

Clinical Engineering outsourcing services & Open Innovation

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IMAGINING THE FUTURE OF HEALTH CARE: DIFFERENT PERSPECTIVES



Many highly innovative solutions... that do not interact each other

WHAT WE ARE TALKING ABOUT: BIOHIGHTECH



BIOINFORMATICS



- Medical and Bio IT
- Cloud & IoMT
- Business Intelligence and High Performance Computing

BIOTECHNOLOGIES



- Red Biotech
- White Biotech
- Green Biotech

BIOMEDICAL



- Biomedical device
- In vitro diagnostic device
- Bioimaging device

BioHighTech Industrial field: World and European Market on % Growth



BioHighTech International Market & Growth

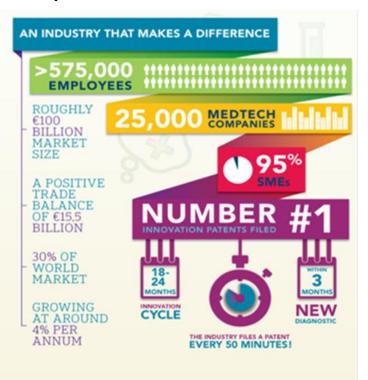
Industry Sector	Market	Growth (CAGR%)	
BioMed (MedTech)	about 300 bln	about 4%	
BioTech	about 150 bln	about 10%	
BioICT (IT Healthcare)	about 150 bln	about 10%	
BioHighTech	about 600 bln	about 7%	

European BioHighTech Market: comparison with other relevant markets





BioMed/MedTech Industry in Europe: Companies & Market



APPROACH TO ENAHNCE THE BIOHIGHTECH: OPEN INNOVATION





«Companies should use their business model to identify a more enlightened role for R&D in a world of abundant information, better manage and access intellectual property, advance their current business, and grow their future business»

«Open Innovation: The new imperative for creating and profiting from technology», Henry William Chesbrough, 2003



IFMBE: CLINICAL ENGINEERING DIVISION

CED Vision Statement:

To become an international forum for developing and promoting of the clinical engineering profession resulting in improvement of global healthcare delivery through **the advancement of safe and effective innovation**, management and deployment **of healthcare technology**.

The IFMBE is the only international professional federation that has a Clinical Engineering Division focusing specifically on the life cycle management of healthcare technology and embracing all those who professionally practice in the clinical engineering field, whether in academic institutions, health care facilities, industry, business, voluntary sector, or government.

Clinical Engineers play a crucial role for enhancing Open Innovation in Healthcare Technology improving connections between research and industry

Trends in Medical & ICT Technologies: Open Innovation for Health and Social Organizations • Hospital and Social Organ

- Digitization & Convergence:
 - Increased penetration of digital information (and the related software applications and hardware infrastructure supporting it);
 - Medical Equipment evolving towards standard hardware/operating system architecture, with added specialized software application and sensors.
 - Integration of Medical Equipment and Hospital ICT.
 - New regulation including all IT systems with "intended clinical use" in Medical Devices calling for application of risk management practices typical of medical equipment.

Technology dispersion:

- The prevalence of chronical diseases and ageing population in developed countries, and the challenge to provide access to Healthcare to huge rural populations in the developing world, are creating the ground for healthcare systems to extend far out of the hospital;
- Such extend system calls for integrated wide area networks connecting patients (home devices), physicians and hospitals (EMR and diagnostic tools).
- Need for Efficiency:
 - Healthcare innovation generating the need for new technology (shorter product lifecycle, faster replacement), while budget constraints call for cost control and better asset utilization in Hospitals.

- Hospital and Social Organizations "pains".
 - Typical technology purchasing and management processes not suitable for facing the challenge.
 - Leading to:
 - Over-purchasing;
 - Inefficient use;
 - Lack of integration
 - Risk / Non compliance.

Hospital and Social Organizations needs:

- "Holistic" approach to Technology Planning:
 - Integrated IT and Medical Equipment;
- Integrated ICT platform to "glue" the system;
- Efficient Integrated Clinical Engineering:
 - Lifecycle management;
 - All Medical Devices (including IT & IoT)
 - In the Hospital and outside
 - Manage functionality and usage.



Clinical Engineering Services in Top EU countries: Focus on Multivendor Medical Equipment Services



Year 2008		Italy	France	Germany	Spain	UK	Total
ledical equipment replacement value	€ bn	10,8	11,4	15,2	5,1	8,4	50,9
ervices on Medical Equipment	€ mn	771	675	996	307	688	3437
Of which: Biomed	€ mn	381	418	586	178	409	1972
Diagnostic Imaging	€ mn	390	257	411	129	279	1466
linical Engineering Outsourcing	€ mn	204	78	166	60	41	549
enetration on Services		26%	12%	17%	20%	6%	16%
M maintainance	€ mn	316	279	482	153	307	1537
enetration on Services		41%	41%	48%	50%	45%	45%
n House services	€ mn	251	318	349	94	341	1353
Penetration on Services		33%	47%	35%	31%	50%	39%

- 5 major European Countries account approximately for 75% of Eu29 services on Multivendor Medical Equipment.
- Value of Multivendor Maintenance Services Market estimated as a % of Medical Equipment replacement value
 - Biomed: average of 5,6% of installed base replacement value;
 - DI: average of 8,7% of installed base replacement value
- Current Maintenance Services market is covered by In House Hospital departments, OEM's maintenance and Clinical Engineering Outsourcing maintenance services (independent players providing a range of multivendor services)

Clinical Engineering Outsourced Services



Hospital need:

- Guaranteed uptime of equipment also with IIoMT;
- Access to continuously upgraded technology skills.
- Compliance.
- Optimization of technology buying process.
- "Certain" budget
- Optimization of cash flow;

Clinical Engineering Outsourced services provides:

- Lifecycle management of Medical Equipment, other selected Devices and the associated spare parts and consumables (test, calibration, maintenance, repair, disposal,...);
- Leading to approximately 20% reduction in maintenance cost and increased availability!
- Added Value Services linked to Lifecycle management services:
 - Assessment and Planning consultancy;
 - Equipment utilization tracking and optimization;
 - Bundles with financial/insurance services.
 - IIoMT Services
- Leading to 5-10% reduction in Capital Expenditures and 3-14% reduction on purchase of consumables!
- Medical Equipment (the historical focus of the outsourcing market);
 - A wider range of **Medical Devices** (large opportunity to widen the market) leveraging synergies with the historical core market:
 - ICT systems
 - Technology related Business Process Outsourcing processes (digitization, technical facilities,...).

What Technologies?

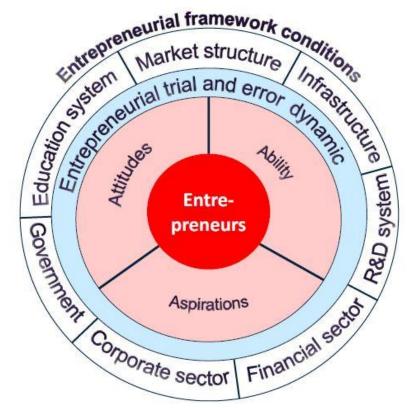
What Services?

- Unique point of contact managing hundreds of OEM's also with IIoMT;
- To contain cost through economies of scale also with IIoMT.



CLINICAL ENGINEERING OUTSOURCED SERVICES & OPEN INOVATION: CRUCIAL ROLE FOR CONNECTING THE ENTREPRENEURIAL AND THE RESEARCH ECOSYSTEM WITH HOSPITALS AND CITIZENS AT THE INTERNATIONAL LEVEL

Global Entrepreneurial Index (GEI Index)



Entrepreneurial Ecosystem



The modern temple of the entrepreneurial ecosystem is like many temples of the ancient world: both are held up by pillars. Like the pillars of ancient temples—made of sand and limestone held together by cement—the pillars of the economic ecosystem are made of individuals and institutions that are held together by the "cement" of incentives created by institutions that influence the behavior of people

The entrepreneurial ecosystem rests on 14 pillars of development, which hold up three large building blocks consisting of attitudes toward entrepreneurship, entrepreneurial abilities, and entrepreneurial aspirations. The pillars must be of similar height and strength for a fully developed economy to flourish, and they need constant attention, continuous improvement, and careful maintenance.

Entrepreneurship and Economic Development



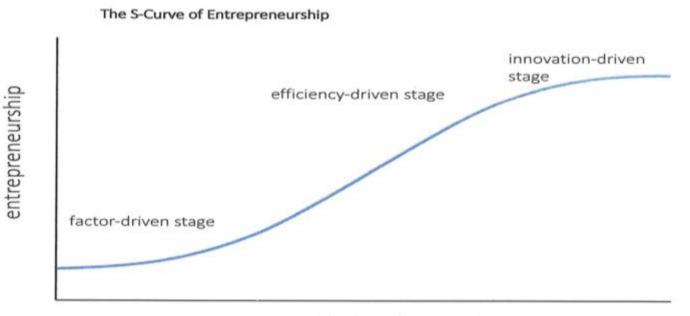
GEI defines entrepreneurship as "the dynamic, institutionally embedded interaction between entrepreneurial attitudes, entrepreneurial abilities, and entrepreneurial aspirations by individuals, which drives the allocation of resources through the creation and operation of new ventures."

In his classic text, The Stages of Economic Growth, W. W. Rostow suggested that countries go through five stages of economic growth.

While focused on the age of high mass consumption, Michael Porter followed recent developments in the economics of innovation. Porter has provided a modern rendition of Rostow's approach by identifying three stages of development: (1) a factor-driven stage, (2) an efficiency-driven stage, and (3) an innovation-driven stage.



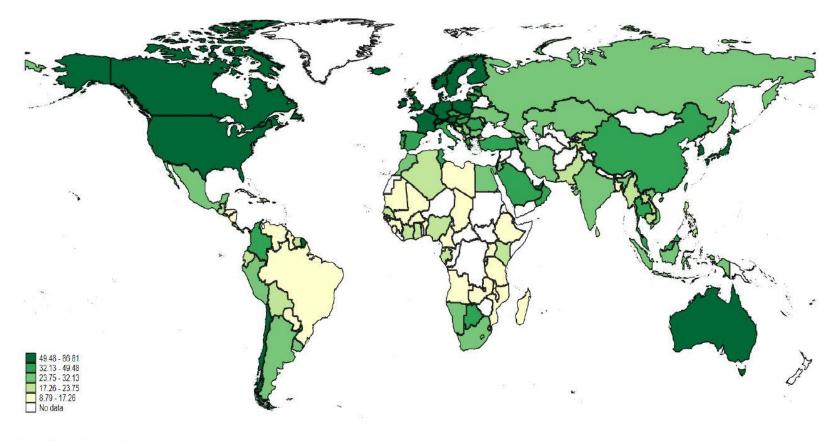
Relationship between entrepreneurship and economic development: the s-curve of entrepreneurship



economic development



GLOBAL ENTREPRENEURSHIP 2019 INDEX MAP



Top Ten Countries

TOP TEN COUNTRIES IN THE 2019 GEI INDEX



Country	GEI 2019 Iower limit	GEI 2019 upper limit	GEI 2019	GEI Rank 2019	GEI Rank 2018	Country
United States	80.1	93.5	86.8	1	1	United States
Switzerland	74.3	90.1	82.2	2	2	Switzerland
Canada	74.3	86.1	80.4	3	3	Canada
Denmark	64.5	94.1	7 9.3	4	6	Denmark
United Kingdom	7 3.5	81.5	77.5	5	4	United Kingdom
Australia	66.6	79.7	73.1	6	5	Australia
Iceland	62.6	83.3	73.0	7	7	Iceland
Netherlands	66.2	78.5	72.3	8	11	Netherlands
Ireland	64.5	78.0	71.3	9	8	Ireland
Sweden	64.6	75.9	70.2	10	9	Sweden

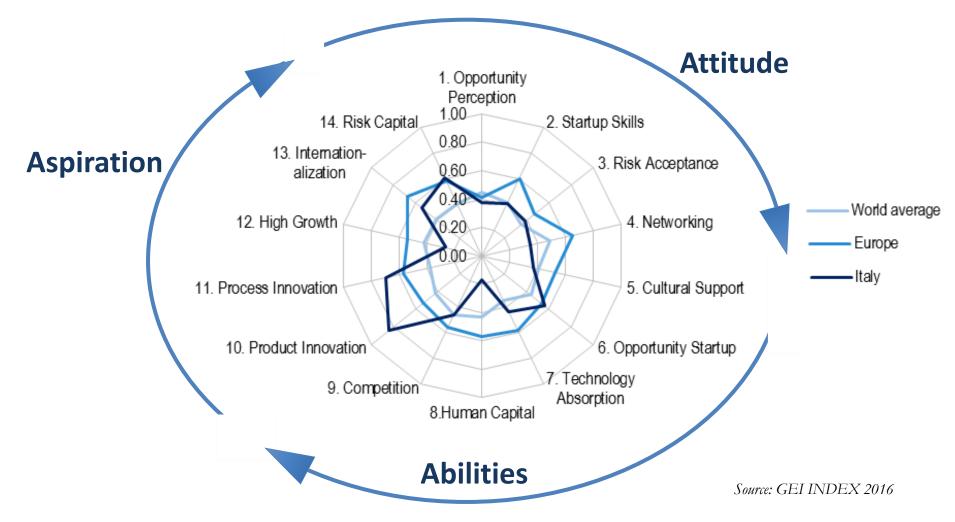
2019 GEI SCORE AND RANKING OF 137 COUNTRIES



COUNTRY	RANKING	GEI
United States	1 /137	86.8
Switzerland	2 /137	82.2
Canada	3 /137	80.4
Denmark	4 /137	79.3
United Kingdom	5 /137	77.5
Australia	6 /137	73.1
Iceland	7 /137	73.0
Netherlands	8 /137	72.3
Ireland	9 /137	71.3
Sweden	10/137	70.2
Finland	10/137	70.2
France	14/137	67.1
Germany	15/137	66.7
Austria	16/137	64.9
Slovenia	23/137	56.5
Spain	31/137	46.9
Italy	36 /137	45.1

Source: GEI INDEX 201916

GLOBAL ENTREPRENEURSHIP INDEX (GEI): ITALY vs EUROPE vs WORLD



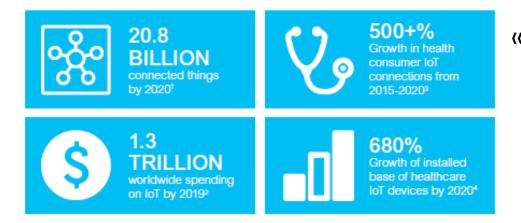
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Group

OPEN INNOVATION: TRENDS IN DIGITAL HEALTHCARE FROM 2015 TO 2020



«Healthcare payers will step up their efforts to deploy new ways to connect IoT data with healthcare plans» (i-scoop)



"The installed base of healthcare IoT devices (excluding wearables like fitness trackers) will grow from 95 million in 2015 to 646 million in 2020»
(Rif. BI Intelligence, a research service of Business)

Insider)

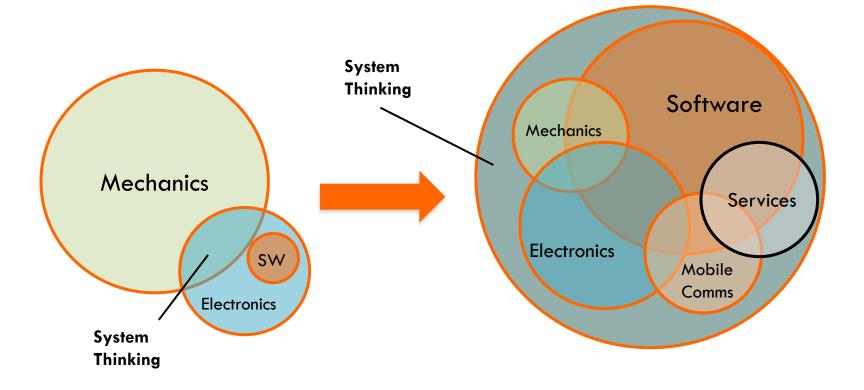
DigitalHighTech Industrial Sector: Growth % in World Market



Industrial Sector	Market	Growth (CAGR%)
Big Data	About 50 Md \$	20%
Cyber Security	About 167 Md \$	10,9%
Artificial Intelligence	About 62 Md \$	40 %
IoT	About 0,826 Md \$	19,9%
Cloud Computing	About 371 Md \$	17,5%



INDUSTRY 4.0: SOFTWARE-DEFINED MACHINES



Source adapted from "Software gibt den Takt vor", C. Kühnl in Mechatronic & Fertigung", 2010

INDUSTRY 4.0: Data Deluge



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Data Deluge

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Exabyte

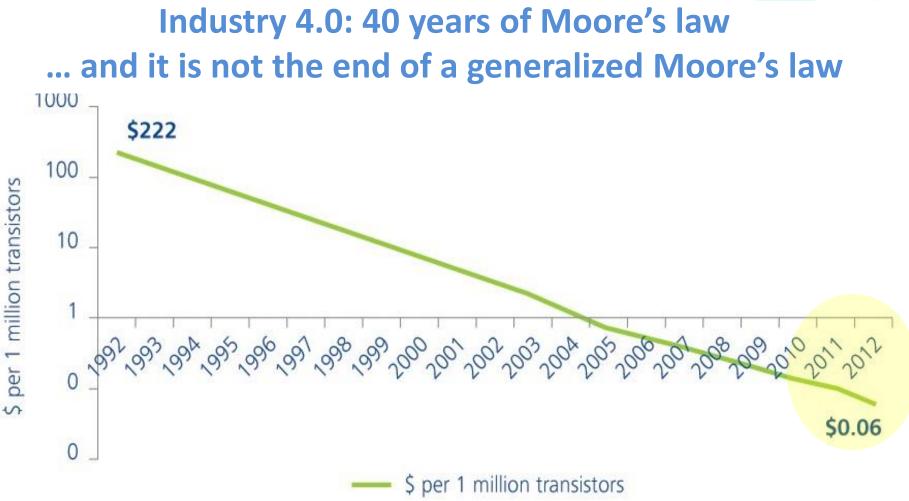
<u> Zettabyte ~ 250</u>

The total amount of data being captured and stored by industry doubles every 1.2 years

HD Video

Every 2 days we create as much information as we did from the beginning of time until 2003 Over 90% of all the structured data in the world was created in the past 2 years





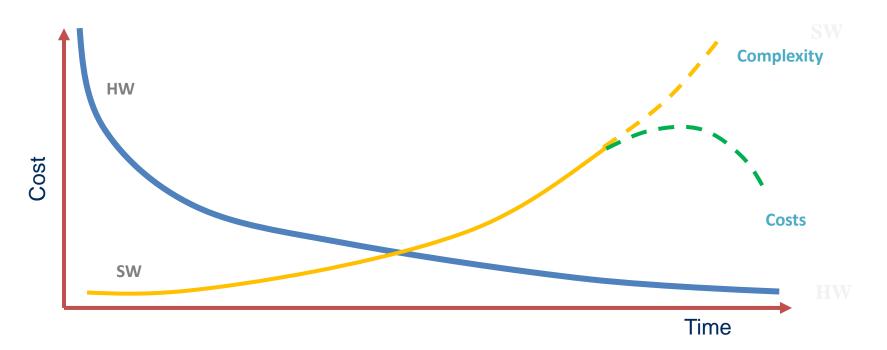
Source: Leading technology research vendor



Industry 4.0: Complexity and Costs

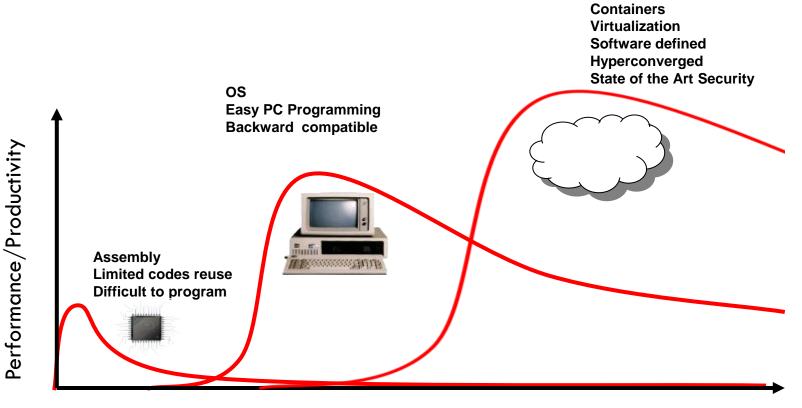
Moore's law : Number of transistors doubles approx. every 18 months

Wirth's law: Software gets slower faster than hardware gets faster





Industry 4.0: Complexity and Performance



Complexity and Size



DATA ARE THE NEW RAW MATERIAL

New source of innovation & lever to achieve business sustainability

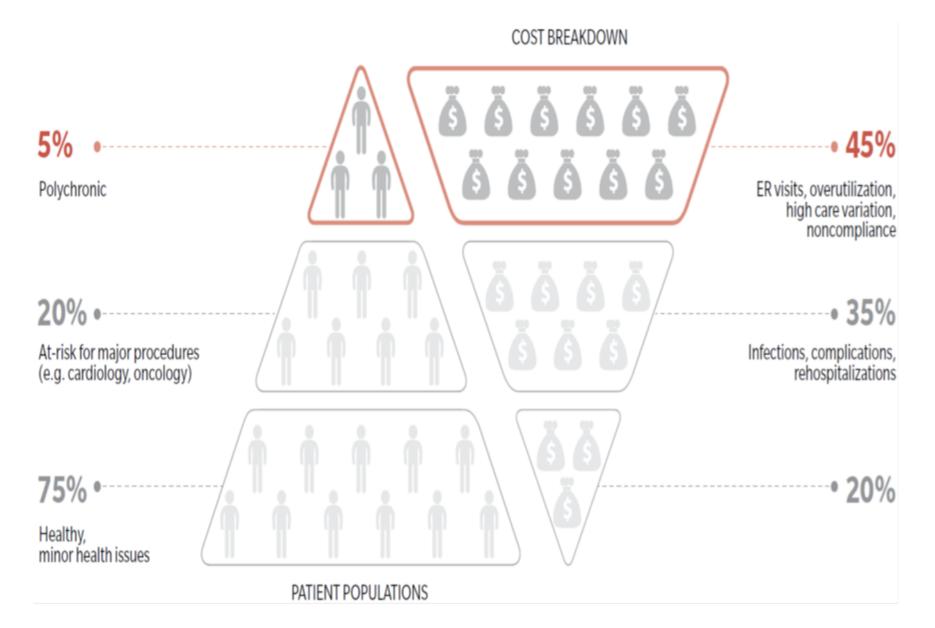


"If you went to bed last night as an **industrial company**, you're going to wake up this morning as a **software and analytics company**"

Jeff Immelt - GE CEO

Populations and Health Expenditure





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Social determinants of Health

Factors that Determinate the State of Health in Industrialized Countries



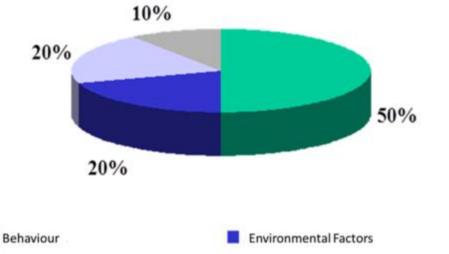
Genetic Factors





Neighborhood and Built Environment



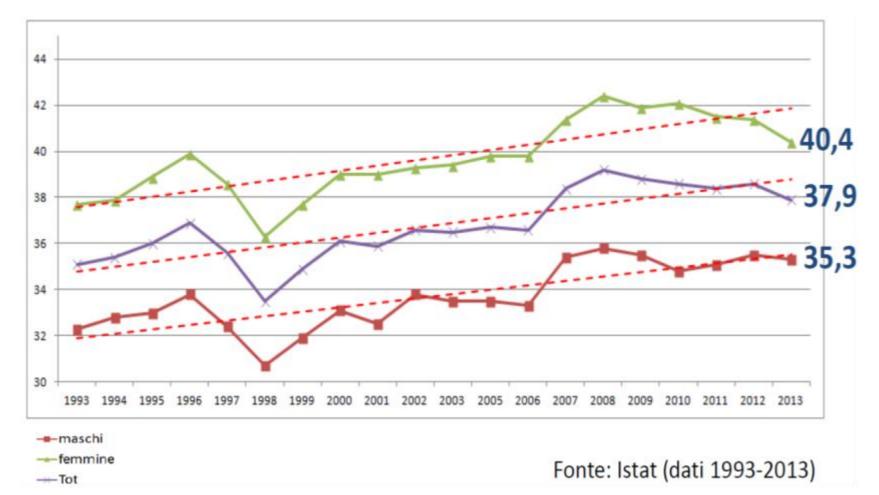


Access to Healtcare Facilities





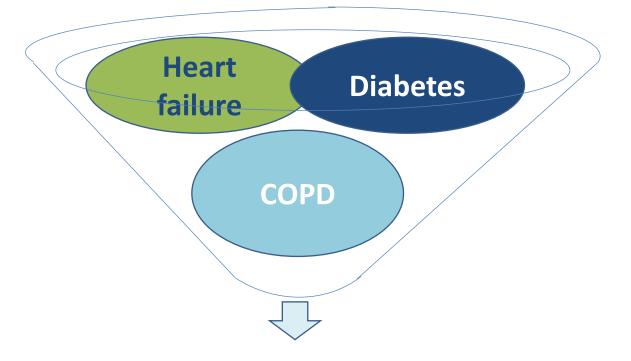
Italy: people with at least a chronic disease (in%)



28

Healthcare expenditure in Italy for the Chronicity



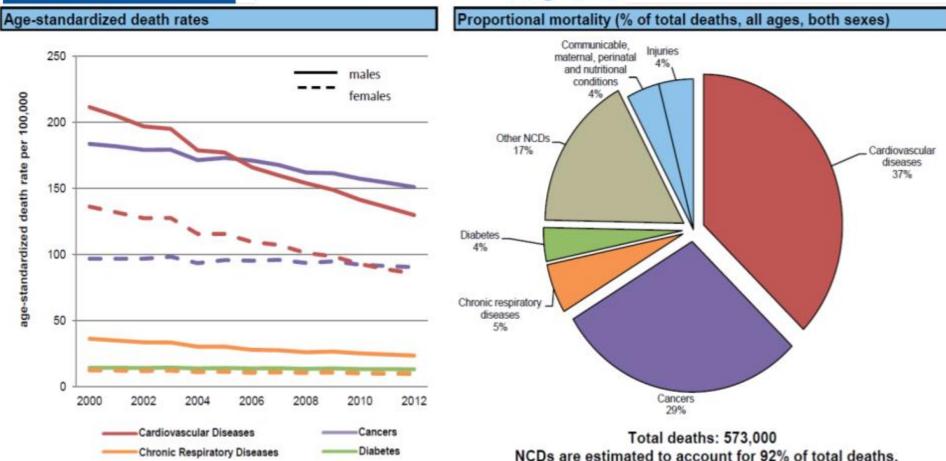


18,5 bln €/year = ~ 16,5%





World Health Organization Noncommunicable Diseases Country Profiles 2014



If the actual 5% of the population with poly-chronic diseases would become 20%, the cost of the health expenditure would double



Biovalley Group Kaiser Permanente (USA): Great Healthcare ICT (HIT) Investments Enabled Quality Improvements on 10 mln people and it reduced costs of chronic diseases

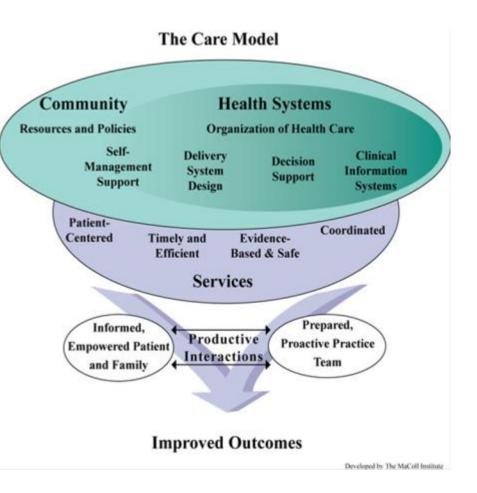


- HIT-Enabled Diabetes Care
 - 44% lower failure rate of metformin treatment for type 2 diabetes
- HIT-Enabled Cholesterol Management²
 - 40% more very high risk patients achieve national cholesterol guidelines
- HIT-Enabled Screening ³
 - Best breast cancer screening rates in US
 - Best HIV/AIDS screening rates in US
- HIT-Enabled Cardiac Care⁴
 - 24% lower probability of death from heart attack
 - 62% lower probability of serious heart attacks doing permanent damage
 - 90% lower mortality from second heart attacks
 - 89% lower all-cause cardiac mortality
- HIT-Enabled Patient Satisfaction ⁵
 - Higher patient involvement in care
 - Over 800% more scheduled e-visits
 - Almost 600% more secure messaging with doctors
 - 24% fewer office visits

Enabling factors for the reduction of costs chronic diseases with Health 4.0

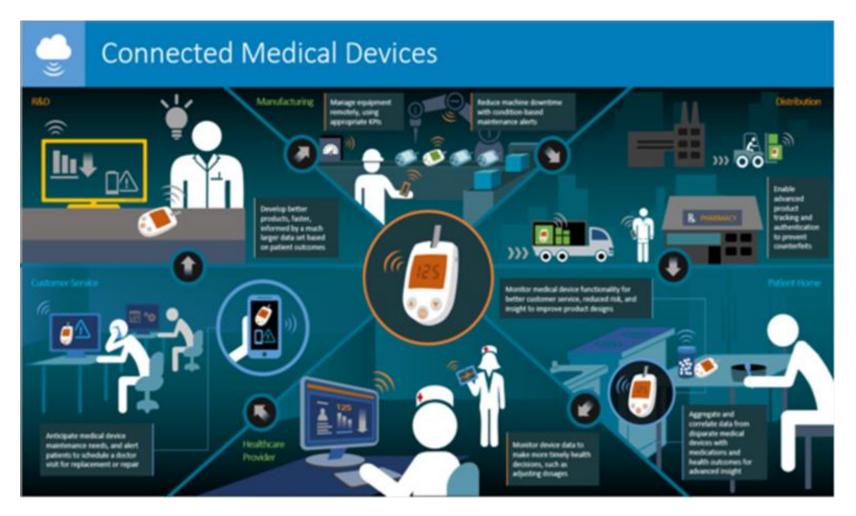


Enabling factor for the transition from the «reactive medicine», structured to answer to the expressed needs of the patient, towards «proactive medicine» the whose purpose is to answer to the needs not yet expressed of the healthy people an to optimize the management of the chronicity according to the chronic care model.



Healthcare 4.0 Role: BioHighTech Enabling Factors

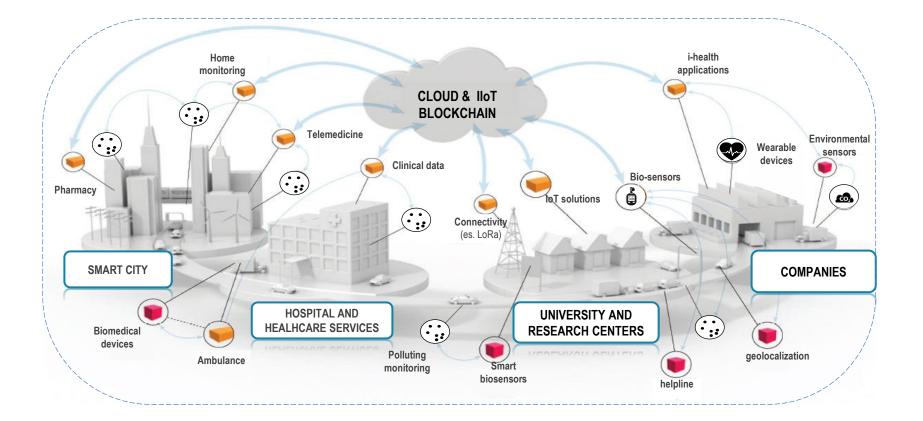




To integrate the BioHighTech technology with the Internet of Things technologies (es. Gatway, Clouds, Mobile Phone) to start the population health management processes. Therefore we could manage the health whenever and wherever it is needed with the proactive medicine, avoiding the healthcare expenditure cuts with economically a more sustainable model 34

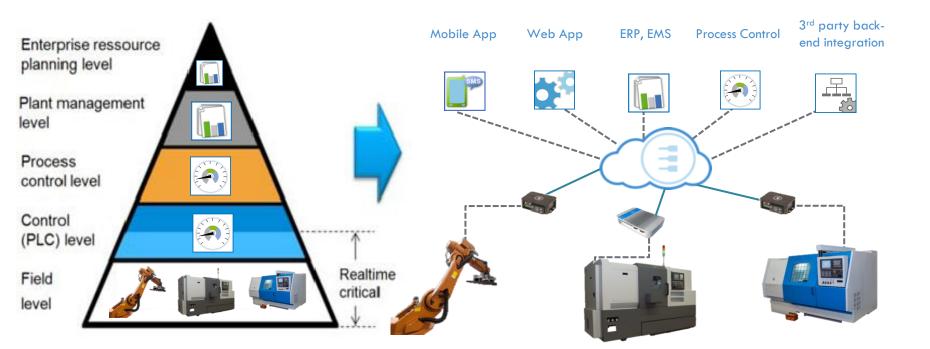
SMART CITIES: HEALTHCARE 4.0 WITH BIOHIGHTECH DEVICES





THE DATA LAKE: THE DAWN OF HEALTH 4.0

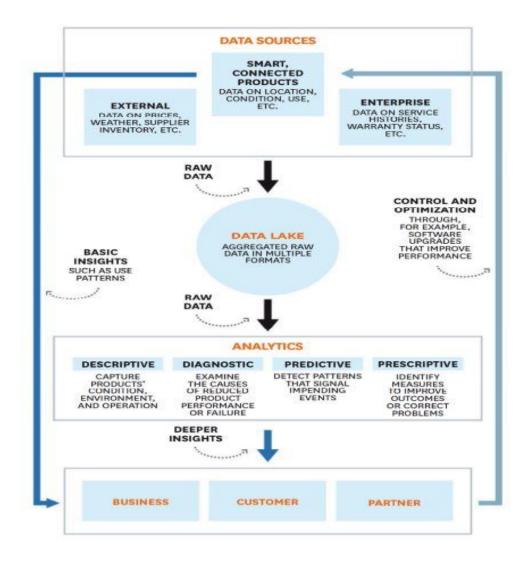




IIoMT is instrumental to the generation of the Data Lake



THE DATA LAKE: PRODUCTS AND ADDED VALUE FOR HEALTH 4.0



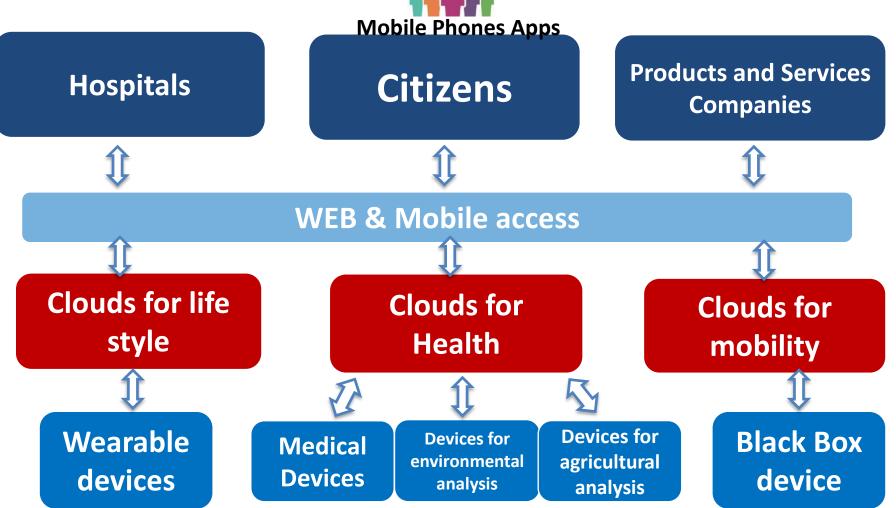
HEALTHCARE 4.0: CLOUD HPC DATA CENTER ROLE







HEALTHCARE 4.0: Industrial Internet of Medical Things Role (IIoMT)



HEALTHCARE 4.0: NEAR AND LONG-TERM IMPACT OF BIG DATA ON THE BUSINESS MODEL





WEF – Industrial Internet Report 2016



HEALTHCARE 4.0: INDUSTRIAL COST MAINTENANCE ADVANTAGES



- Saving on scheduled repairs $\rightarrow \sim 12\%$
- Reduced maintenance costs \rightarrow ~ 30%
- Fewer breakdowns \rightarrow ~ 70%



APPLICATION

HEALTHCARE 4.0: EXAMPLE OF OPERATIONAL AND CLINICAL APPLICATIONS

INDUSTRIAL IoT APPLICATION **IoT GATEWAY** IoT PLATFORM ξÕ _ **DATA ANALYTICS**

> REMOTE MAINTENANCE AND SUPPORT

BIOVALLEY GROUP COMPANY: VISION

Biovalley Group is set as a "Family and Friends Office" by Diego Bravar (founder of TBS Group) for investing in the BioHighTech industrial field and for accelerating the development of the equity value of the target innovative companies in a disruptive entrepreneurial ecosystem also with clinical Engineering outsourcing services.

Alpe Adria geographical regions for target companies:

- Friuli-Venezia Giulia Region in Italy
- Bordering Regions in Italy (Veneto, Trentino-Alto Adige)
- Bordering Countries (Austria, Slovenia, Croatia)
- BioHighTech industrial fields:
- MEDICAL TECHNOLOGY
- BIO TECHNOLOGY
- BIOINFORMATIC & MEDICAL INFORMATIC

Size of BioHighTech Target companies:

 Althea (Large Company) and other Micro, Small and Medium Size BioHighTech Companies







BIOVALLEY GROUP COMPANY: MISSION



- Develop a disruptive entrepreneurial ecosystem in FVG Region and other Alpe Adria Regions accelerating the incubation process of BioHighTech companies from a network of universities, health & social research centers and science & technology parks
- Develop a disruptive entrepreneurial ecosystem starting from FVG Region investing minority equity in micro, small, medium size BioHighTech companies for accelerating the development of their equity value and for supporting the stable development and the equity value growth of a large size BioHighTech company (TBS Group – Althea Group)
- Develop a disruptive entrepreneurial ecosystem starting from FVG Region accelerating the growth of BioHighTech companies improving research & innovation activities between the BioHighTech companies networks and the Research Centers and Hospitals networks for developing innovative products and services

Activity of Biovalley Group from 2017 until 2022: To accelerate the incubation and the industrial growth of the regional BioHighTech sector in order to develop a "disruptive" entrepreneurial open innovation ecosystem





ROADMAP 2017-2022



Activity of Biovalley Group from 2017 until 2022: Business Network Mentoring

- Follow up and management of the BioHighTech Net 4.0 companies network (more than 30 regional – Friuli Venezia Giulia - companies) in order to facilitate the identification of the «Target» companies for equity investments.
- Follow up and management of the BioHighTech Net 4.0 also in order to facilitate the companies' networking and their collaboration with the Research Institutions and Hospitals for attending the research tenders related to the Smart Health Specialization Programs of FVG Region financed by European funds and to other specific regional European research programs.
- Organization of yearly events devoted to biomedical, biotechnology and bioinformatic sector, but also to digital and energy in 2022.





OPEN INNOVATION IN FRIULI VENEZIA GIULIA REGION: FROM RESEARCH ECOSYSTEM TO INNOVATION COMPANIES' NETWORK (BIOHIGHTECH NET 4.0)



OPEN INNOVATION in Friuli Venezia Giulia Region: BIG Group SpA will enhance BioHighTech Net 4.0 companies business development with IoT & Cloud HPC Computing



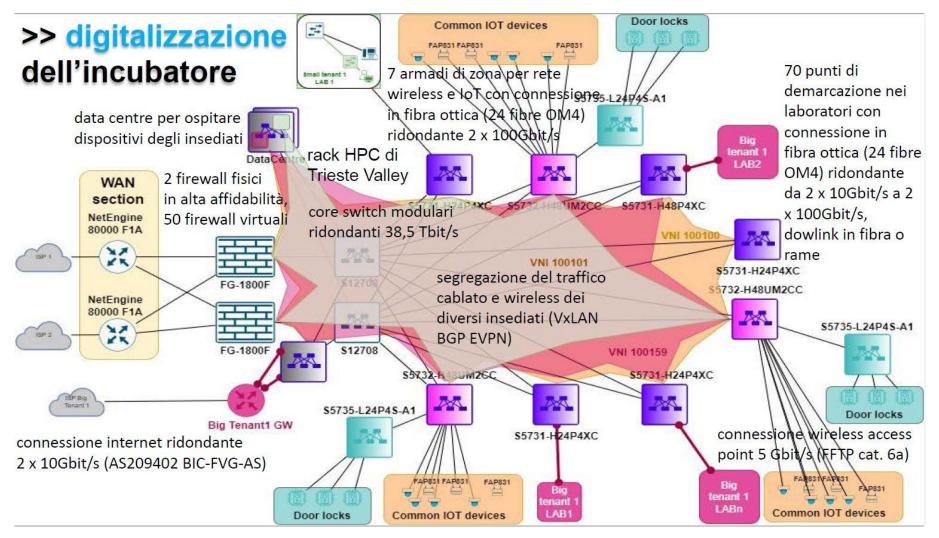
BIG Group SpA strongly focuses on IoT, Cloud and Industry 4.0 to increase innovation in healthcare sector for supporting BioHighTech companies growth.

> Trieste Valley Srl is a Company of the Big Group SpA that acquired a High Performance Computing by Eurotech in 2020.

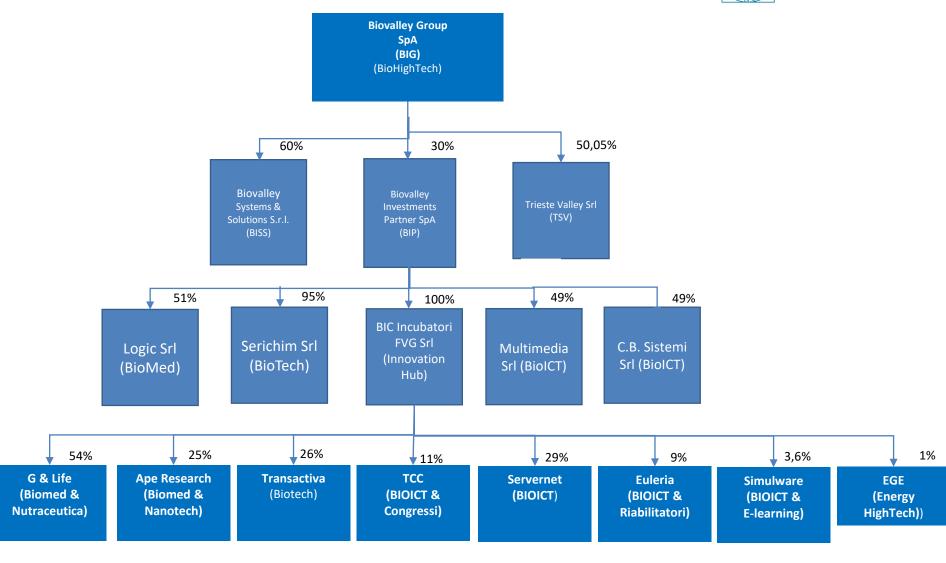


OPEN INNOVATION IN BIC INCUBATORI FVG: BIG Group will enhance with the digitalization the 49 settled companies business development with the IoT and the Cloud HPC Data Center





OPEN INNOVATION in Friuli Venezia Giulia Region: BIG Group investments in innovative SMEs and start ups



Biovalley Group



OPEN INNOVATION in Friuli Venezia Giulia Region: a regional example of connections between entrepreneurial and research ecosystems

TRIESTE SHOWS ONE OF THE HIGHEST RESEARCHERS DENSITY IN ITALY AND IN EUROPE...

- 37 researchers out of 1,000 workers (Italian average 4.9; European average 7.9)
- 10,400 researchers and academics in scientific institutions and universities (out of 204,000 inhabitants 5% of the population)
- The number of foreign researchers in Trieste institutions exceeds 5,200 units (50% of the total)

...TRIESTE ALSO HAS THE HIGHEST ENTREPRENEURS DENSITY IN INNOVATIVE START-UPS IN ITALY

- They work in **58 Innovative High-Tech Start-Ups**
- Trieste is the first Italian city for innovative start-ups density, equal to 1.42% of the total number of companies

Friuli Venezia Giulia (FVG) is the third Italian region in terms of innovative start-ups incidence (more than 200 innovative start-ups), thanks to its excellent research, innovation and educational system and is the Region where the activities of the main European clinical engineering outsourcing services company started in 1987. (TBS Group now Althea Group)

Open Innovation in Friuli Venezia Giulia Region : Smart Health Cluster



FVG Region (Italy) has the "real" possibility of transforming the knowledge ("oil") that is in many research institutions and regional Hospitals with innovation, accelerating the incubation and growth of regional BioHighTech companies (about 5.000 employees in this sector) having adopted a Smart Specialization strategy on "Smart Health" for European Region Research Program (2015-2022).

Trieste as a regional capital with a potential high GEI index could become the potential Capital of innovation in the BioHighTech sector with an "immediate" use of the huge "national" and "international" investments made with the support of Italian Government in this city during the last 30 years (about 300mln of Euro per year – 1.500 Euro per capita) to develop the innovation from the research activity of various Universities and Research Centers even in the Smart Health field (i.e. 2 Universities, 2 Academic Hospitals, Sincrotrone Elettra, International Center for Genetic Engineering and Biotechnology, International Center for Theorical Phisics, etc.).

Indeed Euroscience selected Trieste as European Capital of Science from 2018 to 2020 for organizing the ESOF2020 and the Health Care has become one of the main topic treated from different perspectives (science to science, science to citizen, science to policy and science to business).



Trieste Valley Innovation Hub Project (2022-2025)

The aim of the project «TRIeste valley innovaTION hub», acronym TRITION, is to create a technological infrastructure for innovation to strengthen the collaboration and connection between scientific bodies and SMEs operating in the fields of life sciences, artificial intelligence and energy transition. The project is promoted by OGS with an international outlook and will be implemented with the participation of Trition Srl company, of which BIC Incubatori FVG is a shareholder; BIC boasts more than thirty years of experience in services for the establishment, growth and consolidation of innovative companies. The main infrastructure output of the project will consist of three new laboratories specialized respectively in life sciences (BioHighTech), artificial intelligence (Digital HighTech) and energy transition (Energy HighTech), obtained from the expansion and modernization of some existing buildings in the ex Olcese disused industrial area (near BIC). The labs will be made available to OGS and other scientific entities and private companies to foster shared R&D projects that will be overall managed by BIC Incubatori FVG.

Trieste Valley Innovation Hub Project (2022-2025)



In the energy transition area, R&D projects will be managed by Serichim (the second Trition Srl shareholder) and will be focused on the Green Hydrogen innovative transport, and on Innovative Energy Storage Solutions. In the life science area, R&D projects will be managed by Serichim and will be focused on Chemical, Biochemical, Cellular and Molecolar Biology, Sensors and Biomaterials. In the artificial intelligence area, R&D projects will be managed by Trieste Valley (the third Trition Srl shsareholder) and will be focused on High Performance Computing (HPC), High Throughput Computing (HTC), and High Performance Data Analysis (HPDA).

The topics to be developed with the R&D project of this OGS proposal have been selected by the Italian Minister of University and Research considering the scientific and academic know-how localized in Friuli Venezia Giulia Region represented by OGS (scientific project promoter) with the involvement of the Innovation Hub and the high specialization of SMEs of FVG competences and bordering Countries and Regions (Slovenia, Croatia, Carinthia, Styria, Hungary, Veneto). The project basilar assumption is that a strong connection element between the OGS scientific competences and the technological infrastructure for Trition innovation will be the right answer for SMEs execution attitude to develop innovation.



THANK YOU