

# WELCOME

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GLOBAL CONNECTED HEALTHCARE CYBERSECURITY VIRTUAL WORKSHOP SERIES

## IEEE CYBERSECURITY TIPSS FOR INDUSTRY



## Securing IoTs for Remote Subject Monitoring in Clinical Trials

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18 JUNE 2024 | 1PM – 3PM ET

**IEEE SA** STANDARDS  
ASSOCIATION



HEALTHCARE &  
LIFE SCIENCES

 **IEEE**

# WORKSHOP MODERATOR

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## **MARIA PALOMBINI**

Director, Healthcare & Life Sciences  
Practice Global Lead  
IEEE SA

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# ABOUT THE IEEE

## Mission

- The core purpose of IEEE is to foster technological innovation and excellence for the benefit of humanity

## Vision

- IEEE will be essential to the global technical community and to technical professionals everywhere, and be universally recognized for the contributions of technology and of technical professionals in improving global conditions



# ADVANCING TECHNOLOGY FOR HUMANITY

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## ABOUT IEEE

Inspiring a global community of innovation

Where forward-thinking professionals collaborate

Discover what's next in tech innovation

Build technical communities

Shape and share research

Create global standards

Engage in Humanitarian activities

# IEEE BY THE NUMBERS

**450K+**

MEMBERS

**160+**

COUNTRIES

**46+**

TECHNICAL SOCIETIES  
& COUNCILS

**1900+**

ANNUAL CONFERENCES

**5M+**

TECHNICAL DOCUMENTS

# PORTFOLIO OF PROGRAMS & SERVICES

## Industry Connections

Exploring & incubating new tech & its use



## Standardization

Creating markets & protecting public safety through standards development



## Membership

Connecting to experts & resources with advanced participation options



## Conformity Assessment

Providing confidence & assurance & accelerating market adoption

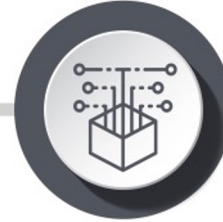


# IEEE SA

STANDARDS ASSOCIATION

## Open Source

Providing a community-powered platform to support open source projects



## Alliance Management

Providing support to alliances & trade associations



## Registries

Providing unique identifiers to support global compatibility & interoperability



# IEEE SA BY THE NUMBERS

**1500+**

STANDARDS  
& PROJECTS

**380+**

CORPORATE  
MEMBERS

**7500+**

INDIVIDUAL  
MEMBERS

**34,000+**

GLOBAL PARTICIPANTS

**180+**

GLOBAL AGREEMENTS



#IEEEHLS



# HEALTHCARE AND LIFE SCIENCES

To improve the global standard quality of life at every step through affordable healthcare and access to medicines; support innovation to improve overall wellness and improve societal outcomes; and to enable innovation through open and standardized means.

Three Major Branches of Focus

1. Pharma/Biotech
2. Clinical Health
3. Global Wellness

<https://ieeesa.io/hls>



GLOBAL CONNECTED HEALTHCARE CYBERSECURITY VIRTUAL WORKSHOP SERIES

# IEEE CYBERSECURITY TIPSS FOR INDUSTRY

UPCOMING SESSION

**TUESDAY, 18 JUNE 2024 | 1:00 – 3:00 PM ET**

SPEAKERS



**GILLES  
LUNZENFICHTER**  
CEO and Founder,  
Medisanté



**RYAN WRIGHT**  
CEO, NVlope LLC;  
Missouri Ambassador,  
Blockchain in  
Healthcare Today



**MARIA PALOMBINI**  
Director, IEEE SA  
Healthcare & Life  
Sciences



**FLORENCE HUDSON**  
Executive Director,  
Northeast Big Data  
Innovation Hub



**REGISTER TODAY: [ieeesa.io/tipss-workshops](https://ieeesa.io/tipss-workshops)**

# VIRTUAL WORKSHOP HOUSEKEEPING ITEMS

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- This session will be recorded in its entirety.
- The first half of this session is one-way broadcast. The audience is automatically muted.
- Questions for the panelists may be submitted through the Q&A feature
- There are interactive polling questions to get your perspective on the challenges in this area
- The second half of this broadcast will be a brainstorming session to build the use case requirements for this industry use case of IEEE 2933

# Audience Poll Q1

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Which of the following features do you consider most critical in evaluating wearables/ IoTs/sensors for remote subject monitoring in a clinical research project?

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# Audience Poll Q2

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Which of the following do you consider the biggest challenge in using wearables/sensors/IoT s for remote subject monitoring?

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# BRAINSTORMING SESSION



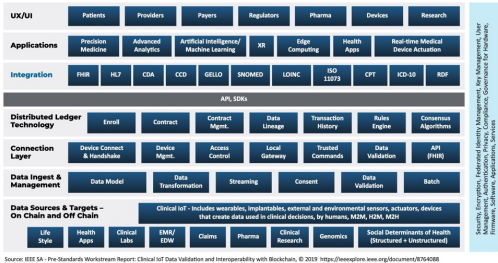
## GUIDELINES

- Build on the ideas of others
  - Stay to the topic
  - No judgements
  - Think big
  - Think out of the box
-

# BRAINSTORMING TO BUILD USE CASE REQUIREMENTS

### ARCHITECTURE

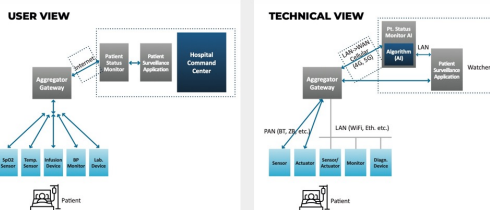
#### IEEE TIPSS Architectural Framework for Clinical IoT Data and Device Interoperability



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### IEEE P2933™ USE CASE: HOSPITAL @ HOME

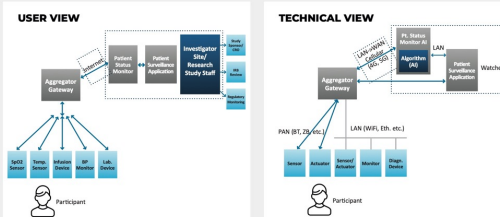
#### IEEE P2933™ Use Case 1: Hospital to the Home\*



\*Source: IEEE SA - Pre-Standard Work Item Report: Clinical IoT Data and Device Interoperability with TIPSS – Trust, Identity, Privacy, Protection, Safety, Security

### PROPOSED CT USE CASE: REMOTE PARTICIPANT MONITORING

#### Proposed CT Use Case: Remote Participant Monitoring

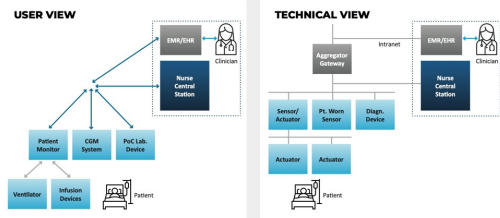


This poster demonstrates an approach to leverage the framework of IEEE P2933™ - Standard for Clinical Internet of Things (IoT) Data and Device Interoperability with TIPSS – Trust, Identity, Privacy, Protection, Safety, Security, to enable DCTs as a care option using Hospital at Home and local healthcare providers approaches for remote patient monitoring. Considering the synergies that exist between the standard healthcare system and clinical research following patient-centric approaches, the IEEE has two programs in progress for global technical standards for IoTs used in Hospital at Home (IEEE P2933™) and the implementation enabled by Digital Health Technologies (DHTs), IEEE P2968.2™) that includes Technical Recommended Practices for Decentralized Clinical Trials Threat Modeling, Cybersecurity, and Data Privacy. The new standards will support trusted adoption of digital technologies that enable patients to participate in DCTs from the ecosystems where they live while having key physiological parameters monitored 24/7

**SCAN THE QR CODE TO LEARN MORE ABOUT THIS PROGRAM**

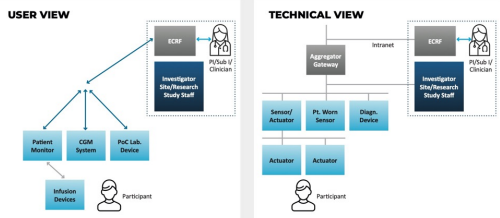


### IEEE P2933™ Use Case 2: Home to Hospital\*



\*Source: IEEE SA - Pre-Standard Work Item Report: Clinical IoT Data and Device Interoperability with TIPSS – Trust, Identity, Privacy, Protection, Safety, Security

### Proposed CT Use Case: Participant to Research Site



# NEXT STEPS

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## GET INVOLVED IN THE PAR STUDY GROUP FOR IEEE 2933 TIPSS FOR CLINICAL IOTS IN REMOTE SUBJECT MONITORING

To get involved write to [m.palombini@ieee.org](mailto:m.palombini@ieee.org) by 31 August 2024

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# UPCOMING WORKSHOPS

GLOBAL CONNECTED HEALTHCARE CYBERSECURITY VIRTUAL WORKSHOP SERIES

## IEEE CYBERSECURITY TIPSS FOR INDUSTRY



### TIPSS FOR PRECISION AGRICULTURE

16 JULY 2024 | 11 AM – 1 PM ET

### TIPSS FOR CONNECTED VEHICLES

24 SEP 2024 | 11 AM – 1 PM ET

### TIPSS FOR TRANSACTIVE ENERGY

12 NOV 2024 | 11 AM – 1 PM ET





# DIGITAL HEALTH TECH FORUM & RECEPTION

TUESDAY, 30 JULY 2024 | 1:00 – 6:00 PM ET

Hyatt Regency Boston

## SPEAKERS



**JIM MATTHEWS**  
IEEE SA President



**MICHAEL CARTER**  
Senior Director,  
Enterprise Architect  
Mass General Brigham



**FLORENCE HUDSON**  
Executive Director,  
Northeast Big Data  
Innovation Hub



**BRUCE HECHT**  
CEO, VG2PLAY



**GEOFFREY GILL**  
CEO & Founder,  
Verisense Health



**GARY STUEBING**  
Chair, IEEE CAG  
Board



**DR. RABEEH MAJIDI,  
PhD**  
CEO & Co-Founder,  
OrthoKinetic Trac



**DR. YURI QUINTANA,  
PhD, FACMI**  
Chief of the Division of  
Clinical Informatics, Beth  
Israel Deaconess Medical  
Center



**MARIA PALOMBINI**  
Director, Global Healthcare  
and Life Sciences Practice,  
IEEE SA

**REGISTER TODAY: [ieeesa.io/DigitalHealthBoston](https://ieeesa.io/DigitalHealthBoston)**



# IEEE PRE-STANDARDS INCUBATOR PROGRAMS: AI + HEALTH



**TRANSFORMING THE TELEHEALTH PARADIGM: SUSTAINABLE CONNECTIVITY, ACCESSIBILITY, PRIVACY, AND SECURITY FOR ALL**  
This program provides a platform for the global community to openly develop technical solutions to challenges impeding trust and validation, security, interoperability, accessibility, feasibility and integration telehealth systems. <https://ieeesa.io/telehealthic>



**CLINICAL TRIALS TECHNOLOGY MODERNIZATION NETWORK**  
Prioritize the areas DCT using DHT standards can accelerate adoption, mitigate risks, and optimize efficiencies with sponsors, regulators, sites, technologists, service providers, patient advocacy organizations, and other relevant stakeholders. <https://ieeesa.io/rct>



**ZERO TRUST CYBERSECURITY FOR HEALTH TECHNOLOGY TOOLS, SERVICES, AND DEVICES**  
Develop a roadmap to a suite of new zero-trust network access (ZTNA) standards that integrate commercial and open-source products to showcase robust security features of Zero Trust Architecture (ZTA) when applied to enterprise IT use cases. <https://ieeesa.io/zerotrusthealth>

# JOIN YOUR PEERS

## Telehealth Start-up Global Community

- TAP TECH MENTORS
- EARN DEMO OPP & CREDITS
- CREATE PARTNERSHIPS
- BECOME A CHANGE AGENT

**LEARN MORE**

[ieeesa.io/telehealth-startup](https://ieeesa.io/telehealth-startup)



## How we collaborate?

- Think tank for identifying challenges and potential solutions in telehealth innovation
- Supporting start-ups with industry knowledge, tools and resources
- Creating an environment to form partnerships and knowledge sharing

*Sign up at [ieeesa.io/telehealth-startup](https://ieeesa.io/telehealth-startup)*

# THANK YOU

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## **MARIA PALOMBINI**

Healthcare & Life Sciences  
Practice Global Lead, IEEE SA

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[Linkedin.com/in/mpalombini](https://www.linkedin.com/in/mpalombini)

<http://ieeesa.io/hls>

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# APPENDIX

# INCUBATOR PROGRAMS – HEALTHCARE & LIFE SCIENCES

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- Clinical Trials Technology Modernization Network
- Transforming the Telehealth Paradigm
- Neuro Tech for Brain-Machine Interfacing
- Ethical Assurance of Data-Driven Technologies for Mental Healthcare
- Zero Trust for Cybersecurity of Healthcare Devices and Technologies (NEW)
- Global Initiative on Blockchain-based Omnidirectional Pandemic
- The IEEE Global Artificial Intelligence Systems (AIS) Well-being Initiative
- Synthetic Data
- Digital Inclusion, Identity Trust and Agency (DIITA)
- Surveillance AI Systems for Governance for Cities
- Enabling A Smart And Equitable Agriculture Ecosystem

<https://standards.ieee.org/industry-connections/activities.html>

# IEEE STANDARDS PROJECTS RELATIVE TO TOPIC

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- P1528.7 - Guide to Assess the Electromagnetic Fields (EMF) Exposure of Internet of Things (IoT) Technologies/Solutions
- P2802 - Standard for the Performance and Safety Evaluation of Artificial Intelligence Based Medical Device: Terminology
- P2418.6 - Standard for the Framework of Distributed Ledger Technology (DLT) Use in Healthcare and the Life and Social Sciences
- **IEEE 2933 -2024 Standard for Clinical Internet of Things (IoT) Data and Device Interoperability with TIPPSS (Trust, Identity, Privacy, Protection, Safety, Security)**
- IEEE 2791-2020 - IEEE Standard for Bioinformatics Analyses Generated by High-Throughput Sequencing (HTS) to Facilitate Communication
- **P2968.1 - Trial Use Recommended Practice For Decentralized Clinical Trials Patient Safety**
- **P2968.2 - Trial Use Recommended Practice for Decentralized Clinical Trials Threat Modeling, Cybersecurity, and Data Privacy**
- IEEE P3493.1 Standard Framework for Secure, Compliant, Coordinated, and Inclusive Healthcare Data Recycling: Cancer Care

# IEEE STANDARDS PROJECTS RELATIVE TO TOPIC

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- IEEE 11073 Suite –Health Informatics - Personal Health Device Communication - Device Specialization
- **IEEE 1752.1 -2021 - IEEE Standard for Open Mobile Health Data--Representation of Metadata, Sleep, and Physical Activity Measures**
- IEEE 2621.3-2022 - IEEE Recommended Practice for Wireless Diabetes Device Security: Use of Mobile Devices in Diabetes Control Contexts
- **P1752.2 – Standard for Mobile Health Data for Cardiovascular Activity**
- P2550 - Standard for Remote Monitoring of a Neonate and the Mother Post-Partum in a Non-Clinical Healthcare Setting
- P2650 - Standard For Enabling Mobile Device Platforms To Be Used As Pre-Screening Audiometric Systems
- **1708-2014 - IEEE Standard for Wearable Cuffless Blood Pressure Measuring Devices**
- P2673 - Standard for Patient Digital Biomedical Data Files with 3D Topological Mapping of Macroanatomy and Microanatomy for Use in Big Data and Augmented Intelligence Systems
- P2418.1 - Standard for the Framework of Blockchain Use in Internet of Things (IoT)