



# **HUMAN FACTOR IN CYBERSECURITY**

## **ACCA 2025**

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[cylcomed.eu](http://cylcomed.eu)

# Cybersecurity Toolbox for Connected Medical Devices



## KU Leuven: Legal and Ethical Partner in CYLCOMED Project

- **Role:** Ensures ethical and legally compliant use of innovative solutions to enhance the cybersecurity of connected medical devices (CMDs).
- **Expertise:** Develops an ethical and legal framework addressing privacy, data protection, CMD regulations, and cybersecurity legislation.
- **Track Record:** Renowned for expertise in AI, autonomous systems, data protection, eHealth, ethics & law, intellectual property, media, telecommunications, and cybersecurity. Longstanding partner in large international and interdisciplinary research projects.



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Education and Research EAER  
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Research and Innovation SERI

# CYBERSECURITY INCIDENTS ARE HITTING THE HEADLINES



CYBERATTACK

The cyberattack that has paralysed Barcelona's Hospital Clínic: "No ransom will be paid"

Major Catalan public hospital hopes to resume some activity progressively from Tuesday after serious ransomware attack

Nura Portella  
Photo: ACN  
Barcelona, Monday, 6 March 2023, 13:07  
Updated: Tuesday, 13 February 2024, 09:46  
Reading time: 2 minutes

Cyber Security News

## Transport for London Faces Cyber Attack Operation Distributed

By Balaji N - September 3, 2024



THE IRISH TIMES

## HSE cyber attack: More than 470 legal proceedings issued against health service after ransomware hit

Leak by Conti, the Russia-based crime group, compromised personal data of almost 100,000 staff and patients

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Forbes

Billionaires Innovation Leadership Money Business Small Business Life

14,889 views | Jun 26, 2019, 05:28am

## FDA Warns Of Dangerous Cybersecurity Hacking Risk With Connected Medical Devices

Zak Doffman Contributor @ Cybersecurity  
I write about security and surveillance.



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## Thousands of UK troops hit in suspected Chinese hack on defense ministry

Defense Secretary Grant Shapps briefed the House of Commons Tuesday afternoon — but is avoiding publicly pointing the finger at Beijing.

Home / Tech / Security

## First death reported following a ransomware attack on a German hospital

Death occurred after a patient was diverted to a nearby hospital after the Duesseldorf University Hospital suffered a ransomware attack.



**2023 DATA BREACH REPORT**

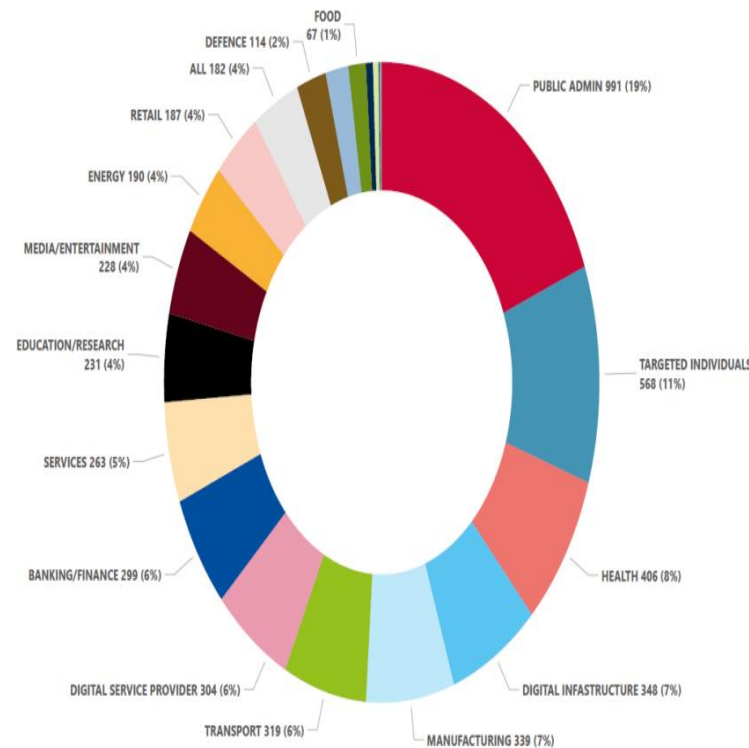
The Annual Data Breach Report explores a dramatic increase in reported data compromises and the underlying trends behind the growth. 2023 represented an all-time high for data compromises reported in the United States.

**ITRC** IDENTITY THEFT RESOURCE CENTER  
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## Top Compromises by Industry



## ENISA THREAT LANDSCAPE 2023



**THE 2024 STUDY ON CYBER INSECURITY IN HEALTHCARE: THE COST AND IMPACT ON PATIENT SAFETY AND CARE**

Independently conducted by:  
**Ponemon INSTITUTE**

**92%**

of organizations in this research had at least one cyberattack over the past 12 months

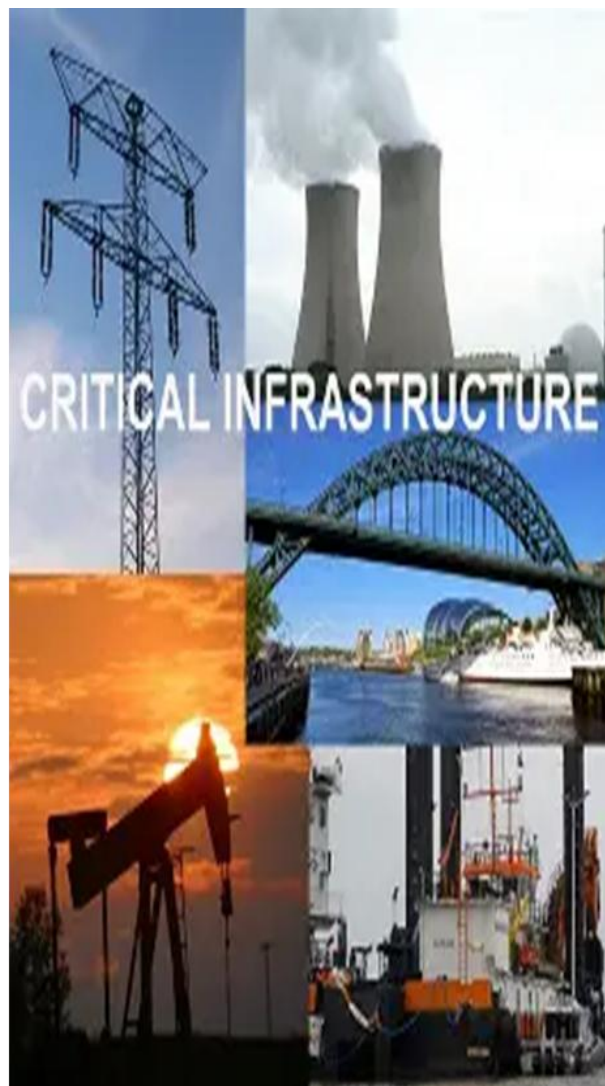
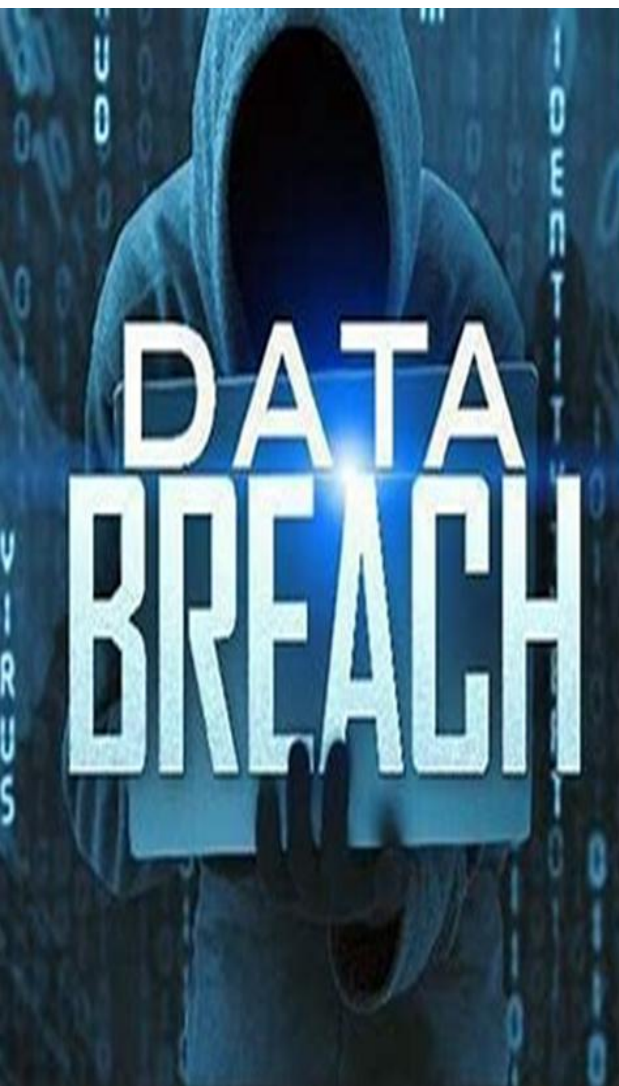
**\$4.7M**

is the average total cost for the single most expensive cyberattack experienced over the past 12 months

**\$1.47M**

in disruption to normal healthcare operations was on average the most significant financial consequence from the cyberattack

# WHAT IS AT STAKE? DIRE CONSEQUENCES OF CYBERATTACKS





- Cybersecurity Strategy for the Digital Decade
- European Action Plan on the Cybersecurity of Hospitals and Healthcare Providers





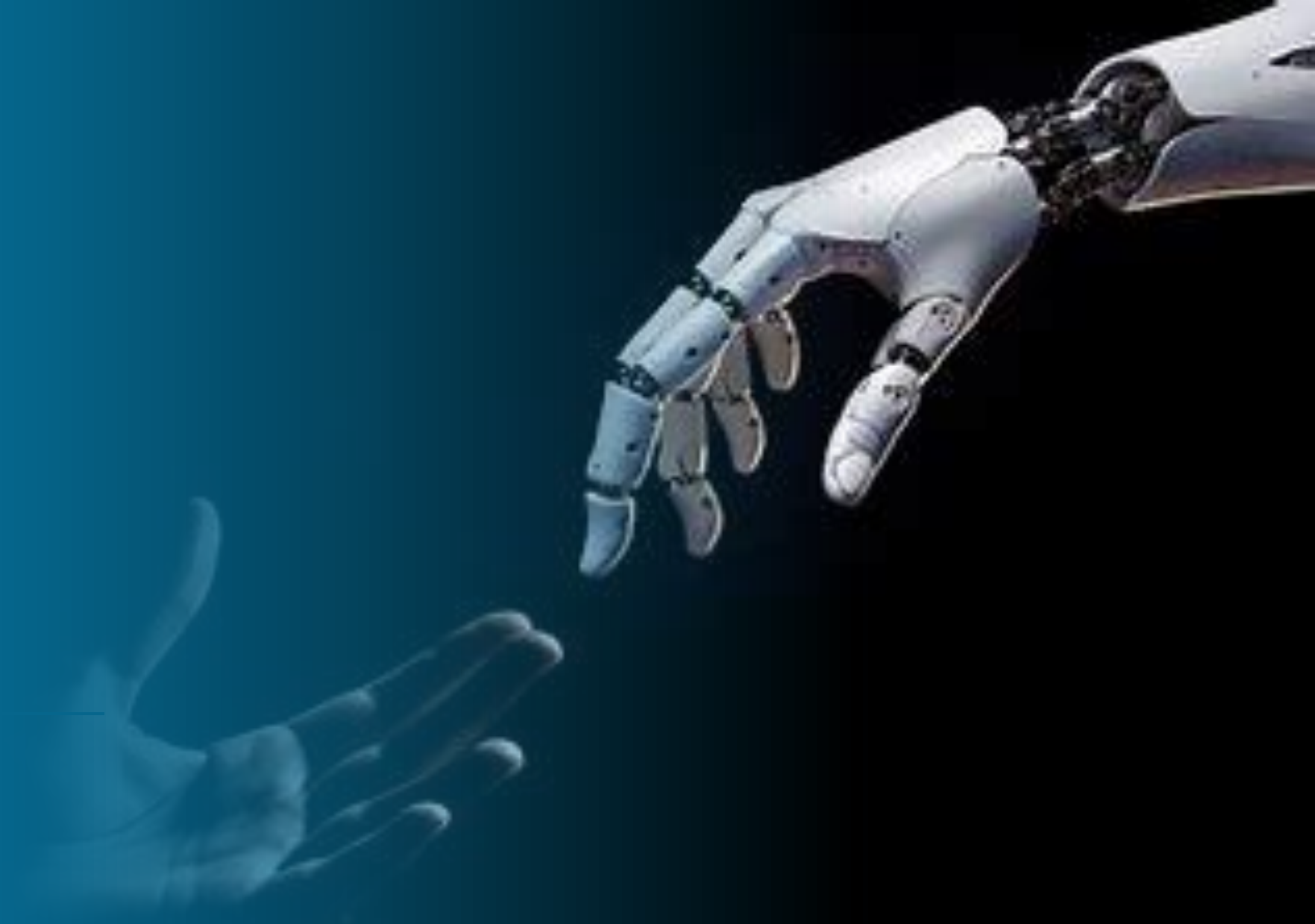
- Cybersecurity Act (CA)
- Network and Information Systems Directive (NIS2)
- General Data Protection Regulation (GDPR),
- Cyber Resilience Act (CRA)
- Artificial Intelligence Act (AI Act)
- Regulation on the European Health Data Space (EHDS)
- Medical Device Regulation (MDR)
- .....



- Encryption
- Anonymisation
- Patch Management
- Multi-factor authentication (MFA)
- Least privilege principle
- Firewalls (hardware or software-based)
- Intrusion Detection Systems (IDS)
- Intrusion Prevention Systems (IPS)
- .....



# HUMAN FACTOR



Human factor contributed to approximately 68% of breaches

Human error remains a critical threat area, consistently ranking highly, if not the top category



## SCHOLARLY LITERATURE

- “human factor”
- “human element”
- “human dimension”
- “insider threat”
- “end-user”
- “human resources security”
- .....

## REGULATIONS

- NIS2 explicitly mentions the “human factor” in its Recital 78, and “human resource security” (Recital 79)
- Recital 8 of the CSA points out that cybersecurity is not only an issue related to technology but also one where **human behavior** is equally important



# HOW TO ADDRESS THE HUMAN FACTOR?



## LACK OF RESOURCES

- NIS investment report highlights significant disparities in investments across critical infrastructure, revealing a gap that threatens the collective goal of a cyber-secure EU
- Healthcare historically faces the underfunding, facing significant trade-offs

## LACK OF CYBERSECURITY EXPERTS

- The ISC2 (2024) report estimated that 299,000 cybersecurity professionals are needed to meet EU workforce demands
- Eurobarometer survey highlights the growing cybersecurity talent gap across the EU
- Some sectors, such as healthcare, are even more under pressure

## NIS2

- Risk management measures shall include at least, inter alia, “basic cyber hygiene practices and cybersecurity training”
- Member States shall ensure that the **members of the management bodies** of essential and important entities **are required to follow training**, and shall **encourage** essential and important entities **to offer** similar training to their employees on a regular basis (NIS Article 20)

GDPR, MDR, AI ACT...

## TECHNICAL AND “ORGANISATIONAL” MEASURES



The infographic features a dark blue background. At the top left, the text 'GDPR' is written in large white letters, with 'General Data Protection Regulations' in smaller white text below it. To the right of this, there is a circular arrangement of twelve yellow stars, with the number '32' in white in the center. A horizontal white line separates the top section from the bottom. In the bottom left, the text 'Article 32: Security of Data Processing' is written in white. To the right of this text is a white right-pointing triangle. Further to the right is a yellow rectangular box with a black border containing the text: 'Organizations must 'implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk' of processing personal data.'



- Should cybersecurity legal frameworks incorporate stronger enforcement mechanisms, accountability models, and proactive human risk management strategies to enhance human factor governance?
- Do we need more terminological clarity, coherence, and legal consistency between legal frameworks regarding the human factor?



**THANK YOU FOR YOUR ATTENTION**



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