Implementing “Moore for Medical”

Innovation in Emerging Medical Devices

Health.E Lighthouse Symposium 8-9 March 2022
Session 1

Introduction, role of OTPs for innovation in electronic medical devices

- Ronald Dekker – Health.E lighthouse
- Rob van Schaijk – Philips, Eindhoven
- Jussi Hiltunen – VTT, Finland
- Jens Kraus – CSEM, Swiss
Lighthouse Initiative

Accelerating innovation in medical devices
Enabling “Moore for Medical”

Ronald Dekker
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8\textsuperscript{th} March 2022
Fading Borders

ECS

Organ-on-Chip
- wound care
- smart catheters

data
e-health

Pharma
- electroceuticals
- drug administration

Medtec
- point-of-care diagnostics
An introduction to 13 emerging medical domains that offer opportunities to the ECS community

Available from:
Health.E website: https://www.health-lighthouse.eu

on-line workshop 26th August 2020
Consumer products

- Open platforms and standards at all levels
- Volumes drive innovation
Typical medical product

- Relatively small volumes
- Innovation gets stuck at device level due to lack of open platforms
Vision:

“Moore for Medical”

Mission:

Motivate the ECS community to work towards open technology platforms for medical devices on a device, system, and data level
Health.E lighthouse:

- **Create Awareness** in the ECS community for emerging opportunities
  - Translate the needs of MedTech and pharma into ECS language
  - Identify gaps in strategic research agendas (SRA)

- **Promote Open Technology Platform** model for medical technologies
  - Funnel innovation for medical devices (reduce fragmentation).

- **Create a Sustainable Ecosystem**
  - Consisting of technology suppliers, device manufacturers, end-users
  - Transcending project boundaries
  - Connect to other European initiatives and communities

Make Europe the innovation hub for medical devices.
Open technology platforms will:

• Stimulate innovation
  ➢ create enough volume for sustained technology development
  ➢ create new and better applications
    “concentrate on the application rather than technology development”

• Increase the agility of the industry
  → shorter time to market

• Reduce risk
  ➢ in developing new products
  ➢ liability

• Lower cost

Reach higher by standing on each others shoulders
OTPs for medical devices?
Challenges, issues and recommendations

Available from:
Health.E website: https://www.health-lighthouse.eu

on-line workshop 12th May 2021
Creating an Ecosystem

Concept creation

Infrastructure

Hospital

Platforms

Moore4Medical

Application domains

WP1 Implantable
WP2 Organ-on-a-chip
WP3 Drug adherence
WP4 Next generation
WP5 Towards X-ray
WP6 Continuous

WP 7 Open platform access & Exploitation

WP 8 Project Management & Dissemination

The Health.E Lighthouse is powered by the Health.E Lighthouse Support Initiative (HELoS) ECSEL Coordination & Support Action (ECSEL-CSA) grant agreement: 871394
Open CMUT platform
The future of ultrasound imaging

1) Diagnostic imaging Hospital → point of care, monitoring, consumer applications
2) Integrated imaging solutions in ‘cath lab’ (intravascular, ultrasound, X-ray)

Low volume → high volume production

- Digitalization
- Integration
- Miniaturization
- Artificial Intelligence
Sweet spot for CMUT ➔ Key technology for ultrasound

1. **General purpose** ➔ $F_c : 1$-$10$ MHz
   - Application: multiple purpose hand-held probes and patches

2. **3D imaging** ➔ integration with ASIC
   - Application: ease of use ➔ together with artificial intelligence ➔ e.g. patches and hand-held

3. **Miniaturization** ➔ $F_c > 20$ MHz
   - Application: catheters and endoscopes

**Old**

**New**

- thick film ceramic piezo transducer

CMUT
CMUT modular technology platform

Technology development in EU projects:

**Low frequency CMUT**
- Moore4Medical
- ULIMPIA

**High frequency CMUT**
- With interconnect technology (F2R)

- **40 MHz** – High Frequency → Catheter
  - DC: 35V, RF: +25V
  - Concept proven

- **25 MHz** – High frequency
  - DC: 35V, RF: +25V
  - Concept phase

- **15 MHz** – Mid range Ultrasound
  - DC: 40V, RF: +20V
  - Concept phase

- **10 MHz** – Mid range Ultrasound
  - DC: 40V, RF: +20V
  - Concept phase

- **8.5 MHz** – Mid range Ultrasound
  - DC: 120V, RF: +60V
  - Process freeze

- **3 MHz** – Low Voltage Ultrasound
  - DC: 35V, RF: +/- 20V
  - Feasibility proven

- **3 MHz** – General Purpose Ultrasound
  - DC: 120V, RF: +60V
  - Process freeze
Pan-European benchmark of MEMS ultrasound transducers

• Benchmark of different MUT technologies
  – Definition of test devices and measurement methods
• Map the different technology options to the medical application space

Challenge:
• Only technology and not full ultrasound system

Info on benchmark: www.position-2.eu
- Benchmark white papers
- Documentary on Position project
Open CMUT platform

- Successful development of CMUT platform with the support of EU projects

- For approx. 4 years our CMUT platform is open for external customers → **Why?**
  - Philips provides solutions nowadays and not only technology or hardware
  - Larger volumes → affordable technology
  - Larger volumes → larger revenues → investments in new applications/roadmap
  - High development costs (silicon processing) → share with multiple customers
  - CMUT platform can be used for multiple applications

- Leading companies exploring multiple applications with CMUT:
  - Medical, Automotive & Industrial

- **MODULEUS**
  - Non ultrasound imaging application: security & biometry application

- **Cephasonics Ultrasound**
  - Development of ultrasound system with CMUT → open for external users
Mission

• **Sustainable Photonics Pilot Line** dedicated to medical devices
• Enable **cost effective development** from prototype devices to manufacturing
• Several photonics and supportive technologies through **a single entry-point**
• Early adoption of **new photonics technologies**
• Develop and support the **entire supply chain**

Aimed at **reducing R&D costs** and **accelerating commercialization**
### Applicability of MedPhab technologies

**Hospital Use**
- Users → Medical Professionals
- Technology → Fiber optic modules, Reader units

**Home Care Diagnostics Services**
- Users → Citizens jointly with professionals
- Technology → Minituarized modules for wearables

**Equipment for in-vitro Diagnostics**
- Users → Professionals in laboratories
- Technologies → Disposable microfluidic cartridges, Reader units
Single-entry point for full development chain

1. Fast Learning
   - Proof-of-concepts
   - Feasibility studies
   - Technology consultation
   - Roadmapping

2. Flexible control
   - Development projects
   - Upscaling feasibility studies

3. Industrial control
   - Manufacturing development
   - Technology transfer under formal medical regulations

4. Pre-manufacturing
   - Transition to volume manufacturing partners

5. Manufacturing
   - Production

... but processes to follow regulations.

Front Office
Professionals in medical device domain

RTOs
- VTT
- Philips
- Tyndall
- screenec
- csem
- imec
- JOANNEUM RESEARCH
- AMIRES
- EPIC
- NETHERLANDS CANCER INSTITUTE

Support

ISO13485
### Added value for stakeholders

#### Customers
- Accelerate product development through world-class RTOs and industrial partners who speak “the same language”
- Be matched with the right R&D partners through a single entry point
- Get a comprehensive evaluation of technology readiness and guidance in development priorities
- Medphab covers all project stages from prototyping to manufacturing

#### RTOs
- Improved customer service
- Creditability in medtech community

#### Industrial parties
- Customer cases with higher maturity from RTOs
- Update on the latest photonics technologies

#### Other key stakeholders
+ Investors
+ Other EU-initiatives
Personalized monitoring – Synchronized ECG and PPG tracking

**System description**
Distributed wearable system enables the integration of multiple sensor heads on various body locations.

Depending on the sensor position, the biosignal data acquired can include ECG, heart rate and oxygen saturation.

**ECG electronic-module**
- Currently single channel, multi-lead possible
- Disposable skin patch and reusable electronics engine

**PPG optical module**
- Multi-wavelength optical module
- Optical Heart Rate and Pulse Oximetry (SpO2)
- Wirelessly synchronized to the ECG patch

Technologies to make “production kits”
Enabling fabrication technologies

medphab.eu
Community management platform
### Financial support for Demo-case Projects

<table>
<thead>
<tr>
<th>3rd Party</th>
<th>EU-contribution for MedPhab services (Budget provided to MedPhab partners via MedPhab–Demo case fund)</th>
<th>3rd party in-cash contribution (on top of optional in-kind contribution)</th>
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<tbody>
<tr>
<td>SME (EU-based)</td>
<td>75%</td>
<td>25%</td>
</tr>
<tr>
<td>Large company (EU-based)</td>
<td>50%</td>
<td>50%</td>
</tr>
</tbody>
</table>

- Total budget of MedPhab Demo Case Fund: 1.85 M€
- **Maximum EU-contribution per project: 125 K€**
Thank you for your attention!

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www.medphab.eu
www.linkedin.com/medphab
www.twitter.com/medphab
Digital Health

personalized health(-care),
everywhere and at any time

Jens Krauss, Vice-President, CSEM
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Digital health segments towards patient empowerment

- **Trend Health**
  - Wearables, social media, sports, fitness, ...

- **Tech-Health**
  - Sensors, bio-markers, robotics, genomics, ...

- **E-Health**
  - Electronic patient records, telemedicine, e-medications, ...

- **Data Health**
  - Signal processing, data analytics, Big Data & AI, IoMT, ...

*Inspired by Swiss Digital Health Venture Funding Report 2021
May 2021. Copyright © 2021, Health-Trends*
IoMT and health data as driver of the digital transformation

- Daily use of consumer health wearables has increased in the US to 39% in 2020

- Shipped wearables reaches volume of 275M units in 2020 for a total of 49Bn US$ ($\frac{1}{3} = $ smartwatches)

- Market volume of medical wearables makes up to $\frac{1}{4}$ of the wearables for a total of 11Bn US$

- Health apps as one of the driver for consumer wearables with a total of ~350’000 apps today

- 55% of health apps use wearable sensor data
CSEM DNA: small, precise and low-power

CSEM Status
Incorporated, not-for-profit RTO, supported by the Swiss Government and with a heritage within the Swiss watchmaker industry (majority shareholders)

CSEM Digital Health technologies
Track record of +20 years in consumer health and medical devices to strengthen competitiveness through:

• ISO-13485 certification (since 2014)
• Multi-disciplinary integrated teams
• Operation at the University Hospital Campus BE
Digital Health **technology pillars** leading towards...

- **ASIC design**
- **μ-technologies**
- **sensor electronics**
- **processing & data analytics**

**Medical Device Technologies**

**Medical Device Integration**

**Clinical Validation**
... data health science for prevention, diagnostic and treatment

Setup of clinical study
- protocol design and compliance with ISO

Data gathering
- Collection and secure transfer of clinical data

Data analysis
- Feature extraction & AI algorithm design

System deployment
- Implementation of digital health solutions

Privacy preserving cloud computing

Third party cloud provider should never be trusted, but data privacy laws and regulations should not prevent sharing of health data to progress on new innovative digital health tools.
Potentiel OTP use cases for remote multi vital signs patient monitoring systems
1.1 Photoplethysmography, more than (heart) rhythm

Heart Rate (oHRM)
First CSEM patent on PPG 2001

Respiratory Disorders
SpO2, respiration

oAFD®
Atrial fibrillation detection

oBPM®
Continuous, cuff-less blood pressure
1.2 Revolutionizing **hypertension management** with oBPM™

CSEM algorithms focus on model-based interpretable signal processing methods, but... ...the sharing of big data sets could help improving accuracy and patient safety.
2.1 Cooperative sensors: active, smart, cableless and low-cost
2.2 Data driven **remote patient monitoring** pilot to fight COVID-19

Tedious regulation process makes it impossible to deploy the implemented health solution pilot easily to other care providers.
Some thoughts how to reinforce digital health OTPs

- R&D challenges: regulation issues should not hinder progress in science
- Market challenges: seamless integration into healthcare process
- Data issues: how to ensure data security & privacy by respecting data property
- Consumer health vs medical devices: reliability vs accountability
- New digital health tools facing a lack of reimbursement code
CSEM mission: our digital health technology, your product

www.clicshirt.com
www.avawomen.com
www.decathlon.fr
www.festina.com
www.vexatec.com
www.biospectal.com
www.aktiia.com
www.ifit.com
www.swatchgroup.com
www.festina.com
Session 2

RTO perspective

- Paul Galvin – Tyndall, Ireland
- Alexandre Delalleau & Aurore Lepecq – CEA Leti, France
- Liesbet Lagae – IMEC, Belgium
- Thomas Wittenberg – Fraunhofer, Germany
Open Platform Technologies as Building Blocks for Emerging Digital Healthtech

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Head of ICT for Health Strategic Programmes
Head of Life Sciences Interface Group
Head of Bioelectronics Cluster
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A patient journey through the continuum of care

- Pre-acute
  - Wellness: Prevention
  - Clinical pathway coordination
  - Diagnostics
  - Monitoring
  - Prediction

- Acute
  - Treatment
  - Remote monitoring and surveillance
  - Education

- Post-acute
  - Telehealth
  - Remission
  - Wellness

- Homecare
  - Telehealth
  - Remission
  - Wellness
Smart Healthtech Products and Technologies in the continuum of care
Health Innovation
ABCD ecosystem

Collaborations involving:

• Global Medtech, Pharma & ICT Companies;
• Innovative SMEs;
• Contract Manufacturers;
• Innovative Clinicians;
• Leading Scientists and Engineers;
• Human Factors Design;
• Government agencies (IDA, EI, HRB, HSE, SFI, HPRA, etc)
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Novel Healthtech Solutions With Clinical Utility and Commercial Opportunity
Digital Healthtech - Expert Building Blocks

- Human Factors Engineering
- Clinical
- Software ICT Design - AI, Data Analytics, Cyber
- Hardware ICT Design, Cyber
- Manufacture DTE-DFM Flex-Materials Additive Manufact.
- Medical Device Industry - Commercial
Smart Drug Delivery Systems enable:

- Adherence to prescribed therapeutic programme
- Access to new therapies which require precision in dose levels and early warning of potential adverse events
- Programmable local release of high concentrations of drug to target tissue to minimise side effects
- Remote adjustment of therapeutic dose via telemedicine (with benefits on cost, safety and convenience).
- Closed loop feedback for personalised medicine
- Delivery of the right dose to the right tissue and the right time.
- Participatory medicine where applicable with patient monitoring / adjusting dosages within safe limits.
Smart drug delivery systems
Technology building blocks (1)

• Communications modules
  • BLE and other telecoms chips not optimal for wearables/ implantables
  • Mobile phone as gateway, or IOT (IOT roaming?)

• Power
  • Disposable battery / Energy harvesting / Inductive power
  • Low energy IC design

• Flexible electronics
  • Enable wearable solutions and/or electronics which can be conformal on 3D devices.

• AI
  • Local EDGE-based AI for optimal system performance
  • Cloud-based AI/ML to identify and leverage population patterns

• Human Factors Design
  • Physical form factor and out of the box experience
  • GUI compatible with all mobile platforms
Smart drug delivery systems
Technology building blocks (2)

• Fluidic actuation devices
  • MEMS pumps / valves

• Diagnostics for combination devices
  • Sensor system for verification of drug delivered to target tissue or related biomarker
  • Measurement of biomarkers to trigger initiation of drug delivery or inform threshold therapeutic dose reached.
  • Monitoring of systemic health to provide early identification of adverse events

• Smart delivery vehicles
  • needles for parenteral delivery
  • pills / inhalers / nebulisers for oral delivery
  • implants

• Security
  • Data encryption for GDPR
  • Authentication of drug

• Encapsulation
  • Biocompatibility, robust packaging, etc.
Smart Healthtech Systems Value Chains: Patients at the centre
Digital Healthtech - Innovation Opportunities

- Digital Healthtech can enable Preventative, Predictive, Personalised and Participatory Medicine.

- Convergence in Medtech, Pharma and ICT manufacture and innovation.
  - Open platform technologies are emerging in Digital Healthtech to which should accelerate developments, leading to better clinical outcomes, a more sustainable delivery of healthcare to the community and economic impacts for EU.

- Precision Medicine
  - Decision support and Closed loop systems for treatment and monitoring – therapy can modulated to achieve the desired effect based on real-time monitoring of the patient
  - Digital Health - data collection at the device, patient and population levels will empower big data analytics for managing the supply chain, quantifying the effectiveness of the devices / therapy, and enabling population level analytics to inform future prediction and prevention solutions.

- Service rather than product based business models will be the future basis for reimbursement
  - Requirements for verification of efficacy provides opportunities for high value products with differentiation in the market.
Acknowledgements
Thank you for your attention
paul.galvin@tyndall.ie
CEA-LETI Ready-to-trials MedTech Platforms

How to define an appropriate R&D context to ensure DM-compliant technologies to quicken time-to-market
Micro Nano and bio-technologies (CEA-LETI) for Medical Devices

Two main dedicated departments: DTBS & Clinatec

Development of innovative technologies for diseases diagnosis & patients monitoring
THE CEA POSITIONING AMONG RTOS

A step-by-step guidance: "Medical Devices by Design"

How to Improve MD maturity before industrial transfer?

A decreasing support according to projects' development and depending on partners' maturity.
Most of digital Medical Devices need actual data to develop specific sensor-related algorithms.

Data has to be recorded in a real-"life" situation (hospital, home-care, …) and be compliant with regulation (safety, data management …)

Challenges:
- How to use prototypes in actual clinical trials?
- How to ensure a compliance regulation without influencing the whole research process?
REGULATION: THE RTOS UNLOVED STAGE

Medical devices modification cost versus time

"It alters creativity"
"It will slow-down the entire project"

1. Idea
2. Concepts
3. Proof of concept
4. Demonstration
5. Solution development
6. Clinical trial
7. Production processes and technologies
8. Product launch
9. Product life cycling

$1 to $100
REGULATION : THE RTOS' UNLOVED STAGE

The "by-design" concept

MDR 2017:745, 746
Biocompatibility (ISO 10993)
Software dev (ISO 62304)
Optics (ISO 62471)
Electric safety (ISO 60601-1)
Electromagnetics (ISO 60601-1-2)

Avoid any pitfall while being transfer to industrial partners
Balanced requirements according to maturity stage

A perfect knowledge of the regulation and the MD dev-cycle

A specific methodology and a daily commitment in supporting technical teams

Think "generic" to shorten time, to decrease the regulation impact, and to avoid any pitfall !

Creation of a "cultural" spirit surrounding the MD devs

THE CEA'S MEDICAL DEVICE PLATFORM (MDP)
LS2P: BETWEEN MEDICAL AND INDUSTRIAL WORLDS

Health-tech Innovation for everyone’s health

Physiological study (Medical)

Medical Device Production (Manufacturers)

Collaborations with Practitioners = Human / Innovation link

Collaboration with Industries = Innovation / Techno link

Meaningful data in response of Doctors needs

L2SP Skills

Sensor Integration

Data Aquisition

Data Processing

First prototype for future industries production
The Physiological Monitoring Platform (PMP)

- Generic communication HUB
- Specific sensor frontend electronics
- Energy supply and embedded controller
The Physiological Monitoring Platform (PMP)

DATA ACQUISITION

SENSORS
- Analog inputs, single ended / diff
- SPI, I²C, I2S

SUPPLIES
- Battery
- USB

OTHERS SPECIFICITIES
- Certified for tests on person
- μcontroller & FPGA

USER INTERFACE
- USB, BLE 5.0
- Script python for online processing
FROM PROTOTYPE TO PRODUCTS

Speed up development

-75% Regulatory workforce needed

-50% Regulatory costs

1 Month to integrate and drive a new sensor

Less, less, less Risks of project failure

Tech teams focused on their expertises
More project to be ran simultaneously

Costless projects for industrial partners

Strongly accelerates time to design
TO CONCLUDE

- Facilitate the data collection to develop algorithms / deep learning
- Ensure the highest data quality possible
- Quicken R&D phases and decreases costs
- Drastically decreases the risk of projects' failure and costs evaluation
- Can be used easily to draw some standardized connections to open-manufacturing platforms
Not reinventing the wheel
How imec’s integrated platforms can help health applications

Prof. Liesbet Lagae.  imec Fellow and program director life science technologies
Dr. Wolfgang Eberle  IMEC public funded program manager health
Billions of DNA PCR tests - 30 euro

Millions of NGS tests – 300 euro
All versus one
<table>
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<tr>
<td>Antidepressants</td>
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<td>40%</td>
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<td>Diabetes</td>
<td>43%</td>
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<td>50%</td>
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<tr>
<td>Alzheimer</td>
<td>70%</td>
</tr>
<tr>
<td>Cancer</td>
<td>75%</td>
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</table>

Fig. 3: Amount of patients with ineffectiveness of certain substances. [8]

[The personalized medicine Report]
The patient’s ask

We need more frequent health measurements
→ Powerful health measurements

We need therapies that work better
→ Better preclinical models

We need novel therapies in hands
→ Advanced therapies & their manufacturing

We need to understand the organ that defines us
→ Brain interfacing technology

We need less invasive & more precise surgery
→ Precision surgical tools

We need to continue unraveling biology
→ Technology allowing to peer deeper through digital omics

We need to fully leverage the potential of data
→ Turning shared data into actionable insights
Patient driven healthcare - from discovery to prevention

Therapeutic excellence will require system and technology co-optimization

- **Discovery**
  - Advanced Omics

- **Preclinical**
  - Neurotech
  - Preclinical models

- **Therapeutics**
  - Precision therapies & Personalized Biomanufacturing

- **Diagnostics & Monitoring**
  - Surgical interventions
  - Powerful health measurements (Dx, imaging)

- **Prevention**
  - Digital Health - Digital twin

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**Applications**

- Privacy-preserving, secure, large-scale, multi-party analytics
- HWV Solutions
- Chip R&D platforms
- Process technology and material exploration
Scalable chip platforms at the heart of imec’s health program

- Electronic Circuit Platform
- Photonics Circuit Platform
- Fluidic Platform
- Acoustic Platform
- On CMOS Monolithic Integration
- 3D Integration
What we offer

R&D COLLABORATION
Example: developing a new product prototype
From feasibility to product

INNOVATION SERVICES
Example: using pilot line services

VENTURING STARTUPS & FUNDS
Example: startup in need for imec IP
Some recent successes

Develop and offer open platforms and pilot lines to not reinvent the wheel

Tailored open technology platforms

Application-specific platform
Some recent successes
Use of platforms by SME companies

Pacific Biosciences
Single molecule DNA sequencing

Evonetix
3rd generation gene synthesis

Roswell
Single molecule DNA sequencing

Spectricity
Spectral sensing

Midiagnostics
Point of care – breathalyzer

Pulsify
Heart monitoring using ultrasound

Sarcura
carT cell instrumentation

Antilope Dx
Point of care – saliva sensing
An example R&D Collaboration for chip integration
Feasibility + Development on Demand + Volume Manufacturing

- **Feasibility Project**
  - Feasibility demonstrated
  - Specifications defined

- **Development**
  - Custom development
  - Proof-of-concept demonstration

- **Prototyping**
  - Prototype chip tested
  - Ready for production
  - Ramp-up

- **Low Volume Production**
  - Qualified product = 500-1000 wafers depending on process flow

- **Transfer to HVM Partner**
  - High volume production

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Highly dependent on 200mm and 300 mm pilot line infrastructure
Photonics platform

Powerful commodity imager platforms combined with monolithic (visible range) photonic integration

CMOS image sensor

+ 2 M Optical filters

1 M Optical lens

1 M Visible range photonic waveguides

1 M zero mode waveguides
Multi electrode array platform

Large portfolio of electrode capabilities for sequencing, synthesis, electrophysiologic recording, stimulation and biosensing

Biocompatible and CMOS compatible electrodes

TiN electrodes $\sim 150 \, \text{k}\Omega$ @ 1kHz

Ru tracks buried in SiNx

Pt electrodes (exposed or coated) 10nm-50nm

Ru electrodes (exposed or coated) 10nm-50nm

More than 300 research labs around the world rely on Neuropixels probes
Precision fluidics platform

- Lower cost and high turnaround times
- Sample-to-result in one chip
- Full PCR analysis in less than 10 minutes
- Customizable chip functionalities
- Integration with CMOS

Ultra fast PCR microreactor:
40 cycles in 3 minutes

Packaging: combine low-cost, large volume plastics with small, high precision silicon microfluidics

Integrated droplet generator, sorter & merging and on-chip digital PCR

Integrated filters for DNA / protein purification / separation

Crossflow filter for on-chip enrichment and plasma separation
Boost technology uptake in medical devices via strategic partnering and via startup support

5-7 years for medical devices while only 3-5 years for consumer products; largely conservative and regulated sector

Academic proof of concept
Platform based proof of concept
Platform based prototype
Field tests
Clinical studies
Regulation
Upscaling

ACCELERATE CHIP DEV'T
FASTER FORWARD using PILOT LINES AND SKILL BASE THAT IS BEING BUILD UP ACROSS EUROPE

STRATEGIC PARTNERING
STRATEGIC PARTNERING ACROSS ECOSYSTEM TO BRIDGE THE ‘LONG’ VALUE OF DEATH IN HEALTH

SUPPORTING VEHICLES
FUNDING AND FINANCING NEED TO FOLLOW THESE LONGER TIMELINES TOWARDS MARKET

Let us not reinvent the wheel everytime.
emec
embracing a better life
Fraunhofer Society: Structure

- Founded in Munich in 1949
- 75 institutes across Germany total staff of over 29,000 P.
- Five Fraunhofer centres in the USA
- Representative offices and senior advisors in Asia, the Middle East and Moscow
- Total budget > €2 billion with €1.5 billion of income generated from contract research
Fraunhofer Society: Mission

- We live in an increasingly dynamic world.
- Technological cycles are getting shorter, lifestyles and requirement change dramatically.
- Needed are innovative solutions adding value for all stakeholders.

- Applied research is the foundation of our organization.
- We partner with companies to transform original ideas into innovations that benefit society and strengthen the economy.

- Fraunhofer is the international leader of applied research.
- As an innovation driver, we lead strategic initiatives to master future challenges and thus achieve technological breakthroughs.
Fraunhofer Alliance AAL: „Assisted Healthy Living“

... is an interdisciplinary **alliance** of 10 institutes of the Fraunhofer-Gesellschaft (Fraunhofer IGD, IIS, HHI, IAO, IPA, FIT, ITEM, IMS, IIST, IZM)

... for a **joint offer** of research, development and evaluation of technologies and services

... for the fields of homecare, care, prevention, rehabilitation, diagnostics and therapy.
Fraunhofer AAL: Topics

• Sports & Personal Wellbeing
• „Smart home“ and "Home Care“
• Outpatient & Inpatient Care
• Outpatient & Inpatient Computer Assisted Therapy
• Outpatient & Inpatient Computer Assisted Rehabilitation
• Image- and Device-based Computer Assisted Diagnostics
The AAL Alliance pursues the goal of a **holistic system concept** in which **various technical components** and **digital assistance systems** can be integrated seamlessly and spontaneously. We research, develop and evaluate relevant technologies for our partners:

- **Vital and environmental sensors** (including point-of-care diagnostics).
- **Infrastructures for telematics**, networking, data exchange, communication & transmission.
- **AI-based data analytics** for condition and event detection, including diagnostics
- User-friendly **human-machine interfaces** and device operations &
- **Actuator technology** for robotics, mobile service platforms and therapeutic measures
Fraunhofer AAL: Services for »Assisted Healthy Living« (1/3)

Development and integration of hardware and software:

High-quality, safe and economical development of software and hardware as well as integration of existing components into challenging environments, e.g. clinical or home-car settings,

Data evaluation and curation, software-as-a-service (SaaS):

Data and information from sensors, devices and processes arise along the entire clinical care chain. Fraunhofer AAL offers support for the collection, processing and AI-based evaluation of such data collections, provides solutions for sensor-based or cloud-based evaluation, as well as "software-as-a-service"
Studies on user acceptance & accessibility, usability, user experience:
Good usability of interactive devices and their acceptance by end users are elementary for their success. Important requirements are e.g. accessibility and intuitiveness to find an access to the product. Fraunhofer AAL offers studies for the evaluation of human-machine interfaces.

Empirical and systematic evaluation of infrastructures and technologies:
The benefits and reliability of systems must be adequately evaluated and tested both before they are used in care and medical applications and during ongoing operation. Fraunhofer AAL experts are specialized in analyzing complex issues effectively and efficiently and can provide reliable and neutral support in this evaluation.
Development of business models, processes and concepts:
In order to transfer new products to the healthcare market, it is necessary to create suitable business models, new work processes, and integration concepts along the entire value chain with the involvement of all stakeholders from the healthcare sector. Fraunhofer AAL provides support here on the basis of many years of expertise and experience.
Thank you very much!

Contact

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Session 3

Industrial perspective

- Christine Dufour – XFAB, Germany
- Maartje van der Zalm – Salvia BioElectronics, Eindhoven
- Christoph Hennersperger – OneProjects, Germany / Ireland
- Johan Feenstra – SMART Photonics, Eindhoven
Standard noble metal platform for silicon microfluidic applications

Benefits and challenges of standardization

Christine Dufour – Program manager silicon microfluidic, X-FAB
March 2022
We are a specialty foundry offering a unique combination of analog/mixed-signal, low noise transistors, high-voltage devices and embedded non-volatile memory options with sensor and actuator integration.

- We focus on automotive, industrial and medical end markets.
- We provide best-in-class design and prototyping support to enable first-time-right design.
- All of our sites are automotive certified.
Your foundry partner for medical products

Silicon-based microfluidic devices

› lab-on-a-chip based point-of-care testing (PoCT) for viral and microbiological diagnostic
› analysis of single molecules, including DNA, RNA and proteins.
› DNA synthesis
› Micro Electrode Arrays for electrical cells monitoring
› ...

Dry Film Resist with Fluidic Channels / Chambers / Protection layers

Glass Lid with Fluid ports

CMOS with noble metal electrodes
Sensors and/or BioMEMS
Noble metal standard process module

Integrated with standard CMOS technologies

- Mixed-signal standard 0.35µm and 0.18µm CMOS/SOI technologies with low-noise transistors, for small signal detection
- Combined with tailored passivation interface and noble-metal electrodes
  - Integrated tungsten through passivation vias
  - Deposited and patterned of noble metals (Pt or Au)

Must be compatible with

- Post processing to create microfluidic structures on top
- Fluidic environment during usage (for cells cultures, for DNA detection, immunoassays)
- Biofunctionalization, cells attachment
- Post processing for final product packaging (Through Silicon Vias connection, plastic molding ...)
- ...
Standardization benefits and challenges

☑ Structural and electrical process parameters are characterized and documented:
  • Metal sheet resistance, leakage, parasitic capacitances ... are monitored continuously (PCM structures). Thickness, roughness is measured.

☑ Design support and Design Rules are delivered for CMOS CAD and verification tools to ensure proper manufacturability of the noble metal module
  • If the customer requirements are within our process specifications and guidelines, the design can start right away

☑ Compatibility with other X-FAB process modules ensures good integration:
  • The quality of the noble metal and passivation is not jeopardized (avoid risk of scratches and particles deposition) during further post-processing and heterogeneous integration
  • The good adhesion of the interface with a variety of materials to create the microfluidic structures on top is optimized
  • Proven manufacturing flows
  • ...
Electrode characterization versus requirements for biofunctionalization (oligonucleotide probe spotting, enzyme, antibodies/antigens immobilization, cells attachment on top of the electrodes...) is customer/application specific:

- biological protocol validation defined by the customer
- long feedbacks time
- risk of delay before inappropriate surface quality is detected
- surface property can be affected by further post-processing, packaging and storage conditions

Can we further standardize:

- define meaningful surface properties requirements (like surface tension measurements ...)
- faster characterization tests at wafer level, at device level (fast spotting evaluation tests...)
- storage conditions
- ...
To qualify the noble metal standard process module, reliability tests are conducted:

- Impact of the noble metal process module on CMOS transistors performances
- Integrity of the passivation interface (no cracks, pinholes)
  - Avoid the risk of corrosion of the CMOS metallization and vias due to the fluidic environment

Automotive standards can be reused to qualify our noble module, but some tests are inadequate for disposable medical biochips

These standards do not address the specificities of the microfluidic environment

How do we qualify our semiconductor technology in a microfluidic environment?
  - Define relevant test and standards
X-FAB is developing a comprehensive toolbox for smart integrated biochips to tackle the future opportunities of digital healthcare.

- Mitigate standard approach and customer specific needs
  - time to market, risk, performance and cost

- We are building this standard offer with our customers and partners, and we value their experience and feedbacks

- We offer prototyping capabilities that support the implementation of noble metal structures directly on to X-FAB CMOS wafers

- In order to be successful, semiconductor companies, packaging companies and biomedical actors need to cooperate closely

“Let’s pave the way for further innovation by vertical integrated value chains and standardized key elements.”

>> Check out X-FAB’s unique Prototyping Platform for Si-based Microfluidics

Thank you.
Salvia BioElectronics

Maartje van der Zalm
Salvia BioElectronics – What do these people have in common
Salvia BioElectronics – What do these people have in common

Migraine: 400,000,000

1 in 7 globally will suffer migraine attacks
Salvia BioElectronics – What do we stand for

Migraine: Drugs are not always the answer

80% stop preventive meds within 1 year
Salvia BioElectronics – How it started

Nerves: information high-ways of the body
Nerve signals trigger biochemicals release
In chronic migraine nerve signals are different
Nerves: information high-ways of the body
Nerve signals trigger biochemicals release
In chronic migraine nerve signals are different

Bioelectronics influence signal patterns
Restore the body’s biochemical balances
Treat chronic pain
Salvia BioElectronics – How we change the life of patients

Devices currently used (off label)

Minimal invasive implant achieved by collaboration in several open platforms
**Salvia BioElectronics – From design to manufacturing**

InFormed – 2018
- Salvia starts with 5 engineers, 1 test set-up in collaboration with InForMed partners.

Position – 2019 to 2021
- Salvia grows to 15 engineers, 2 labs and manufactures first implant through supply chain for biological testing

M4M – 2021 to current
- Salvia gains ISO certification, passes several audits and is getting ready for verification testing.
Salvia BioElectronics – Collaboration is the key to the future

Life-time testing for encapsulated implants
Salvia BioElectronics – Collaboration is the key to the future

Miniaturization of non-hermetic cans
Salvia BioElectronics – Collaboration is the key to the future

Ultra thin flexible electrode array
Salvia BioElectronics – Collaboration is the key to the future

Electronic design for flexible implants
Salvia BioElectronics – Collaboration is the key to the future

Power transfer for in-vivo testing
Salvia BioElectronics – Collaboration is the key to the future

Powering for pre-clinical tests
Salvia BioElectronics – Collaboration is the key to the future

Thin layer encapsulation
Salvia BioElectronics – Collaboration is the key to the future

Life-time verification testing
Salvia BioElectronics – Collaboration is the key to the future

Manufacturing of flexible electrodes
Salvia BioElectronics – Collaboration is the key to the future

Soft polymer implant manufacturing
Salvia BioElectronics – Collaboration is the key to the future

Implant tools
Salvia BioElectronics – Collaboration is the key to the future
Salvia BioElectronics – Collaboration is the key to the future

Products in hand
Salvia BioElectronics – Our path to the future

Verifying life-time reliability of fully integrated devices

Device passes Cytotoxicity, Biocompatibility, 6 month in-vivo animal implantation tests
THE NEW WAVE OF DISRUPTIVE INNOVATION IN CARDIAC IMAGING

MARCH 9TH, 2022 – HEALTH.E LIGHTHOUSE SYMPOSIUM
DR. CHRISTOPH HENNERSPERGER
For more information on OneProjects please contact: christoph.hennersperger@one-projects.com
THANK YOU

(WE ARE HIRING)

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SMART PHOTONICS –
A GENERIC PLATFORM FOR INTEGRATED PHOTONICS CHIPS
AGENDA

- Intro to Integrated Photonics
- SMART Photonics: position in value chain
- Generic platform approach with customers
- Some examples of healthcare demonstrators
PHOTONICS HELPS SOLVE MAJOR SOCIETAL ISSUES

Photonic integrated circuit (PIC) integrate multiple photonic functions, like electronic ICs but with light instead of electrons...

One chip:
- Light sources
- Light transport
- Signal modulation
- Light detection
...

... which has many advantages over incumbents

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<thead>
<tr>
<th></th>
<th>More data</th>
<th>Increased speed</th>
<th>Increased reliability</th>
</tr>
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<tbody>
<tr>
<td>Less power consumption</td>
<td>Low cost</td>
<td>Lower cost</td>
<td>Small form factor</td>
</tr>
</tbody>
</table>

High power consumption in Communications

Fast and safe sensors for autonomous driving

Personalization in healthcare
SMART PHOTONICS: MADE IN EINDHOVEN

**PHILIPS**

Early 1980s: start of activities

First commercialization of components

Acquisition by JDS Uniphase for €1.2B

1991

1994

**TU/e**

Eindhoven University starts R&D on monolithic integration

1998

2002

NanoLab

Established first shared facility for integrated Photonics prototyping

2012: Spin-off as independent pure-play foundry

2013

First Multi Project Wafer produced

2017

Move to own cleanroom at High Tech Campus

2020

New Investment for capacity ramp up
VALUE CHAIN POSITION

- We are producing Photonics chips: chips based on light instead of electronics
- We are the first player offering **production of integrated photonic chips as a foundry**.
- Our customers are predominantly OEMs and system companies
- Providing prototyping services and volume production
SMART PHOTONICS - STATE OF THE ART FACILITY

- 1400 m² Production facility
  - >1000 m² 3” Production cleanroom (Class 1000)
  - Epitaxy growth, Front-end processing, testing
  - Unique lithography capabilities allowing extremely precise feature definition (100nm)
  - Operating on 3” wafers (equipment ready for 4” and 6”)

- 850 m² fully integrated R&D facility at Nano Lab, Eindhoven University Technology Science Park
DESIGN TOOLS

Designer

Circuit Simulator

Physical Simulations

Design Kit

Mask Generator

Foundry
OPEN PLATFORM APPROACH

- Modulator
- Balanced PD
- Low linewidth laser
- EAM
- SOA
- DBR
- Passives
- Polarization rotator
- Polarization independent waveguide
- Balanced PD
- Low linewidth laser
- Low-loss waveguide
- Passives
- Modulator
- DFB
- EAM
- Phase modulator
- Tuneable laser
MRI ASSISTANCE

Article

Photonic Integrated Interrogator for Monitoring the Patient Condition during MRI Diagnosis

Mateusz Słowikowski 1,2,*, Andrzej Kaźmierczak 1, Stanisław Stopiński 1,3, Mateusz Bieniek 1, Sławomir Szostak 1, Krzysztof Matuk 4, Luc Augustin 5 and Ryszard Piramidowicz 1,3,∗
GAS SPECTROSCOPY AT 2UM

Monolithically integrated widely tunable laser source operating at 2 μm

S. Latkowski,1,3* A. Hänse1, P. J. van Veldhoven,1 D. D’Agostino,1 H. Rabbani-Haghghi,1 B. Docter,2 N. Bhattacharya,2 P. J. A. Thus,1 H. P. M. M. Ambrosius,1 M. K. Smit,1 K. A. Williams,1 and E. A. J. M. Bente1

1Cobra Research Institute, Eindhoven University of Technology, De Rondom 70, 5612 AP, Eindhoven, The Netherlands
2Optics Research Group, TU Delft, Lorentzweg 1, 2628 CJ, Delft, The Netherlands
3EFFECT Photonics B.V., Torenlaan 25, 5617 BC, Eindhoven, The Netherlands

*Corresponding author: S.Latkowski@tue.nl

Absorption gas spectroscopy for Ammonia, CO (2um)
OPTICAL COHERENT TOMOGRAPHY

Investigation of the wavelength tuning of an integrated laser system system on InP for Optical Coherence Tomography.

J. Hazan, T. Couka, R. Pajkovic, K.A. Williams, E.A.J.M. Bente

1Photonics Integration Group, Department of Electrical Engineering, Eindhoven University of Technology; PO Box 513, 5600MB Eindhoven, The Netherlands
2Ecole Nationale Superieure d’Ingénieurs de Caen (ENSICAEN), CS 45053 - 14050 CAEN Cedex 4, FRANCE
E-Mail: j.hazen@tue.nl

Widely tuneable laser fabricated via Multi-Project Wafer
At 1530 nm, also available in 1310
Investigation of tuning strategies for OCT
HOW IS WORKING IN HEALTHCARE DIFFERENT FROM OTHER MARKET AREAS?

- Large OEM’s addressing the market, but they are looking for solutions from their suppliers
- Scattered playing field with many smaller parties
- Technically, integrated photonics can offer solutions, but sometimes require adaption specifically for healthcare
- Currently volumes of applications still relatively small
SUMMARY

- SMART Photonics is a key player as the foundry in the integrated photonics industry.
- Integrated photonics is a very versatile platform, built on generic technology.
- Photonic IC’s provide exciting opportunities for breakthrough applications in healthcare, thanks to miniaturization and ultra-high sensitivity.
Session 4

European / societal perspective and outlook

- Patrick Boisseau – MedTech Europe
- Yves Gigase – Key Digital Technologies (KDT)
- Peter Zandbergen – Strategic Research Agenda
- Andreas Lymbertiou – Head of the EIC:
  European Innovation Council,
  Challenge-based Accelerator Sector
Introducing the Innovative Health Initiative

Innovative Health Initiative at a glance

• Joint Undertaking (based on Article 187 TFEU)
• Cross sectorial between
  • pharmaceutical sector (EFPIA, Vaccines Europe, EuropaBio)
  • medical technologies sector (MedTech Europe, COCIR)
• Budget over 7 years
  • €1.2 billion in cash from EC
  • €1.2 billion in kind from industry and contributing partners
New Strategic Research and Innovation Agenda

The Science and Innovation Panel

One and two stage calls

- The way we’re governed will change.
- The scope of the partnership is broader than IMI as it will cover the entire continuum of care.
- There will be new, specific objectives that align with the EU’s latest health policy strategies.

Funding comes equally from the public and industry partners.
- Calls for proposals will be open and competitive.
- Projects started under IMI will be managed by IHI.
IHI SRIA – background

Focus

- Cross-sectoral approaches to facilitate creation of new products and services to prevent, intercept, diagnose, treat and manage diseases and foster recovery more efficiently.

Goal

- Lay foundations for development of safer and more effective health care products or solutions that respond to unmet public health needs and that can be implemented into healthcare systems.
• Better understand the determinants of health and priority disease areas
• Integrate fragmented health research and innovation efforts
• Demonstrate the feasibility of people-centred, integrated health care solutions
• Exploit the full potential of digitalisation and data exchange in health care
• Develop new and improved methodologies and models for the assessment of the added value of innovative and integrated health care solutions.
Call 1 – Ideas - Single-stage

1. Innovative patient-facing care pathways for patients with neurodegenerative diseases and comorbidities

2. Next generation imaging and image-guided diagnosis and therapy for cancer

3. Precision oncology: Innovative patient-centric, multi-modal therapies against cancer

4. Access and Integration of heterogeneous health data for improved health care in diseases areas of high unmet public health need
Call 2 – Ideas - Two-stage

1. New tools for prediction, prevention and monitoring of cardio-metabolic diseases including secondary manifestations to enable timely intervention

2. Strengthening EU clinical development excellence and innovation attractiveness: Harmonised methodology to promote the uptake of early feasibility studies (EFS)
Eligibility rules: participation

- Any legal entity or international organisation regardless of its place of establishment
- At least 3 independent legal entities established in a different Member State or Associated Country
- IHI specific eligibility criterion NOT applicable: stage one of two-stage calls:
- Costs related to contributions provided by participants shall amount to at least 45% of the total project cost.
- IKOP, IKAA or FC

IMPORTANT!
1 legal entity should be established in a Member State
Timeline

2022

April: Publication of draft topics

Late June: Launch of call

End Sept: Submission Full proposal (1-stage), Short proposal (2-stage)

End Nov: Information to the applicants - evaluation outcome (1-stage)

End March 23: Grant Agreement (1-stage)

April 23: Evaluation Outcome letters to the applicants (2-stage)

July 23: Grant Agreement (2-stage)

2023

End Febr 23: Submission Deadline (2-stage)

End March 23: Grant Agreement (2-stage)

July 23: Grant Agreement (2-stage)
Open Technology Platforms in IHI

- IHI calls are industry oriented, aka designed for impact (products, solutions)
- Medtech companies might use and test OTPs sometimes in real environment (TRL >6) within IHI projects
- But no fundamental developments supported in IHI projects
- IHI is focusing on precompetitive developments
Getting involved in IHI

At programme/strategic level

- Join one of the industry trade associations who are IHI founding members (COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe)

- Apply as an IHI contributing partner (similar to the status of IMI2 associated partner) [ihi.europa.eu/shape-our-future-research/become-contributing-partner](ihi.europa.eu/shape-our-future-research/become-contributing-partner)
Getting involved in IHI

- Become an evaluation and review expert: 

- Be part of the Patient Pool: 
  [ihi.europa.eu/projects-results/health-spotlights/impact-patients-research](ihi.europa.eu/projects-results/health-spotlights/impact-patients-research)

- Propose new ideas:  [ihi.europa.eu/shape-our-future-research/propose-ideas](ihi.europa.eu/shape-our-future-research/propose-ideas)
Getting involved in IHI

● Apply to IHI calls:
  ○ IHI website: Future opportunities and Open calls
    ihi.europa.eu/apply-funding/future-opportunities
    ihi.europa.eu/apply-funding/open-calls
  ○ Funding & tender opportunities Portal:
    ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home

● Participate in the brokerage events & info-days organised at Call launch
More information

Strategic Research and Innovation Agenda:

Horizon Europe General Model Grant Agreement
(Annex 5 - Specific rules for JU Actions):

Keep up to date
[ihi.europa.eu/news-events/newsroom](ihi.europa.eu/news-events/newsroom)

Subscribe: IHI Newsletter
[ihi.europa.eu/news-events/newsletter](ihi.europa.eu/news-events/newsletter)
OUTLOOK FROM THE ECSEL/KDT JU OFFICE

Yves GIGASE, Head of Programmes
Health.E Lighthouse Symposium
Eindhoven, March 9th 2022
FUNDING ECS INNOVATION FROM ECSEL TO KDT

ECSEL-JU (2014-2021)

- 96 projects including 4 CSAs
- 3,220 beneficiaries from 35 countries / 29 participating states
- Budget: 4.69 B€ cost, 2.28 B€ (EU+national)
- 408,500 Person-months

KDT-JU (2021-2027)

- New partnership to help speed up transition to green and digital Europe
- Budget: 6 B€ funded by 1.8 B€ (EU)+1.8 B€ (national)
- EU Chip Act: key role of KDT
TARGET OBJECTIVES

1. Transform healthcare so that it becomes more and more applicable outside the hospitals.
2. Open digital health platform ecosystem for healthcare appliances and applications
3. Mobile healthcare systems for improved quality of life for e.g. elderly people with chronic disease
4. Medical equipment and devices to support minimal invasive surgery (e.g. imaging)

Completed Projects:
- CSI (ENIAC)
- HIGH PROFILE (ARTEMIS)
- CHIRON (ARTEMIS)
- DeNeCor (ENIAC)
- INCITE (ENIAC)
- EXIST
- INFORMED
- ASTONISH
- ENSO
- SCOTT
- ENABLE-S3

Ongoing Projects:
- POSITION II
- FITOPTIVIS
- Moore4Medical
- HELoS → Health.E LI (Lighthouse Initiative)
# The European Chips Act

## 3 Pillars

<table>
<thead>
<tr>
<th>Chips for Europe Initiative:</th>
<th>New framework to ensure security of supply by:</th>
<th>Coordination mechanism between the Member States and the Commission for monitoring the supply of semiconductors, estimating demand and anticipating the shortages.</th>
</tr>
</thead>
<tbody>
<tr>
<td>pool resources from EU, MS and other, as well as the private sector, through: the “Chips Joint Undertaking”</td>
<td>A. Attracting investments and enhanced production capacities.</td>
<td>monitor the semiconductor value chain</td>
</tr>
<tr>
<td>• strengthen R&amp;D&amp;I</td>
<td>B. Chips Fund to facilitate access to finance for start-ups to help them mature their innovations and attract investors.</td>
<td>common crisis assessment</td>
</tr>
<tr>
<td>• ensure deployment of:</td>
<td>C. Dedicated semiconductor equity investment facility under InvestEU to support scale-ups and SMEs to ease their market expansion.</td>
<td>coordinate actions to be taken from a new emergency toolbox</td>
</tr>
<tr>
<td>• advanced semi-conductor tools,</td>
<td></td>
<td>react swiftly and decisively together</td>
</tr>
<tr>
<td>• pilot lines for prototyping,</td>
<td></td>
<td></td>
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<tr>
<td>• testing and experimentation of new devices,</td>
<td></td>
<td></td>
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<tr>
<td>• train staff</td>
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<tr>
<td>• develop an in-depth understanding of the semi-conductor ecosystem and value chain.</td>
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The Chips for Europe Initiative will largely be implemented by the new Chips JU

The Chips JU is a strategic re-orientation of the KDT JU, with an increased public budget from 3.6 billion to 11.0 billion EUR

What new actions by the Chips JU for the Chips for Europe Initiative? (New as on top of the KDT actions for R&D&I)

1. Design capacities for integrated semiconductor technologies
2. Pilot Lines for preparing for innovative production, and testing and experimentation facilities
   a) Pilot lines to experiment, test, and validate, including through PDKs, the performance of IP blocks, virtual prototypes, new designs and novel integrated heterogeneous systems in an open and accessible way.
   b) New pilot lines on semiconductor technologies such as FD-SOI down to 10-7 nm, advanced Gate-All-Around and leading-edge nodes (e.g. below 2 nm), complemented by pilot lines for 3D heterogeneous systems integration and advanced packaging.
3. Advanced Technology and Engineering Capacities for quantum chips
   a) Innovative design libraries for quantum chips
   b) Pilot lines for the integration of quantum circuits and control electronics
   c) Testing and experimentation facilities
4. A network of competence centres and skills development
5. ‘Chips Fund’ activities for access to capital by start-ups, scale-ups, SMEs and other companies in the semiconductor value chain
Stimulate the development of OTPs

Recommendations

• “Stimulate... development and implementation of open platforms an explicit part of the requirements of project calls ...development of OTPs that can also serve potentially high-volume non-medical applications”

• “Include requirements related to the development of open security/privacy tools on each call that relates to the handling of medical data”

• “Broaden evaluation .. to include criteria related to practicality, ease of implem., eval. of technologies “in the field” e.g. by means of (pre-) clinical trials.”

➢ Convincing the JU of this, JU being private and public partners

➢ The reference document to drive project call topics and requirements for the ECS community is the ECS SRIA².

• See e.g., Multifunctional integration, Cross-sectorial needs, Specific requirements for Health & Wellbeing
• Include security aspects for such topics

➢ Focus Topics as a new instrument in KDT calls part of the top down approach

• Explicit requirements can be uptaken
• But needs convincing Public authorities of urgency and need for such topic.

---

1 Open Technology Platforms for Emerging Medical Domains, A Health.E lighthouse whitepaper

2 The Electronic Components & Systems (ECS) Strategic Research and Innovation Agenda (SRIA) 2022 final edition was published on 17 January 2022 by the three Industry Associations AENEAS, EPoSS, and Inside.
Increasing the long term impact

Recommendations
• “Enhance multi-disciplinary cooperation by promoting the integration of clinical validation within highly innovative research initiatives ...technology projects are too short to also include the necessary clinical evaluations…”
• “Organize pan-European benchmarks for competing technologies”
• “Ensure that physicians, hospitals, caregivers and patients have an impact on the development roadmap from the very beginning”
• role of RTOs

➢ Look for synergies and common actions with IHI JU (other PPPs?)
  • when it comes to clinical trials/validation
  • for benchmarking different medtech solutions
  • for roadmapping exercises

➢ Keep an eye on EC priorities
  • Independence goals incl. sovereignty
  • Other related roadmaps like the AI roadmap, Open-source tech roadmap
  • Green deal, sustainability, circular economy,...

1 Open Technology Platforms for Emerging Medical Domains, A Health.E lighthouse whitepaper
Capitalization/commoditization of assets leveraging OTPs and ecosystems:

Recommendations:

➢ All this relates to deployment and so should be analysed in the frame of the Chips JU (Chips Act)
➢ Access to open industrial platforms must be based on transparency (standard specs and APIs), modularity (Apps, tools, design, ) and clear rules (IP management, standards, maintenance, ...).
➢ Public databases are eligible for ECSEL/KDT funding but their continuity should be assured via other self-sustained communities under specific business models.

1 Open Technology Platforms for Emerging Medical Domains, A Health.E lighthouse whitepaper
Thank You

Special thank you to the Health.E lighthouse initiative and the Helos project
ECS-SRIA

Peter Zandbergen (Philips)

Chapter Lead Health and Wellbeing
The ECS-SRIA 2022
EU Main Objectives covered by SRIA

1. Boost industrial competitiveness through interdisciplinary technology innovations

2. Ensure European digital autonomy through secure, safe and reliable ECS supporting key European application domains

3. Establish and strengthen sustainable and resilient ECS value chains - the Green Deal

4. Unleash the full potential of intelligent and autonomous ECS-based systems for the European Digital Age

Ensure engineering support across the entire lifecycle of complex ECS-based systems

**Foundational technologies**

The Foundational Technology Layers cover the technology stack of a typical digitalization solution based on ECS.

They have hierarchical dependencies, due to the inherent nature of ECS and the way they compose and integrate in complex entities.

Essential to creating the main components of a digitalization solution.

Represent a very fertile ground where new interdisciplinary technologies, products and solutions can grow.
Cross sectional technologies

Four Cross-Sectional Technology chapters focus on transversal areas, where innovative results emerge from the interdisciplinary contribution of the foundational layers.

E.g.: embedded intelligence on the edge requires

- new integrated circuits
- to develop innovative electronic components
- that can be used to develop smarter and more connected components, modules and entire systems,
- running smart software that will offer new functionalities and capabilities
- that will allow these systems to interact, cooperate and merge in larger Systems of Systems.

The innovation generated by cross-sectional technologies influences foundational layers and amplifies the effect of innovation also in the application domains.
Six Application chapters describe the challenges of specific ECS application domains, that are key for Europe, and identify the required R&D&I efforts.

Finally, the Long-Term Vision chapter illustrates our vision of the ECS beyond the time horizon covered by the other chapters:

- it seeks to identify the research subjects that must be addressed at low TRL levels
- and help the research programs in the continuous improvement of European digital technology
Five major challenges have been identified for the healthcare and wellbeing domain:

- **Major Challenge 1**: enable digital health platforms based upon P4 healthcare.
- **Major Challenge 2**: enable the shift to value-based healthcare, enhancing access to 4P’s game changing technologies.
- **Major Challenge 3**: support the development of the home as the central location of the patient, building a more integrated care delivery system.
- **Major Challenge 4**: enhance access to personalized and participative treatments for chronic and lifestyle-related diseases.
- **Major Challenge 5**: ensure more healthy life years for an ageing population.
Links with Lighthouse Health.E

- **Digital Health Platforms**
  - Secure IoMT systems; Early Diagnosis; ...

- **Value Based Healthcare**
  - MEMS Ultrasound for large area body conformal; Flexible electronics; Lab-on-Chip; ...

- **Healthcare at Home**
  - Textile integration and the patch-type housing of electronics; Low-cost MEMS Ultrasound; ...

- **Personalized and Preventive**
  - Smart implantables; Organ on Chip; ...

- **Healthy Life Years**
  - Low-power technology for sensors, microprocessors, data storage and wireless communication; ...
ECS-SRIA

Thanks for the attention. Any question?
EIC

Backing visionary entrepreneurs

Andreas Lymberis, EISMEA, EIC Accelerator
Andreas.Lymberis@Ec.Europa.eu
Europe’s most ambitious innovation initiative

- **€10 billion** programme to identify, develop and scale up breakthrough technologies and disruptive innovations in Europe
- **Unique** in the world to combine research on emerging technologies with Accelerator for startups, SMEs and scaleups
- EIC set to become **largest deep-tech investor** in Europe (over €3 billion)
- Enhances the **European innovation ecosystem** (partnerships with EIT, ERC, etc)
- **First work Programme** adopted 18 March 2021, €1.5 billion
- **Second Work Programme** adopted 7 February 2022, **€1.7 billion**
EIC main instruments and characteristics

**Pathfinder** (TRL 1-4)
- For consortia
- Early stage research on breakthrough technologies
- Grants up to €3/4 million

**Transition** (TRL 4-6)
- For consortia and single entities
- Technology maturation from proof of concept to validation
- Business & market readiness
- Grants up to €2.5 million

**Accelerator** (TRL 6-9)
- For individual SMEs
- Development & scale up of deep-tech/ disruptive innovations by startups/ SMEs
- Blended finance (grants up to €2.5 million; equity investment up to €15 million or above)

- Focus on **breakthrough, market-creating, deep-tech**
- **Mainly bottom up** complemented by targeted funding on strategic technologies/ challenges
- Steered by **EIC Board** of leading innovators (entrepreneurs, investors, researchers, ecosystem)
- **Business Acceleration Services** (coaches/ mentors, corporates, investors, ecosystem)
- **Pro-active management** (roadmaps, reviews, re-orientations, etc) with EIC Programme Managers
- **Fast track access** to Accelerator for results from EIT, EIC Pathfinder,
>5000 short applications submitted

Average time to inform of outcome of short applications: 3 weeks

164 companies selected for funding
- 96 blended finance
- 34 grant first; 9 grant only
- 5 equity only

Total funding up to €991m: €641m investments; €350m grant

Approx. 144 Seals of Excellence
EIC Business Acceleration Services Achievements in 2021-2022

- +50 Initiatives
- +800 innovators took part
- +2000 Corporate & investors involved
- +600 1:1 meetings with business partners
- 20% Business follow-ups & deals
- 89% satisfaction
- 1k coaching sessions
- EIC Pavilion at Top Global Trade Fairs
Impacts of the EIC pilot: > 5000 startups/SMEs supported; €9.6 billion follow up investments; €50 billion valuation; 4 ‘Unicorns’, 91 ‘Centaurs’
EIC Work Programme 2022 - overview

• **Budget: €1.69 billion**
  - EIC Pathfinder: €350 million (+€50m)
  - EIC Transition: €131 million (+€31m)
  - EIC Accelerator: €1.16 billion (+€70m)

• **Strong continuity** for main calls

• Some **simplifications and improvements** in application process

• Evolution of **EIC challenges**

• Additional support for **scaleup companies** and **women innovators**

• **Enhanced Business Acceleration Services** and support actions

• **Continuity with EIC Prizes**
## EIC main calls in 2022 - overview

<table>
<thead>
<tr>
<th>Program</th>
<th>Short applications</th>
<th>Full applications – 3 cutoffs in 2022:</th>
<th>Full applications – 2 cutoffs in 2022:</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Accelerator</strong></td>
<td><strong>Apply any time</strong></td>
<td>23 March, 15 June, 5 October</td>
<td>4 May, 28 September</td>
<td>~€623m (grant &amp; equity)</td>
</tr>
<tr>
<td><strong>Pathfinder</strong></td>
<td></td>
<td>4 May</td>
<td></td>
<td>~€183m</td>
</tr>
<tr>
<td><strong>Transition</strong></td>
<td></td>
<td></td>
<td></td>
<td>~€70.5m</td>
</tr>
</tbody>
</table>

### Accelerator – Challenges
- Technologies for **Open Strategic Autonomy** (healthcare, critical raw materials, quantum, space, security etc)
- Technologies for ‘**Fit for 55**’ (energy, buildings, mobility, land use, green digital, etc)

### Pathfinder – Challenges
- Carbon dioxide & nitrogen management and valorisation;
- Mid-long term, systems-integrated energy storage;
- Cardiogenomics;
- Healthcare continuum technologies;
- DNA-based digital data storage;
- Alternative quantum information processing, communication, and sensing

### Transition – Challenges
- Green digital devices for the future;
- Process and system integration of clean energy technologies;
- RNA-based therapies and diagnostics for complex or rare genetic diseases
Pathfinder calls 2022 – Summary table

<table>
<thead>
<tr>
<th></th>
<th>Pathfinder Open</th>
<th>Pathfinder Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total budget</strong></td>
<td>€183 million</td>
<td>€167 million</td>
</tr>
<tr>
<td><strong>Proposals (indicative)</strong></td>
<td>Up to €3 million</td>
<td>Up to €4 million</td>
</tr>
<tr>
<td><strong>Funding rate</strong></td>
<td>100% of eligible costs</td>
<td>100% of eligible costs</td>
</tr>
<tr>
<td><strong>Opening</strong></td>
<td>1 March 2022</td>
<td>16 June 2022</td>
</tr>
<tr>
<td><strong>Deadline</strong></td>
<td>4 May 2022 at 17.00 CET</td>
<td>19 October 2022 at 17.00 CET</td>
</tr>
<tr>
<td><strong>Length of proposal</strong></td>
<td>17-page proposal (part B)</td>
<td>25-page proposal (part B)</td>
</tr>
</tbody>
</table>
| **Applicants**        | Consortia: min. 3 partners from 3 different MS/AC (of which at least 1 partner in a MS) | 1. Single legal entities in a MS/AC (conditions apply)  
2. Consortia:  
  - If 2 partners: from different MS/AC, otherwise  
  - Min. 3 partners from 3 different MS/AC (of which at least 1 partner in a MS) |
EIC Transition Open and Challenges 2022

Why EIC transition?

- Supports the maturation and validation of novel technologies beyond proof of principle (TRL 5-6) and business activities towards commercialisation
- The Open funding supports all technologies and innovations
- Challenges: predefined thematic priorities aiming to establish portfolios of projects

Who can apply?

- H2020 FET schemes and EIC pilot
- ERA NET call - FET (CHISTERA, QUANTERA, FLAGERA)
- ERC PoC projects

Financial contribution

- **Max** EUR 2.5 m €
- Booster grants up to EUR 50k to undertake portfolio activities
EIC Transition Call 2022 cut-offs

- **Total budget:** 130M€
  - Open: 70M€
  - Challenge Green Digital devices for the future: 30M€
  - Challenge Process & system integration of clean energy technologies: 15M€
  - Challenge RNA-based therapies and diagnostics: 15M€

- **Publication and Opening:** 9 February respective 2nd March

- **1st cut-off Open and Challenges:** 4th May
  - Interviews: planned for 2nd week of July (+/-) Results: last week of July

- **2nd cut-off Open and Challenges:** 28th September
  - Interviews: planned for 1st week of December (+/-) Results: end of the year

- Part B, sections 1 to 3, = maximum 20 A4 pages including cover
Why EIC Transition? The 2 core elements of a Transition proposal

The starting point in the project should be a Proof of concept validated in the lab (TRL3/4).

The technology track

The business track

The end point should be a completely functional version of the technology tested or demonstrated in relevant environment (TRL 5-6), supported by a sound and implementable commercialisation strategy.
Can you apply?

• Check the **original project is eligible** (e.g. started more than 12 months, or ended less than 24 months before the date of the Transition call deadline)

• You do **not need** to be a **participant**, Principle Investigator or **result owner** of the previous projects;

• **New participants** are **welcome** and encouraged to apply.

• However you need to prove **the commitment from the owner to negotiate** with you fair, reasonable, non-discriminatory access to the results.
Evaluation of proposals and next steps

- **First remote evaluation phase by experts**
  - Average of the individual scores per criteria (excellence, impact, implementation)
  - Overall score sum of the three averages
  - Feedback 9 weeks after the call deadline

- **If successful, within 2x available budget, invited to a face-2-face interview**
  - You may bring only people mentioned in the proposal
  - Jury composed of max 6 members, may include 1 program manager
  - Convincingly pitch your proposal and answer clarifying questions
  - Recommends a Go/No Go, no change in the overall score
  - Invitation 13w and feedback 17 weeks after the call deadline

- **Grant agreement signed within 6 months from call closing. Project starting <2-3M**
Origin of the successful proposals

- 25 proposals selected for funding are originated by ERC Poc projects (60%)
- 17 proposals selected for funding are originated by FETOpen projects
Deviations need to be justified

- **Budget**: 2.5 M€ is the **standard maximum budget**, 

- **Duration**: 36 months is the **standard maximum duration**

- **Early start** of the project after grant signature (if successful).

**higher amounts and longer durations should be an exception** and very convincingly justified
EIC Accelerator

SMEs Instrument

EIC Pilot
What are we looking for?

Start-ups and SMEs seeking to scale up high impact innovations with the potential to create new markets or disrupt existing ones

Innovations building on scientific discovery or technological breakthroughs (‘deep tech’)

Innovations where significant funding is needed over a long timeframe and are too risky for private investors alone
What can you apply for?

**EIC Blended Finance**

**Equity**
- 0.5 to €15 million

**Grant**
- Up to €2.5 million

**Also**

- Grant only
- With other finance
- Grant first
- With equity follow up
Grant and investment
If you need support for development (TRL 5/6 → 8), deployment and scale-up (TRL 9).

Grant first
If your innovation still requires significant work to validate and demonstrate in relevant environments to assess its commercial potential.

Grant only
If you can prove that you have sufficient financial means for deployment and scale-up (TRL 9).

Investment only
If you are looking to fill the funding gap for rapid scale-up of your high-risk innovation and you don’t need a grant.
EIC Accelerator equity funding

• The EIC invests at *early stage* (seed, start-up, scale-up) from **€0.5 to 15 million** in the form of equity or quasi-equity.
• Intended to finance *market deployment and scale up*.
• *Crowding in* of co-investments and follow-up investments in EIC funded companies of 3-5 times the level of EIC funding
• The EIC may reserve *follow-on capital* to invest in subsequent series.
• The EIC invests across *all technologies and verticals*, across *all EU countries* (and associated countries).
• The EIC provides *patient capital* (investments will normally be made with a long average perspective (7-10 years) with a maximum of 15 years).
• The EIC usually targets *minority ownership* stakes (from 10 to 25%), and up to a blocking minority in cases identified by the EC as of strategic interest for the EU.

* A more than EUR 15 million investment request is allowed in duly justified cases in 2022 on a pilot basis.
The EIC Fund today

• The EIC Fund is a venture capital fund: Reserved Alternative Investment Fund (RAIF), a flexible instrument with possibility for multiple compartments (H2020, Horizon Europe...).

• The European Commission is the shareholder.

• It was established in June 2020 under direct management by the Commission.

• The European Investment Bank (EIB) is the investment adviser.

• Since its incorporation, the EIC Fund has approved 141 deals (EUR 637 million) and signed 75 investment agreements (EUR 375 million).
Success story

Blood test to diagnose pancreatic cancer
672454 - IMMPACT

Founded in 2007 - Stockholm (SE)

Funding:
December 2014: €4M Phase 2
1 December 2015: IPO at NASDAQ
Stockholm
26 April 2018: NASDAQ NYC
Market cap: 200 M€

http://www.immunovia.se/
EIC Accelerator in 2022

- Open Accelerator
- EIC Accelerator Challenge: Technologies for Open Strategic Autonomy
  - *significant reduction of the European dependency on other regions for deep-tech innovations and services of EU key strategic interest; strengthening of European competitiveness, security and open strategic autonomy.*
- EIC Accelerator Challenge: Technologies for ‘Fit for 55’
  - *accelerating decarbonisation by having high potential impact on reducing net CO₂ emissions; more inclusive and steady acceleration towards climate neutrality by 2050*
EIC Accelerator Challenge: Technologies for Open Strategic Autonomy

- **Components, technologies and systems for the pharmaceutical industry** (security of supply e.g. through synthetic biology and novel manufacturing technologies;)
- **Strategic healthcare technologies** building on Europe’s research strengths in cell and gene therapies, including ribonucleic acid (RNA) based therapies to ensure EU leadership;
- **Sustainable and innovative approaches, including circular approaches to critical raw materials (CRM)** for new sources of supply/extraction, processing, use, recovery or replacement aimed at improving efficiency use, so reducing EU dependency on external providers, and to build EU capacity at all stages of the raw materials value chains;
- **New applications of quantum technologies** on the ground and in space
- **Edge computing applications** including new business models to foster EU leading role in their development;
- **Innovative applications making use of data and signals from EU space infrastructures** (Galileo, Copernicus, etc.)
- **Development of space technologies**
- **Critical security technologies** for secure communication, data security and protection of borders
- **Technologies for innovative financial and payment infrastructures and services**
The evaluation step by step

1. You have a disruptive / deep tech idea with a potential to scale up
   - Tell us your story and submit your short application to be assessed by remote evaluators

2. We help you to prepare your business plan and draft a proposal with AI tool and coaching
   - You submit your full proposal

3. Your full proposal is assessed by remote evaluators

4. You pitch your innovation in front of EIC Jury Members
   - If selected, you sign the Grant Agreement

5. In case of investment component, you enter a due diligence process + compliance checks
   - At the end of the process, you sign the Investment Agreement
Thank you!

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