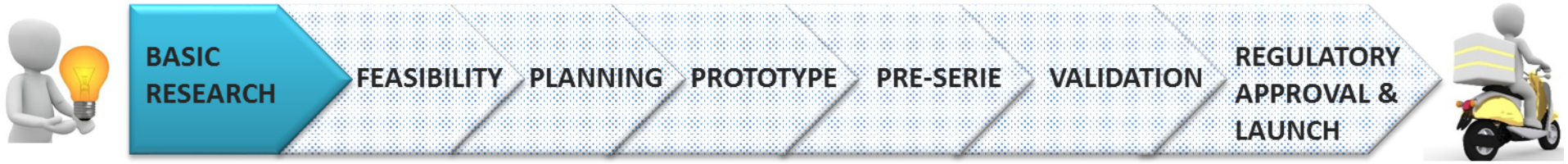
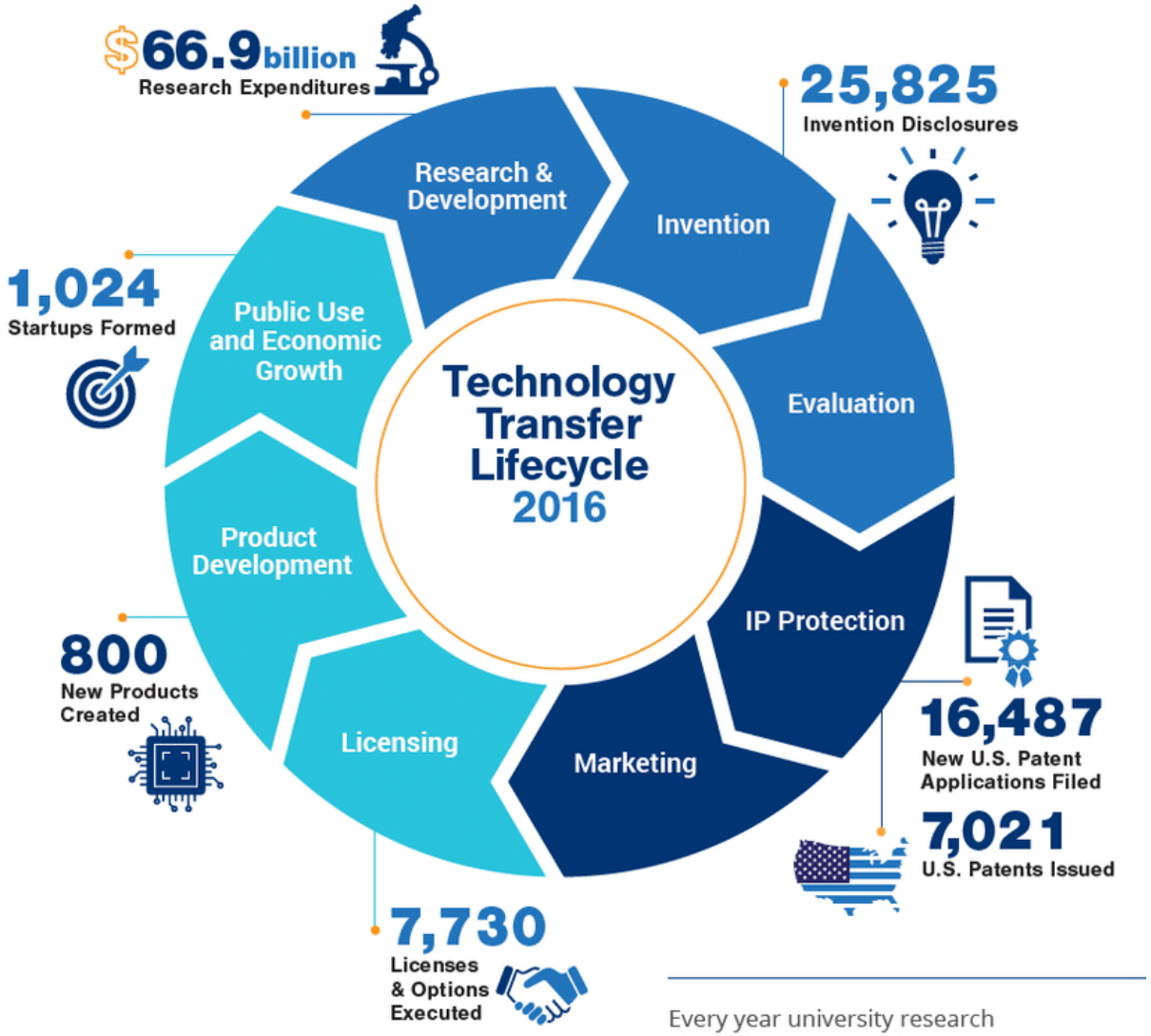


Technology Transfer

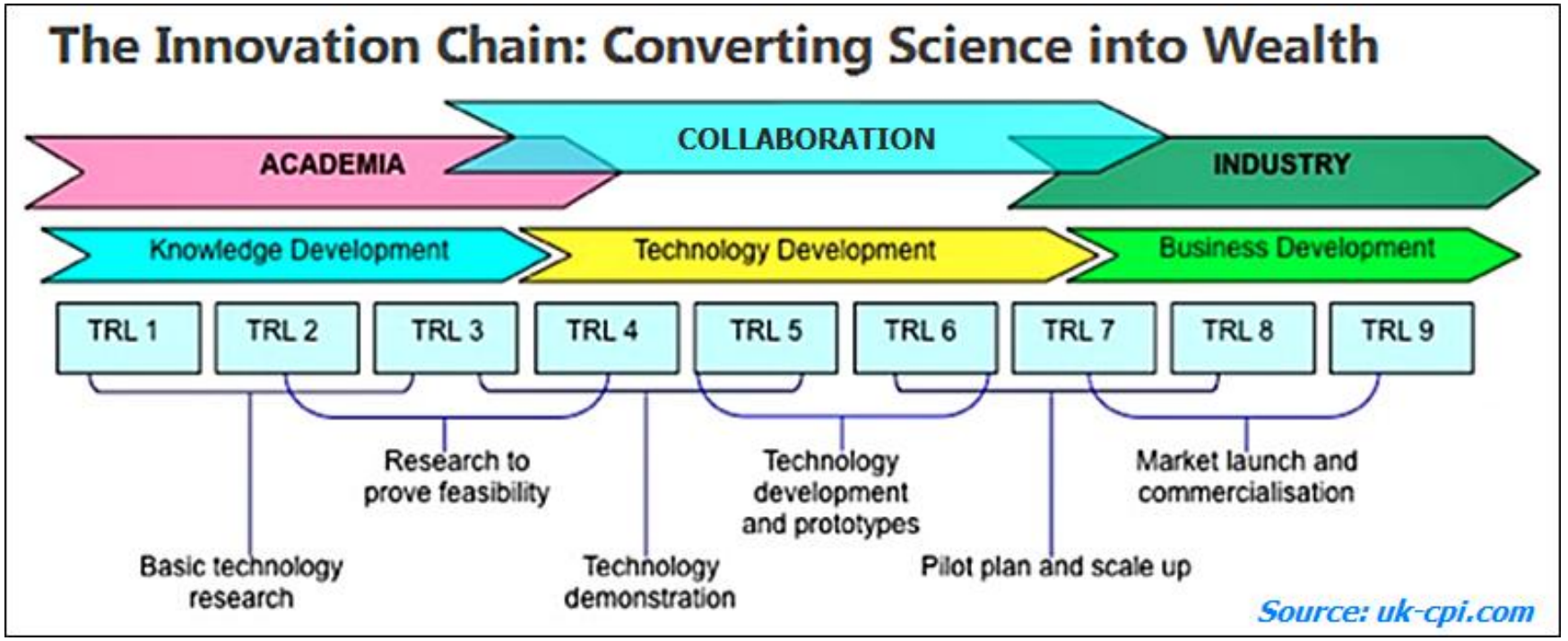


Every year university research yields discoveries with commercial potential.

Sourcehttps://www.researchgate.net/

Technology Transfer

Technology transfer (TT) refers to the process of conveying results stemming from scientific and technological research to the market place and to wider society, along with associated skills and procedures, and is as such an intrinsic part of the technological innovation process.



Technology Transfer

INSIDE INNOVATION

Company

- Idea
- Protocol
- Experiments on clinical samples
- Case studies
- Patent (?)

End user

- Scientific validity
- Feasibility
- State of the art
- Development/Production costs
- Time to market

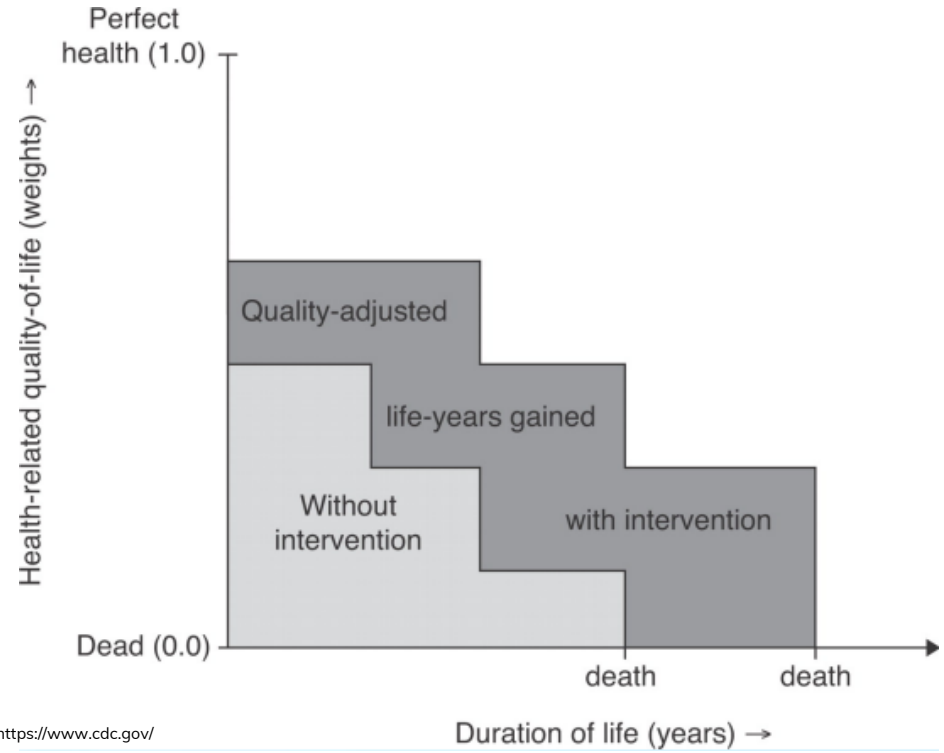
Patient

- Clinical practice feasibility
- Diagnostic accuracy/reliability
- Time to Result
- Cost
- Risk/benefit: QALY/DALY

QALYs (Quality-Adjusted Life Year)= years lived in perfect health gained
DALYs ((Disability-Adjusted Life Year)= years in perfect health lost

DALY and QALY

INSIDE INNOVATION



Source: https://www.cdc.gov/

Source: https://www.publichealthnotes.com/

QALYs is the arithmetic product of life expectancy combined with a measure of the quality of life-years remaining.

One QALY equates to one year in perfect health.

DALYs: the sum of the years of life lost to due to premature mortality (YLLs) and the years lived with a disability (YLDs) due to prevalent cases of the disease or health condition in a population.

One DALY equates the loss of the equivalent of 1 year of full health.

Example of Tech Transfer proposal

4 miRNA x diagnosis of Venous Thrombosis

CLINICAL NEED

Venous thrombosis (VT) is a complex condition and chronic disease with a highly heritable genetic component in people with acquired genetic disorders of hypercoagulation and it is also associated to several conditions such as hospitalization, immobility, trauma, pregnancy and cancer. Common associated life-threatening disorders are Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), which presents a recurrence risk in 30% of all patients within the first 10 years post first event.

Current diagnostic methods both of DVT and PE are based in imaging techniques (MRI, PET, ultrasound, X-ray) and in-vitro procedures (D-dimer blood test) which cannot be used for predictive use.

INNOVATIVE ASPECTS

The identification of these 4 validated innovative plasma miRNAs biomarkers will allow:

- The development of a non-invasive diagnostic and prognostic kit.
- The prediction for the risk of venous thrombosis event based in MicroRNAs.
- The diagnosis/prognosis of those people who would not be detected to develop thrombosis through conventional risk factors.
- To assess the risk of recurrence of thrombosis in patients who have already had it.

MARKET SIZE

VT incidence is estimated at 1 to 2 per 1000 person-years, of which 30% will experience recurrence within 10 years after the first event.

The current market for DVT and PE are focussed in the diagnostic and treatment phases. Therefore, the current invention can address a % of these markets, reducing the cost associated to recurrent events. For instance, the DVT treatment market is expected to witness market growth at a rate of 9.5% in the forecast period of 2021 to 2028.

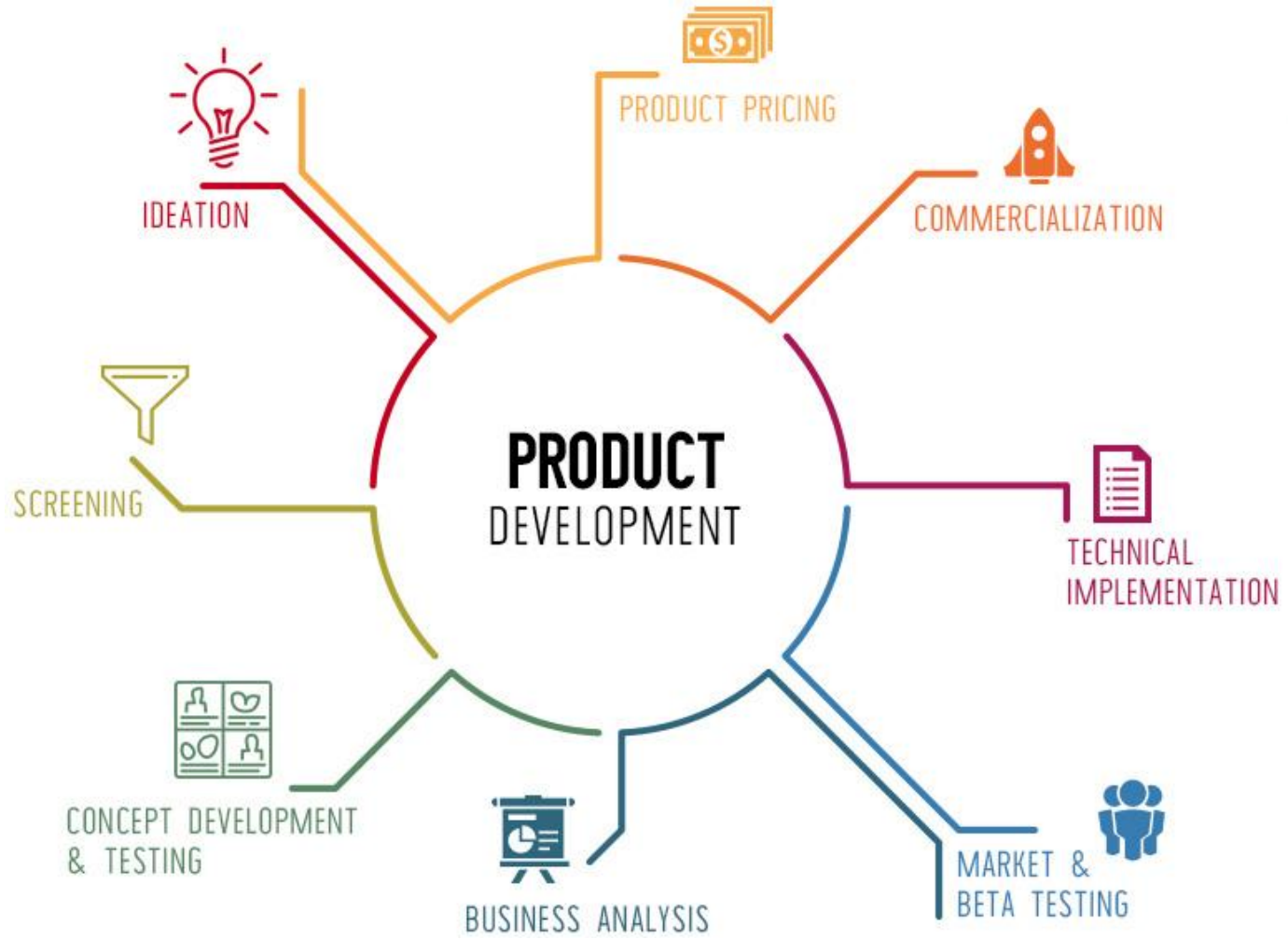
STAGE OF DEVELOPMENT

The current invention has been demonstrated in a research study with the largest sample to have been examined. The 4 miRNAs biomarkers have been validated to be differentially expressed in patients with VT and its potential as predictors of VT discussed. Next steps are to develop a prototype of the diagnostic kit and validate it.

INTELLECTUAL PROPERTY

PCT patent application: PCT/EP2021/055174 (2/3/2021). Priority date: 2/3/2020. The patent protects the use of this set of biomarkers for the diagnosis and prognosis of Venous Thrombosis. As of august 2022, the patent application was filed in the USA and in EU.

A huge effort to develop a product

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