

PHILIPS

TU/e

NEDERLANDSE  
EMC-ESD  
VERENIGING

# State-of-the-art EMC management for complex medical devices

Rob Kleihorst & Anne Roc'h  
Philips IGT-S & TU/e  
December 8, 2023

innovation  you

1



Products come and go ...  
Technologies change ...

But Philips is still  
about one thing:  
Creating meaningful  
innovation that improves  
people's lives

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2



# Philips has reinvented itself many times



**Founded on innovation and entrepreneurship**



**Expanding beyond lighting**



**Global expansion post-WWII**



**Diversified industrial conglomerate**



**Strategic portfolio choices sharpening focus**

Our journey continues...

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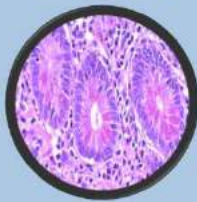
3



# Medical Imaging: Because seeing is believing!



**16th Century**  
Microscope was invented



**1895**  
X-ray machine was invented



**1956**  
Ultrasound was invented



**1972**  
CT was invented



**1977**  
MRI was invented



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4

# Helping our customers address their challenges




**Better health outcomes**

**Improved patient experience**

**Improved staff experience**

**Lower cost of care**

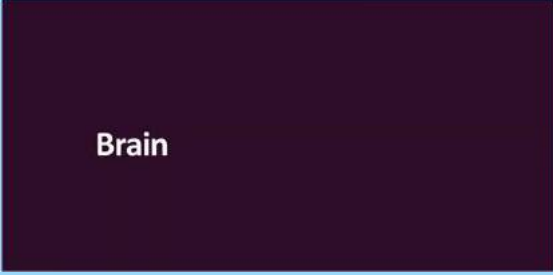



5

## Diagnostic Radiology: MR



## Diagnostic Radiology: CT



**Brain**



Copyright  
Licentiehouder  
gebruikt

Paauwen (1)



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6

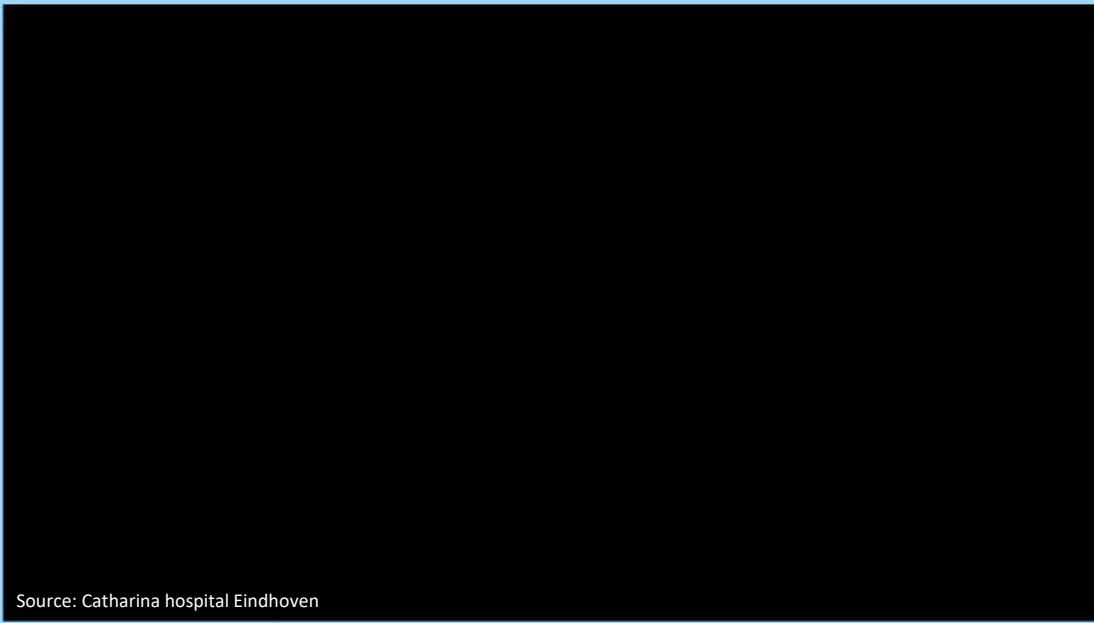
OK, so we do X-ray Diagnostic Radiology ...



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... and, Interventional Radiology X-ray



Source: Catharina hospital Eindhoven

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8





9

## Angiographic X-ray system: Azurion family



**Azurion 3 F12**



**Azurion 3 F15**



**Azurion 7 C12  
Azurion 7 F12**



**Azurion 7 C20  
Azurion 7 F20**



**Azurion 7 C20 with FlexArm**



**Azurion 7 C20 with  
FlexMove**



**Azurion 7 B1212**



**Azurion 7 B2012  
Azurion 7 B2015**

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10



11

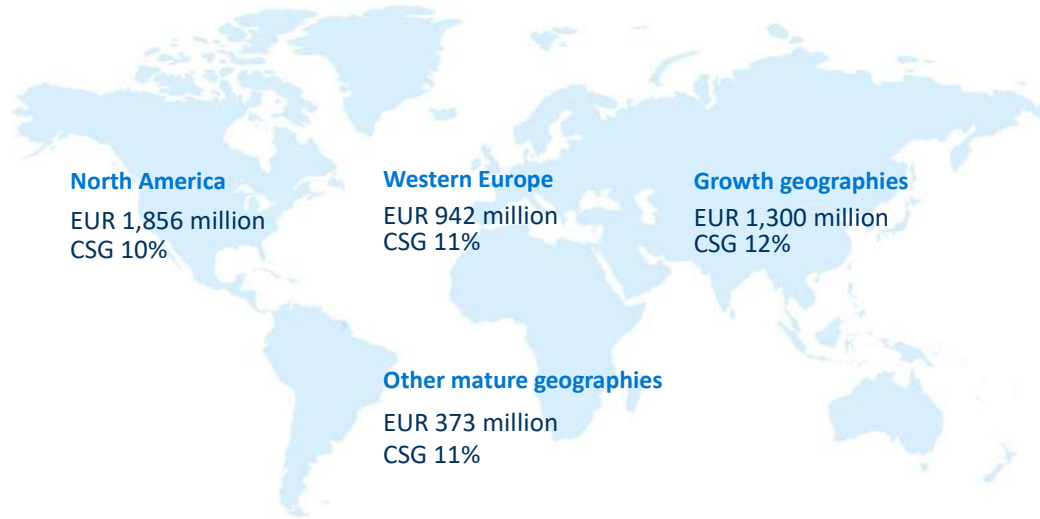


12





## Philips sales per geographic cluster in Q3 2023



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13



## The regulatory landscapes



IMDRF was launched in 2012 and has delivered a number of significant work products:

- Continuation of the Global Harmonization Task Force (GHTF) work items,
- Updates to some of the GHTF documents
- New work items focusing on regulatory approaches for rapidly evolving technologies in medical devices.

IMDRF has focused its attention on developing a total product lifecycle approach to regulating medical devices while enabling timely access to safe and effective devices for the patients.



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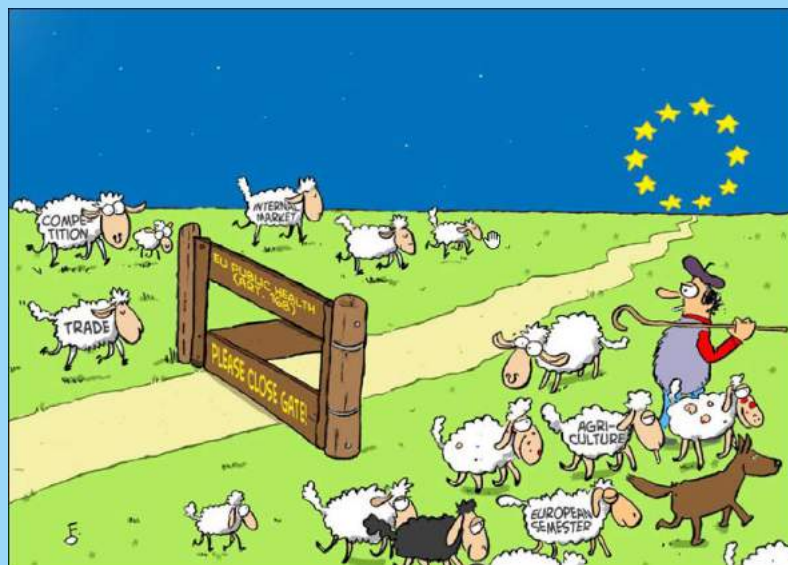
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15

## Regulatory landscapes

“The gate of Article 168 that Member States so laboriously constructed stands alone in a field with no fence, and so other dimensions of EU health policy and integration can simply go around it.”



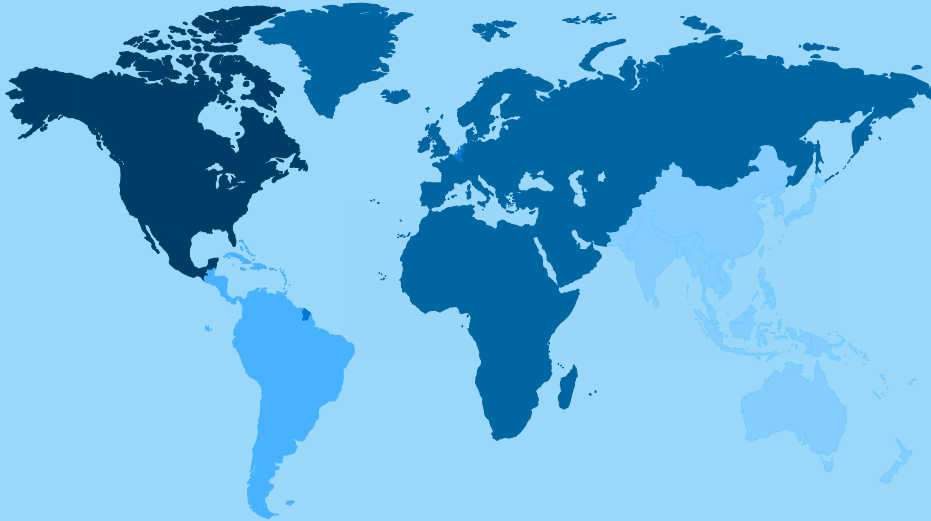
Source: Health Policy Series 54, Everything you always wanted to know about the EU health policies but were afraid to ask. ISBN 978 92 890 51 767, second print, November 2019

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16



# Global design, production, and installed base



Netherlands



India

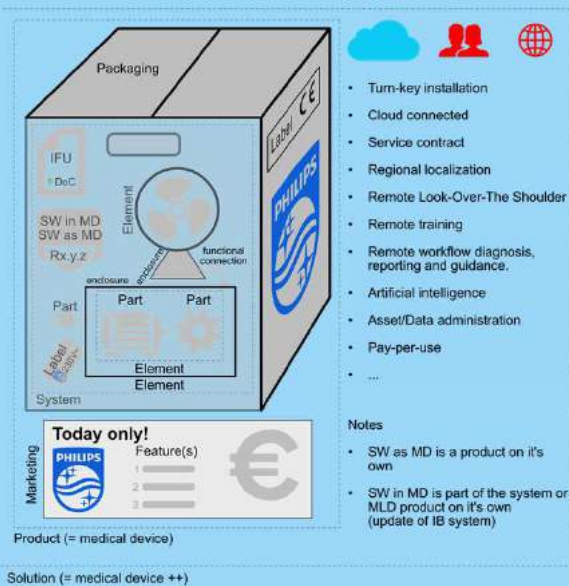


China

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17

# Products, solutions, and EMC processes



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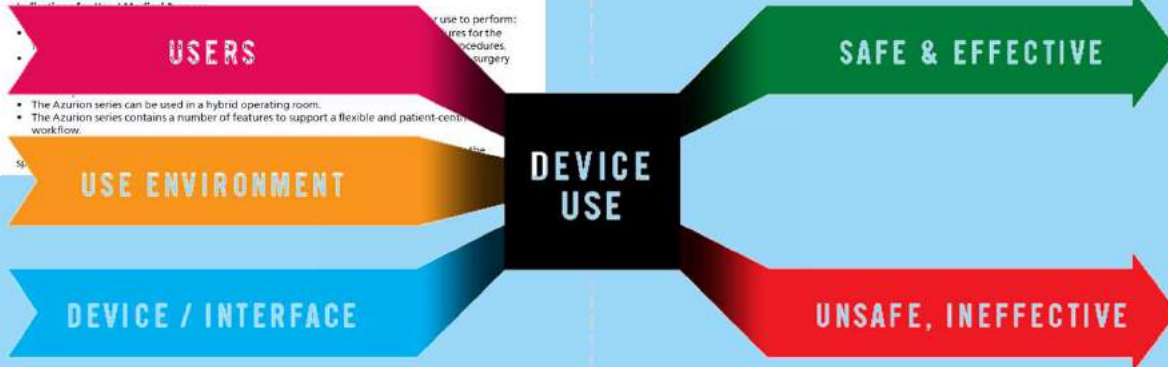


# Medical Device Intended use

## 1.3 Intended Use of the System

**CAUTION**  
In the United States, Federal law restricts this device to sale, distribution, and use by, or on the order of, a physician.

**Product Description**  
The Azurion series consists of a number of monoplane and biplane systems with different detector sizes (12", 15" and 20").



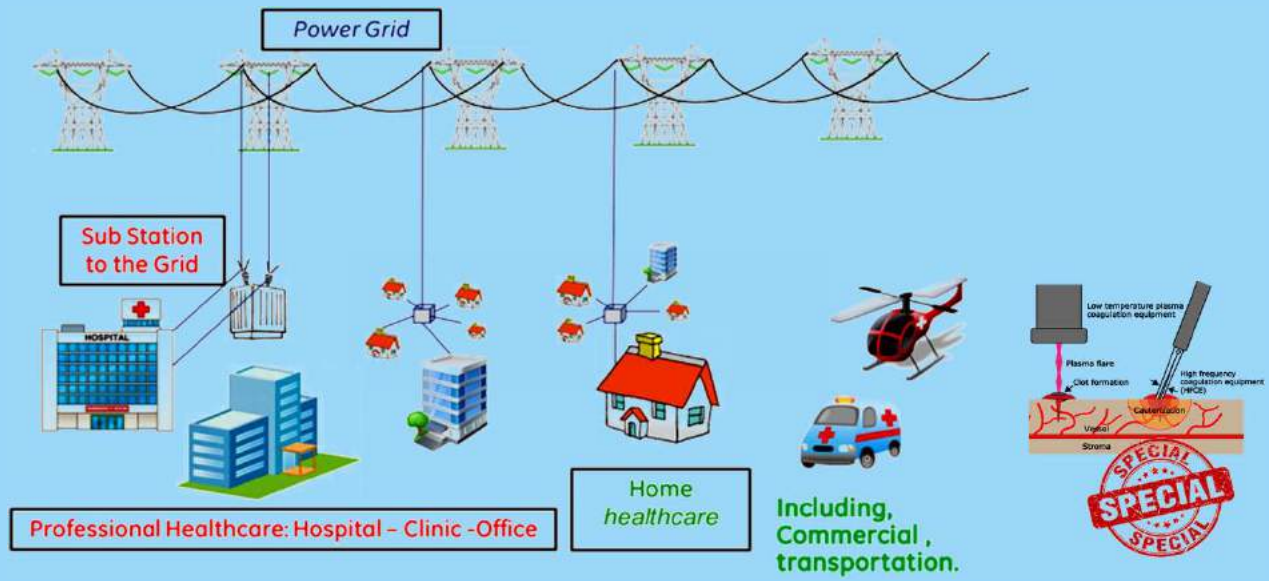
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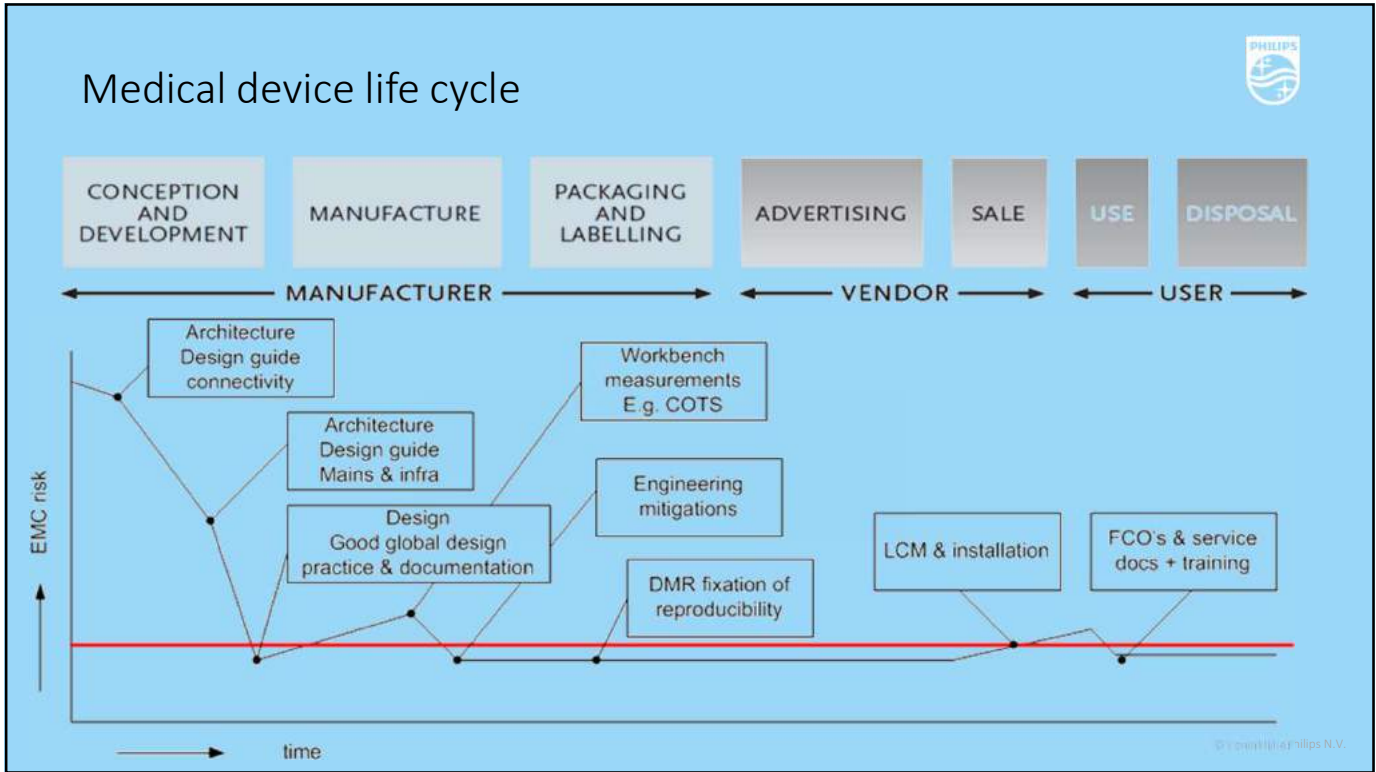
# Intended use environment



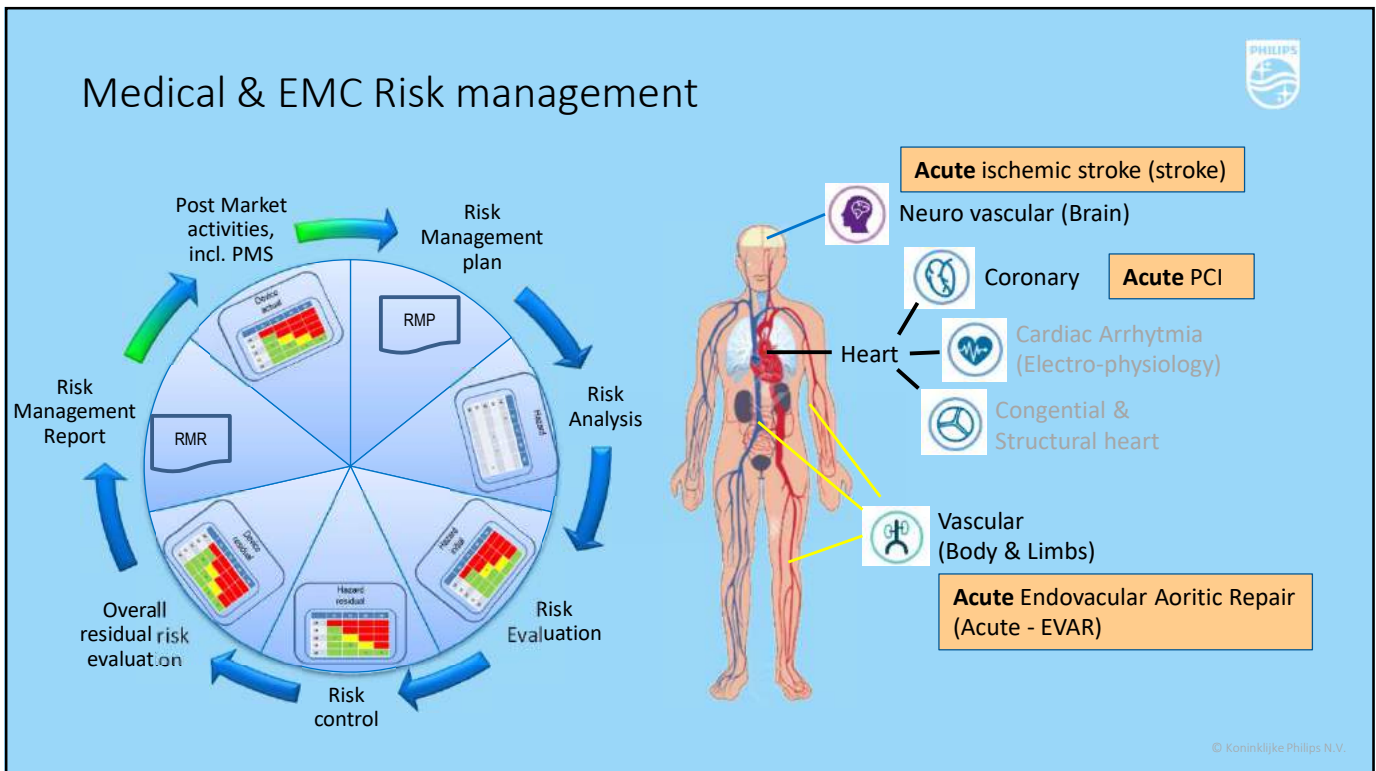
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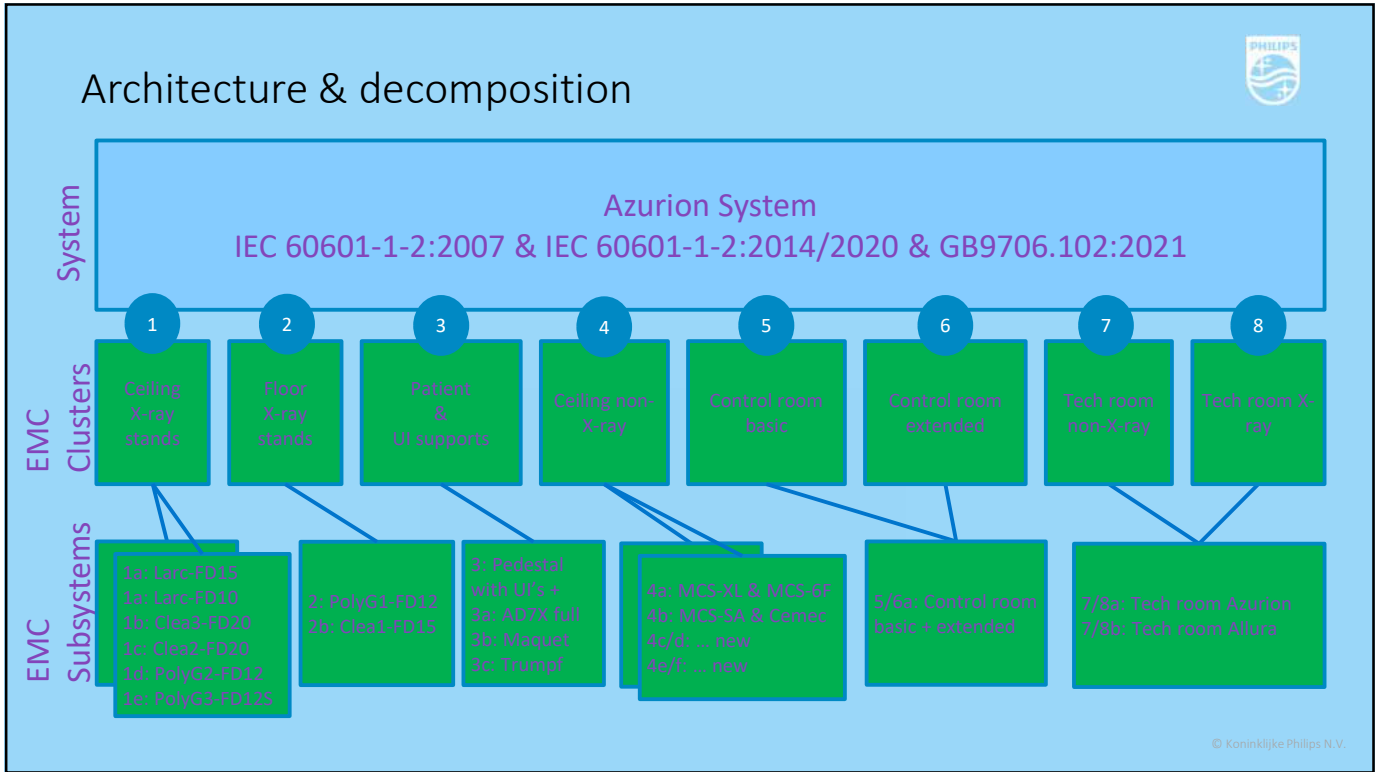


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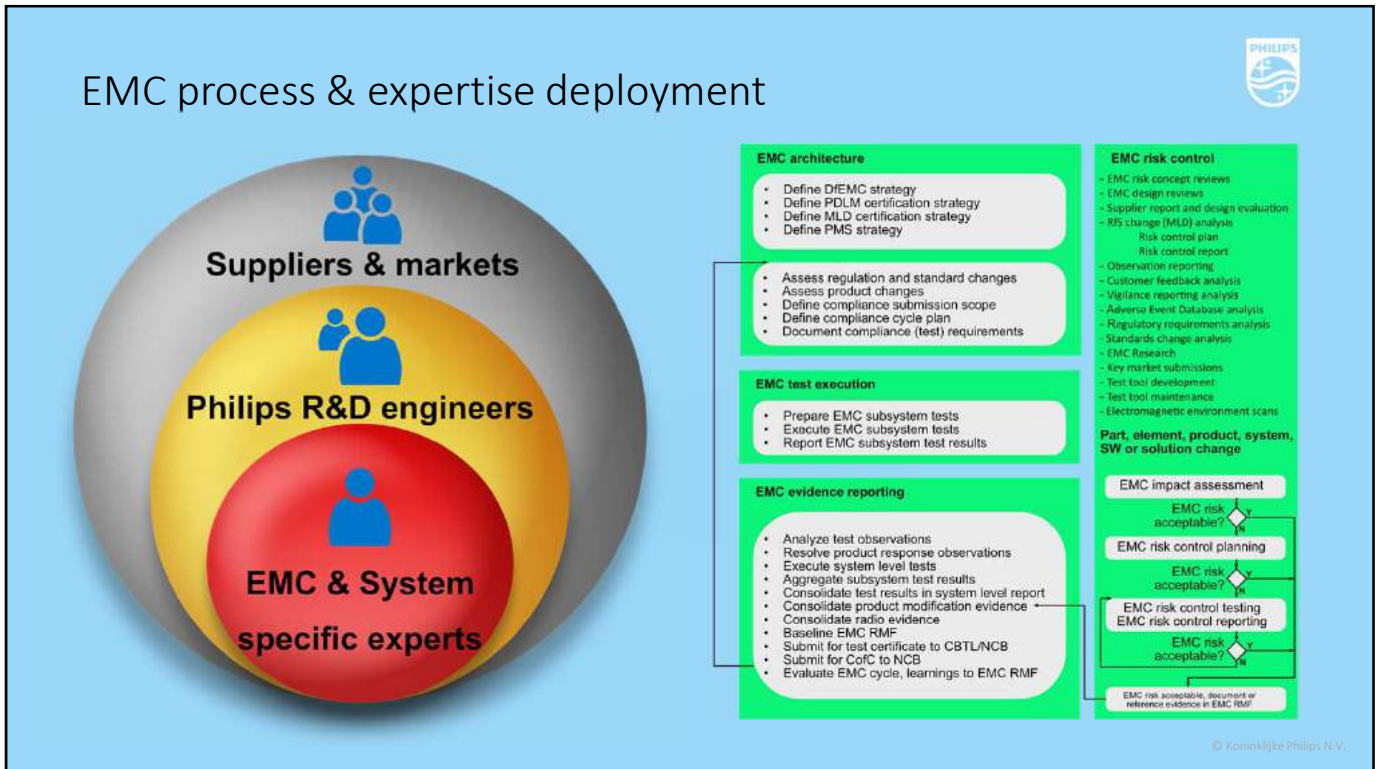


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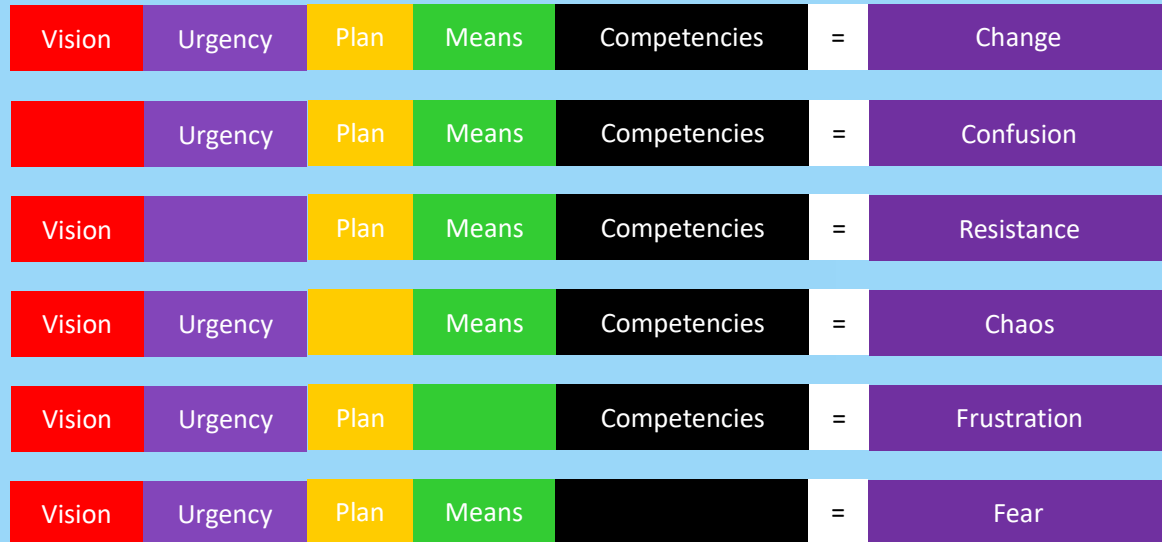


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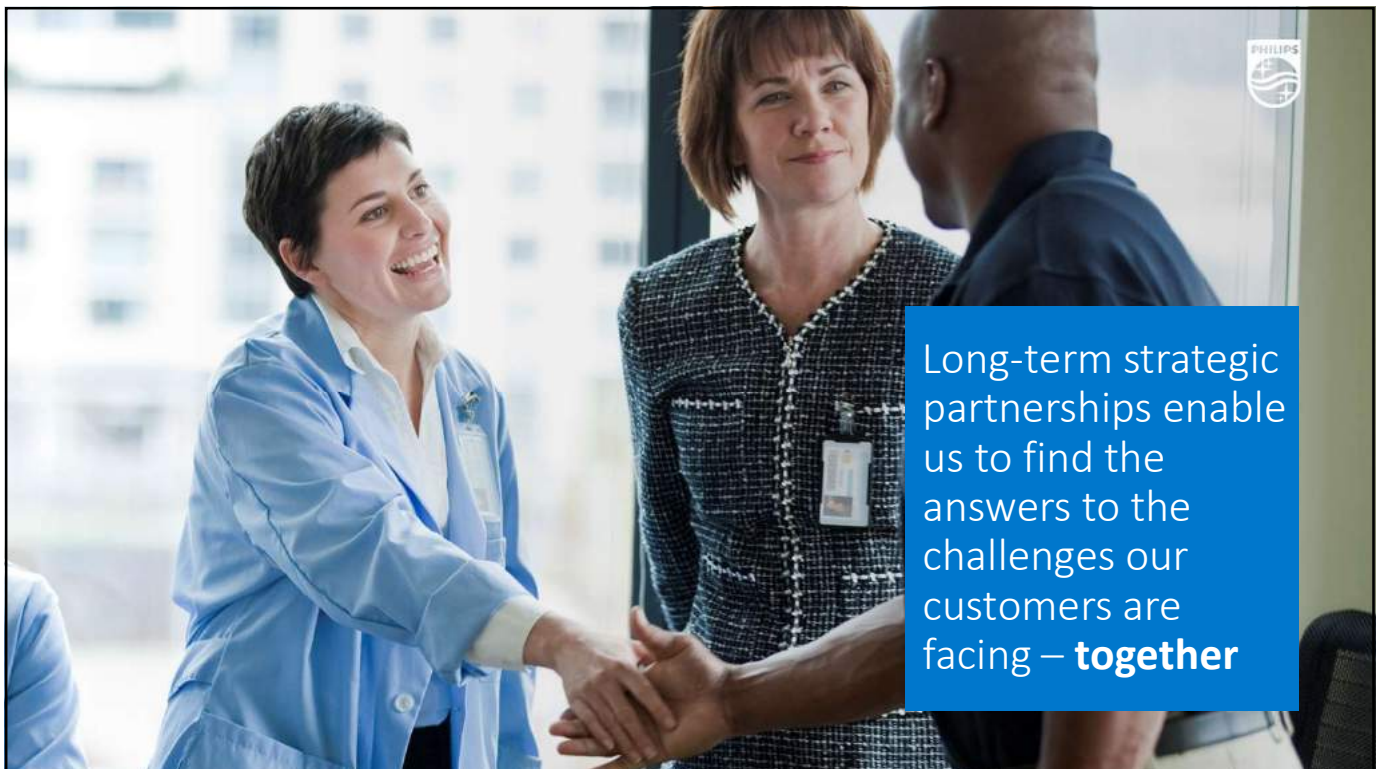
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## What is needed for change



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25



26



# EUROPEAN TRAINING NETWORK ON ELECTROMAGNETIC RISKS IN MEDICAL TECHNOLOGY

 FROM CARE TO PREVENTION  
 QUALITY OF CARE  
 SAFE TRAVEL



This project has received funding from the European Union's EU Framework Programme for Research and Innovation Horizon 2020 under Grant Agreement No. 955.816

27

## Marie-Curie Doctoral Networks?



### The MSCA under Horizon Europe



28



## Marie-Curie Doctoral Networks?



### Doctoral Networks objectives

- **Train doctoral candidates** (~PhD students) resulting in **enhanced career perspectives** in both the academic and non-academic sectors
- **Raise excellence and structure research and doctoral training** in Europe, extending beyond the traditional academic research training setting
- **“International, multidisciplinary and intersectoral”** at two levels
  - Composition of the consortium
  - Mobility of the early-stage researchers (recruitment, secondments)



29

## Marie-Curie Doctoral Networks?



### Important to remember

#### Doctoral Networks

≠ Research project

= RESEARCH TRAINING PROGRAMME



30

# ITN ETERNITY- Project Introduction



<https://eternity-project.eu/>

**e**TERNITY  
~~~~~



This project has received funding from the European Union's EU Framework Programme for Research and Innovation Horizon 2020 under Grant Agreement No. 955.816.

**e**TERNITY  
~~~~~ © Koninklijke Philips N.V.

31

31

## ETERNITY Main's Goal



*"Each of the 14 Early-Stage Researchers (ESRs) will be trained to work in multi-disciplinary and multi-cultural teams, with a new mindset tuned towards the **inclusion of the EMC risk-based approach into innovative design methods**. For this inclusion to occur, each ESR will develop through their research the missing dedicated tools and techniques and apply them to a representative set of medical devices under development."*

**e**TERNITY  
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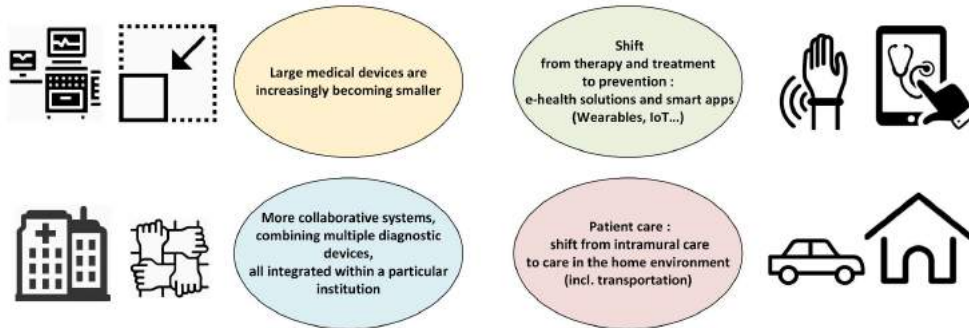
32

32

## Some context : the (European) MedTech



- One of Europe’s most diverse and innovative high-tech sectors : 500 000+ jobs in Europe, 15BEuro in positive trade balance, 95% are Small and Medium enterprises (SMEs),
- First sector in patent application in Europe (7%), close collaboration with patient and an average lifecycle of only 18-24 months,
- EMC Risk-based approach: a lack of understanding and no clearly prescribed risk-assessment methodology in place for a major shift in approach.



33



33

## ETERNITY Consortium



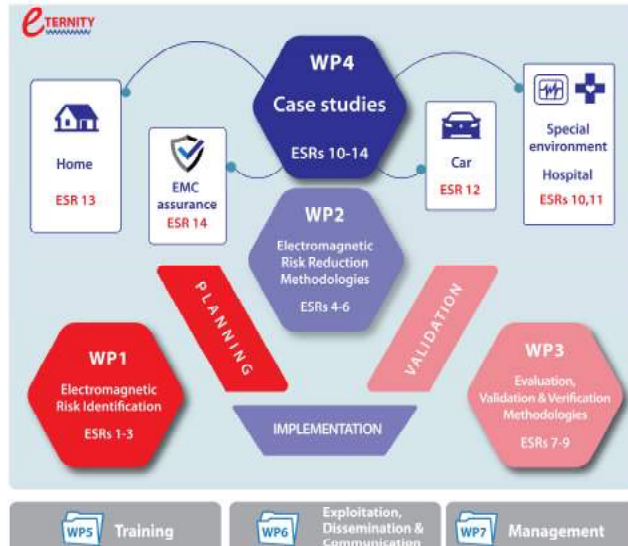
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34



# ETERNITY: Work Package Structure



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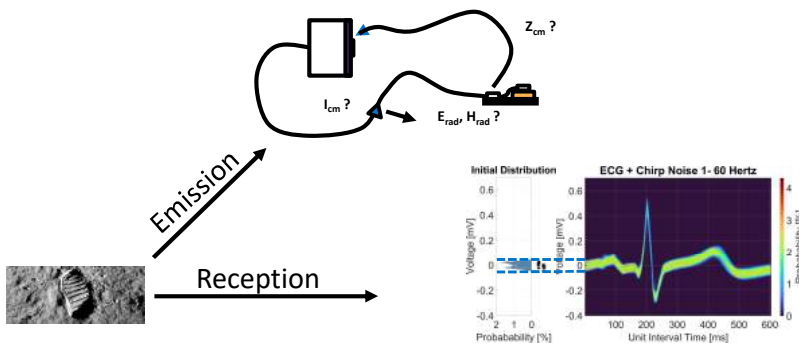
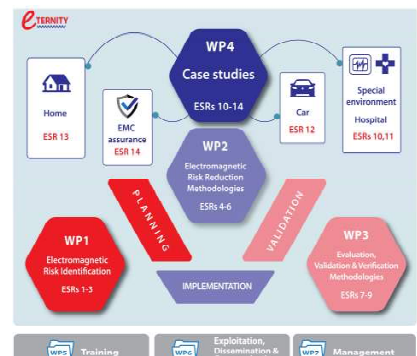
35

# ETERNITY: Early-Stage Researchers

## WP1: ElectroMagnetic Risk Identification



**ESR1: Marc Kopf**  
*EMI Footprint of Medical Devices*  
 Main supervisor: dr. ir. Anne Roc'h  
 Eindhoven University of Technology (TU/e) - NL



36



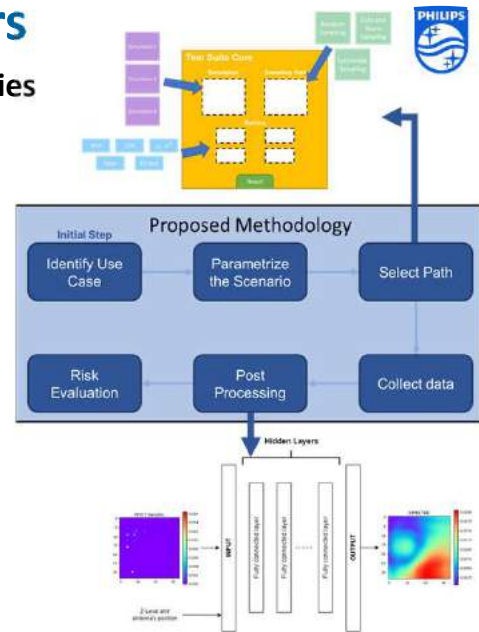
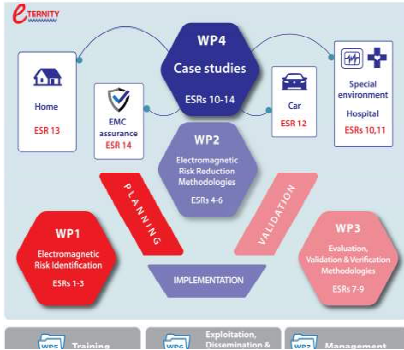
36

# ETERNITY: Early-Stage Researchers

## WP3: Evaluation, Validation & Verification Methodologies



**ESR7: Sebastian Salas Laurens**  
*Behavioral EMI Risk-based testing of Medical Devices*  
 Main supervisor: dr. ir. Anne Roc'h  
 Eindhoven University of Technology (TU/e) - NL



37

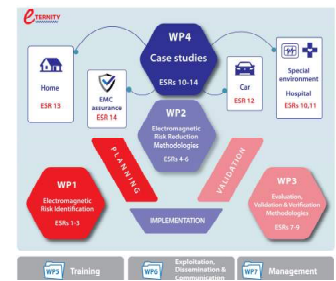
37

# ETERNITY: Early-Stage Researchers

## WP4: Case Studies



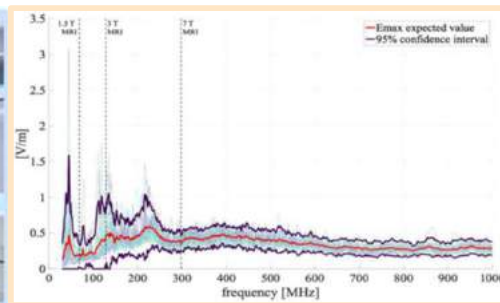
**ESR10: Simòn Rendòn Vélez**  
*Risk-Management in Collaborative Medical System Development*  
 Main supervisor: dr. ir. Mark van Helvoort  
 Philips Medical (+ University of Twente) - NL



Why?

EMI Risk Management in MRIs

EME Evaluation – MRI Room




38

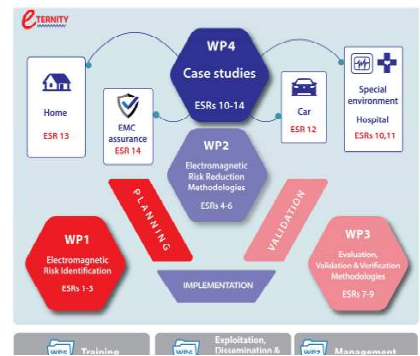
38

# ETERNITY: Early-Stage Researchers

## WP4: Case Studies



**ESR11: Nandun Senevirathna**  
*Evidence of Quantitative correlation(s) between Different Test Environments*  
 Main supervisor: ir. Rob Kleihorst  
 Philips Medical (+ TU/e, Eindhoven) - NL



Absorption increases ←      → Reflections increases



Controlled Anechoic Environment      Real clinical environment      Controlled Reverberant Environment

39

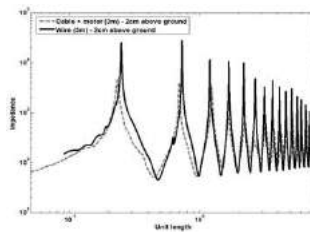
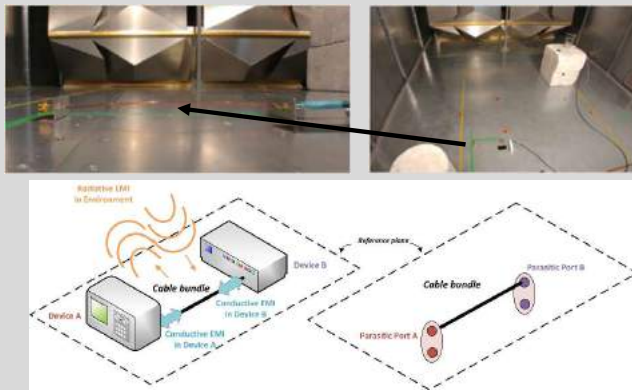


39

## A Paradigm Change in the Emission Management of Medical Cable Harnesses- Mohammad Khorramizadeh



### Equivalence Thin-wire antenna with cables



Experimental equivalence between Thin-wire and a power cable (my own PhD)



Will Start 1<sup>st</sup> March 2022

40



40



Dr. Anne Roc'h, TU/e, the Netherlands

## PARASOL – “European Doctoral Network for Safe and Sustainable Electromagnetic Shielding Solutions for Mobility

41

- The objective of Doctoral Networks is to implement doctoral programmes by partnerships of organisations from different sectors across Europe and beyond **to train highly skilled doctoral candidates, stimulate their creativity, enhance their innovation capacities and boost their employability in the long-term.**



<https://marie-skłodowska-curie-actions.ec.europa.eu/actions/doctoral-networks>



This project has received funding from the European Union's EU Framework Programme for Research and Innovation Europe Horizon under Grant Agreement No 101072881 and UKRI (Public Body for Innovation and Research in UK, for position DR5 and DR9).

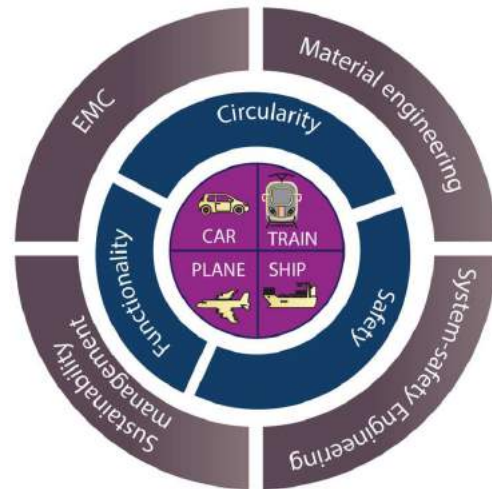
42

42





- PARASOL is a European funded Marie Skłodowska-Curie project, with Beneficiaries and Partners from **the Netherlands, Belgium, United Kingdom, Czech Republic, Poland and Spain.**
- Each of the **12 Doctoral Researchers (DRs)** will be trained to work in multi-disciplinary and multi-cultural teams, with a new mindset tuned towards the **inclusion of the Safe-and-Sustainable-by-Design (SSbD) approach into innovative design methods for EM shielding.**
- For this inclusion to occur, each DR will develop through their research the missing dedicated tools and techniques and apply them to the **complete lifecycle of electromagnetic shielding solutions for vehicles (car, plane, train and ship).**



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43



## Consortium of the DN PARASOL



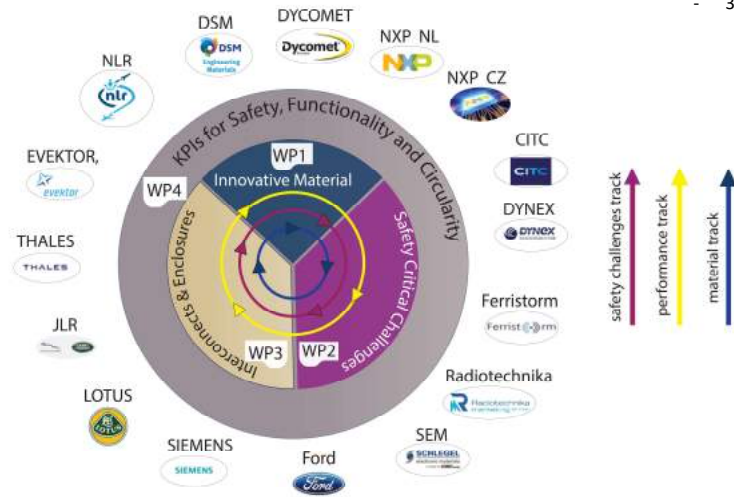
| BENEFICIAIRES                                   |    | Associated Partners                                  |                                                                       |
|-------------------------------------------------|----|------------------------------------------------------|-----------------------------------------------------------------------|
| 1 The Eindhoven University of Technology (TU/e) | 5  | 6 DSM ENGINEERING MATERIALS BV (DEM)                 | 20 SIEMENS MOBILITY LIMITED (SIEMENS)                                 |
| 2 University of Twente (UT)                     | 15 | 7 DYCOMET EUROPE BV (DYCOMET)                        | 21 University of York (UoY)                                           |
| 3 KU Leuven (KUL)                               | 18 | 8 NXP SEMICONDUCTORS CZECH REPUBLIC SRO (NXP-CZ)     | 22 Chip Integration Technology Center (CITC)                          |
| 4 Universidad Politècnica de Catalunya (UPC)    | 19 | 9 NXP Semiconductors Netherlands BV (NXP-NL)         |                                                                       |
| 5 Univerzita Tomáše Bati ve Zlíně (TBU)         | 17 | 10 DYNEX SEMICONDUCTOR LIMITED (Dy nex)              |                                                                       |
|                                                 | 14 | 11 Radiotechnika Marketing Sp. z o.o (RADIOTECHNIKA) | 14 Ford Technologies Ltd (Ford GB)                                    |
|                                                 | 15 | 12 Ferristorm S.A., Poland (FERRISTORM)              | 15 Lotus Cars UK (LOTUS)                                              |
|                                                 | 16 | 13 Schlegel Electronic Materials Belgium Bvba (SEM)  | 16 STICHTING KONINKLIJK NEDERLANDS LUCHT- EN RUIMTEVAARTCENTRUM (NLR) |
|                                                 | 17 |                                                      | 17 EVEKTOR, spol. s r. o. (Ltd.) (EVE)                                |
|                                                 | 18 |                                                      | 18 JAGUAR LAND ROVER LTD (JLR)                                        |
|                                                 | 19 |                                                      | 19 THALES NEDERLAND BV (THALES)                                       |

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44



# Work packages



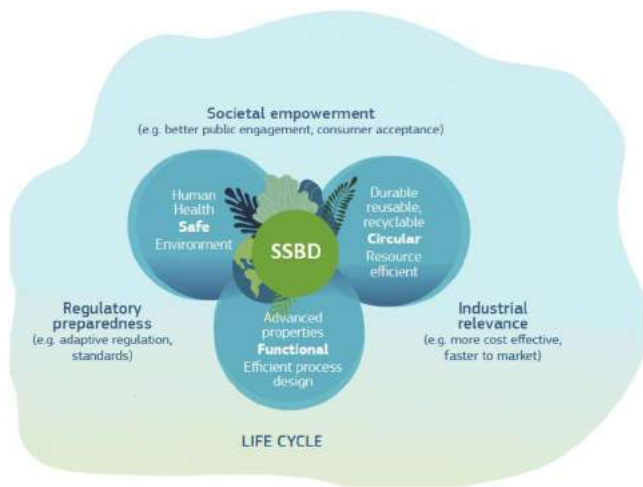
- 21 Partners across the value chain of EM shielding.
- 12 Doctoral Researchers
- 3 Data tracks shared across the value chain

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45



# Safe and Sustainable by Design Framework



The EU has highlighted how the future of public health and the environment will be based on Safe and Sustainable-by-Design (SSbD): a holistic approach that will **integrate the safety, circularity, energy efficiency and functionality of materials, products, and processes throughout their lifecycle.**

*The European Commission published a chemicals strategy for sustainability on 14 October 2020.*

*1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> Workshops on the SSbD framework – March 2021, March 2022 and February 2023*

*All workshops are public (reports on JRC and EC websites + YouTube) and held with the active participations of stakeholders*

***The SSbD framework become an official recommendation of the EU Green Deal on 8<sup>th</sup> December 2022 (adoption by EC)***

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46



# Key Technical challenges

**ESR2: Sadegh Barzegar Klishomi**  
*Novel in-situ material characterization method...*



**ESR8: Furkan Sahin**  
*SE of Cables*

**WP1: Innovative shielding-material development, characterization, and assessment**

- Sustainable polymer-based electromagnetic shields using functional coatings (DR1)
- Novel in-situ material characterization method applied to carbon-fiber-filled plastic (DR2)
- Enable in-situ low frequency (LF) testing (DR3)
- Embedded shielding solutions using innovative layer-by-layer approaches (DR11)
- Time-domain Electromagnetic shielding measurement methodologies for novel materials (DR12)

**WP2: Design and performances assessment of innovative EMI shielding solutions mobility**

- Active Shielding design for capacitive touch-based control applications (DR4)
- Time-domain shielding for on-board power-electronic (DR5)
- Integrated Circuit (IC) and Printed Circuit Board (PCB) Shielding (DR6)

**WP3: Characterization and trade-off for enclosures and interconnects**

- Interconnect's characterization (DR7)
- Shielding Effectiveness (SE) of Cables (DR8)
- Statistical Metric for Enclosures (DR9)
- Trade-off SE solutions for enclosures (DR10)

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47

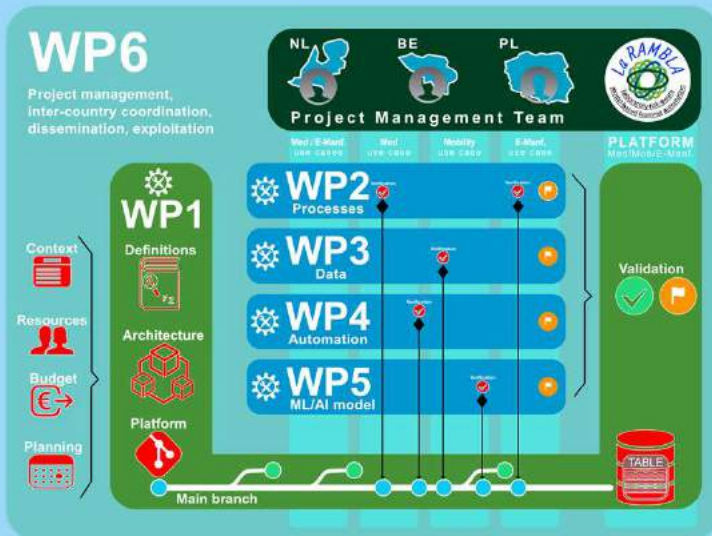


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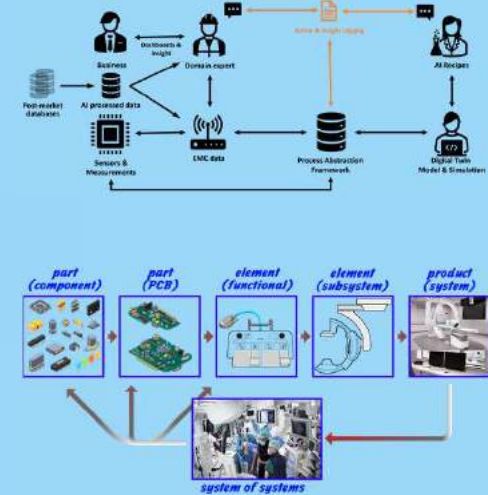
48



## La RAMBLA



## EMC & deployment recipe builder



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49

## Some rules for during the tour

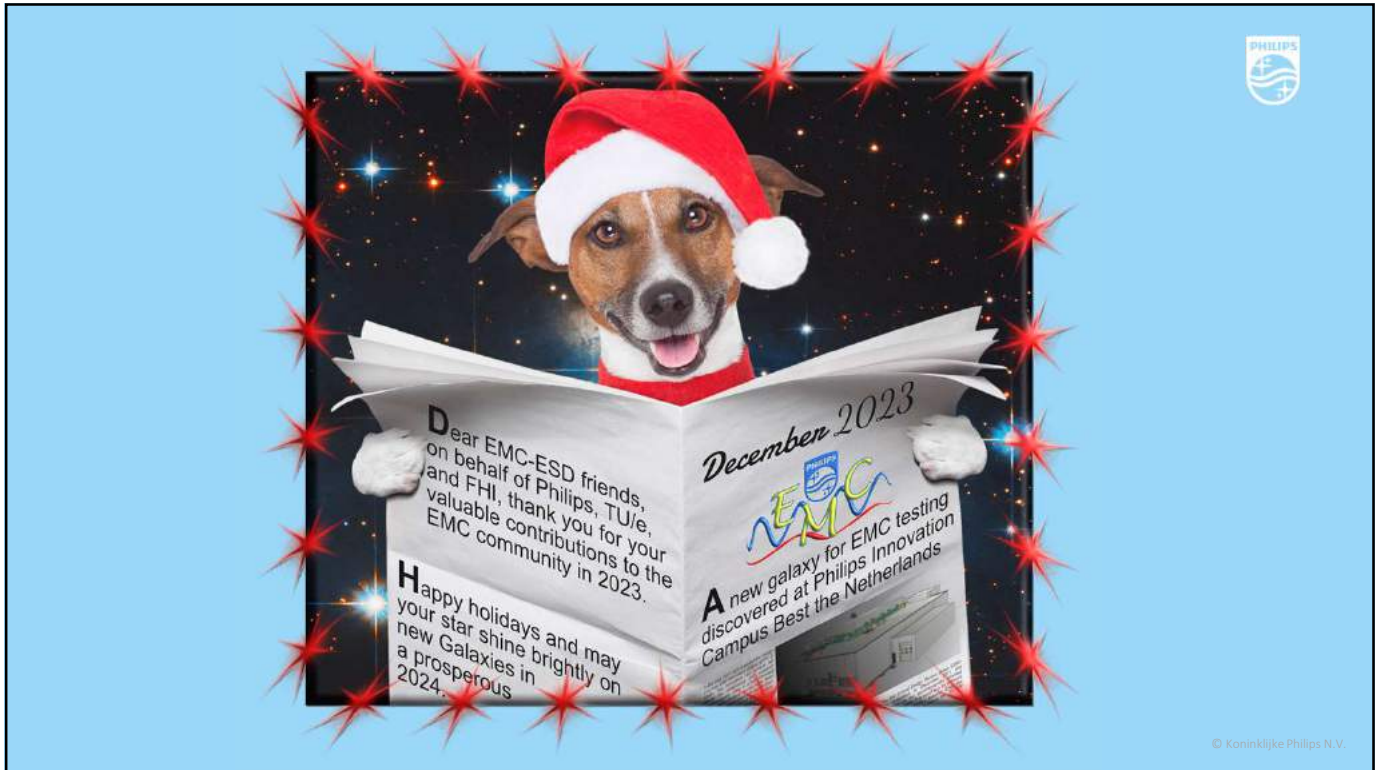
- No pictures please (A group picture will be taken for on the FHI website)
- Please do not touch anything!
- We'll walk to the lab and back as one group
- The group will be split in two, stay together with your group



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50





51



52