

**Supply Chain & Trials Standardized Technology and Implementation
Industry Connections Activity
Initiation Document (ICAID)
Version: 1.0, 31 July 2017**

IC17-012-01 Approved by the IEEE-SASB 28 September 2017

Instructions

- Instructions on how to fill out this form are shown in red. It is recommended to leave the instructions in the final document and simply add the requested information where indicated.
- **Shaded Text** indicates a placeholder that should be replaced with information specific to this ICAID, and the shading removed.
- Completed forms, in Word format, or any questions should be sent to the IEEE Standards Association (IEEE-SA) Industry Connections Committee (ICCom) Administrator at the following address: industryconnections@ieee.org.
- The version number above, along with the date, may be used by the submitter to distinguish successive updates of this document. A separate, unique Industry Connections (IC) Activity Number will be assigned when the document is submitted to the ICCom Administrator.

1. Contact

Provide the name and contact information of the primary contact person for this IC activity. Affiliation is any entity that provides the person financial or other substantive support, for which the person may feel an obligation. If necessary, a second/alternate contact person's information may also be provided.

Name: Carole Carey

Email Address: carolecarey@mac.com, c.carey@ieee.org

Phone:

Employer: C3-Carey Consultants, LLC

Affiliation: C3-Carey Consultants, LLC

Name: Tim Mackey

Email Address: mackey@ucsd.edu

Phone:

Employer: University of San Diego, School of Medicine

Affiliation: University of San Diego, School of Medicine

2. Participation and Voting Model

Specify whether this activity will be entity-based (participants are entities, which may have multiple representatives, one-entity-one-vote), or individual-based (participants represent themselves, one-person-one-vote).

Entity-Based: As an outreach activity in a rapidly evolving technology field, the IC needs to engage with a diverse and widely dispersed technology development and implementation community.

3. Purpose

3.1. Motivation and Goal

Briefly explain the context and motivation for starting this IC activity, and the overall purpose or goal to be accomplished.

The explosive growth of the internet and accessibility to information has created a new class of consumers and patients who have expressed concern and wariness of trust, safety, and security in two critical consumables: food and medicine. The lack of interoperability with current operating systems has created an opportunistic market of fraudulent data and counterfeit products that directly impact patient care and consumer health with adverse effects including death.

[See Addendum 1](#) for statistics on alarming trends on supply chain and clinical trials inefficiencies leading to increased financial and human costs for consumers and patients.

IEEE is one of few organizations seeking to address the issue of security and authenticity of the food and drug supply through interoperability of data systems. The scope of this ICAID encompasses the following work streams that touch upon multiple facets of patient and consumer safety and supply chain and clinical trials optimization.

Work stream 1: Pharmaceutical Supply Chain & Blockchain

- Creation of an incubator program that presents nine models using blockchain as a standard to manage and comply with serialization guidelines for track and trace under the US FDA's DSCSA.
- Identify a framework for standards for blockchain to interoperate with existing track and trace and ERP technologies to combat the rising risk of counterfeits and internet pharmacies, inefficiencies in inventory management, and better anticipate "drug shortages"
- Create a pathway for engaging and developing a community of Pharmaceutical professionals for IEEE
- Exploring capabilities for interoperability on the supply chain to respond to the emerging dynamics around personalized medicine and additive manufacturing (i.e., 3D Printing)
- Creation of an incubator program that explores the use of a public, permissioned blockchain where multiple pharmaceutical manufacturers provide their supply chain data to create comprehensive "know your source" platform to combat pharma counterfeits
- The working groups would like to create white papers, standards recommendations, research reports, webcasts and in-person forums to educate on industry developments

Work stream 2: Clinical Trials & Blockchain

- Explore framework for standards for making blockchain and EDI (Electronic Data Interchange) platforms interoperable to better authenticate data from various clinical sites and phases through the approval process
- Facilitate a more inclusive platform for patient engagement for clinical trials utilizing distributed ledger technologies, AI and wearables/sensors

- The working groups would like to create white papers, standards recommendations, research reports, webcasts and in-person forums to educate on industry developments

Work stream 3: Medical Device Supply Chain and Blockchain

- Identify a framework for standards for blockchain to interoperate with existing track and trace and ERP technologies to authenticate the source of the device and reduce fraudulent devices impacting patient health.
- The working groups would like to create white papers, standards recommendations, research reports, webcasts and in-person forums to educate on industry developments

Potential Work Stream 4: Agribusiness and Blockchain

- Explore the framework for standards for the use of blockchain and IoT to verify the source of food as it travels from multiple destinations to supermarkets and distribution centers
- Explore the framework of sensors, IoT and blockchain for the development of SMART FARMS allowing for more efficient use of water, energy, and space to optimize the food supply chain from farm to table.
- The working groups would like to create white papers, standards recommendations, research reports, webcasts and in-person forums to educate on industry developments.

3.2. Related Work

Provide a brief comparison of this activity to existing, related efforts or standards of which you are aware (industry associations, consortia, standardization activities, etc.).

N/A

3.3. Previously Published Material

Provide a list of any known previously published material intended for inclusion in the proposed deliverables of this activity.

List the previously published material, if any.

3.4. Potential Markets Served

Indicate the main beneficiaries of this work, and what the potential impact might be.

Describe the potential markets.

A major focus will be on standards that facilitate interoperability, security and optimization of supply chains that traditionally direct the quality of care for patients and consumers.

Regulatory agencies, patient advocacy and technology developers will be key contributors to

this work, to help develop recommendations for standards including technical realities and business challenges to be achieved in this vision.

The program will address industry verticals as opportunity arises. Currently identified stakeholder communities are:

- Bio/Pharmaceuticals
- Medical Devices
- Healthcare
- Agribusiness

4. Estimated Timeframe

Indicate approximately how long you expect this activity to operate to achieve its proposed results (e.g., time to completion of all deliverables).

Expected Completion Date: 09/2019

IC activities are chartered for two years at a time. Activities are eligible for extension upon request and review by ICom and the IEEE-SA Standards Board. Should an extension be required, please notify the ICom Administrator prior to the two-year mark.

5. Proposed Deliverables

Outline the anticipated deliverables and output from this IC activity, such as documents (e.g., white papers, reports), proposals for standards, conferences and workshops, databases, computer code, etc., and indicate the expected timeframe for each.

Over the two-year period, a broad range of deliverables are expected from the identified work streams.

Work stream 1, anticipated deliverables include proposals for creation of an incubator program and standards, and proposals for conferences and workshops to promote the awareness of standards and work, development of industry research study (Oct 2017) on gap analysis for adoption of technology

Work stream 2, anticipated deliverables include white papers, reports, and proposals for standards, conferences, and workshop, development of industry research study on gap analysis for adoption of technology

Work stream 3, anticipated deliverables include white papers, reports, proposals for test methodologies and standards, simulation tool models, and proposals for conferences and workshops.

Work stream 4, anticipated deliverables include white papers, reports, proposals for standards, and proposals for conferences and workshops.

6. Funding Requirements

Outline any contracted services or other expenses that are currently anticipated, beyond the basic

support services provided to all IC activities. Indicate how those funds are expected to be obtained (e.g., through participant fees, sponsorships, government or other grants, etc.). Activities needing substantial funding may require additional reviews and approvals beyond ICom.

Industry Connections staff will provide standard support as made available to all IEEE_SA IC activities. Activity members will provide any needed support for hosted meetings, marketing activities that exceed basic IC support.

Sponsorship and associated revenue opportunities may also be utilized in association with events to help offset any related costs.

7. Management and Procedures

7.1. IEEE Sponsoring Committee

Indicate whether an IEEE sponsoring committee of some form (e.g., an IEEE Standards Sponsor) has agreed to oversee this activity and its procedures.

Has an IEEE sponsoring committee agreed to oversee this activity?: Y

If yes, indicate the sponsoring committee's name and its chair's contact information.

IEEE Engineering in Medicine and Biology Society

Chair Name: Carole Carey

Email: c.carey@ieee.org

Sponsoring Committee Name: IEEE Sensors Council

Chair's Name: Gerard Hayes

Chair's Email Address: gerardjameshayes@gmail.com

Chair's Phone: Number, including country code

7.2. Activity Management

If no IEEE sponsoring committee has been identified in 7.1 above, indicate how this activity will manage itself on a day-to-day basis (e.g., executive committee, officers, etc).

- A leadership committee comprised of workstream group leaders by sector and discipline
- Face to face leadership committee meetings at selected conferences; teleconferences at other times, approximately monthly
- Activity management to include a diverse group of global experts from industry, technology, academia, and regulatory
- Coordination with blockchain and IoT communities

7.3. Procedures

Indicate what documented procedures will be used to guide the operations of this activity; either (a) modified baseline *Industry Connections Activity Policies and Procedures*, (b) Sponsor policies and procedures accepted by the IEEE-SA Standards Board, or (c) Working Group policies and procedures accepted by the Working Group's Sponsor. If option (a) is chosen, then ICom review and approval of the P&P is required. If option (b) or (c) is chosen, then ICom approval of the use of the P&P is required.

Will use the baseline Industry Connections Activity Policies and Procedures.

8. Participants

8.1. Stakeholder Communities

Indicate the stakeholder communities (the types of companies or other entities, or the different groups of individuals) that are expected to be interested in this IC activity, and will be invited to participate.

Entities

Cross-Initiative Participation

- IoT Initiative
- Digital Inclusion through Trust and Agency

8.2. Expected Number of Participants

Indicate the approximate number of entities (if entity-based) or individuals (if individual-based) expected to be actively involved in this activity.

Over time 50-100

8.3. Initial Participants

Provide a list of the entities or individuals that will be participating from the outset. It is recommended there be at least three initial participants for an entity-based activity, or five initial participants (each with a different affiliation) for an individual-based activity.

Use the following table for an entity-based activity:

Entity	Primary Contact	Additional Representatives
C3-Carey Consultants, LLC	Carole Carey Carole.carey@ieee.org	Name, Email Address Name, Email Address
University of San Diego, School of Medicine	Timothy "Tim" Mackey tmackey@ucsd.edu	
Health Linkages	Robert Barkovich	
Blockchain Healthcare Review	Brennan Bennett	
Clinical Blockchain	Ed Butskel	
Center for Supply Chain Studies	Robert Celeste	
TraceLink	Elizabeth Waldorf	
Amgen	Vladimir Petrovic	
Sanofi	Dany DeGraves	
Pfizer	Munther Barra	
AmerisourceBergen	Heather Zenk	John Denton
Cmast	Jan Hermans	

ADDENDUM 1

STATISTICS ON SUPPLY CHAIN AND CLINICAL TRIAL INEFFICIENCIES

- The rise in counterfeit pharmaceuticals leading to adverse effects in patients including death. There is an estimation by the WHO that up to 30% of the drug supply in emerging regions is counterfeit.
Source: INTERPOL, <https://www.interpol.int/en/Crime-areas/Pharmaceutical-crime/The-dangers>
- The rise in internet pharmacies is a direct correlation to the rise in “drug” pricing. It is anticipated that 1MM people die each year from counterfeit drugs. 36MM patients have bought medicine from an internet pharmacy without a prescription.
Source: InsightCrime.Org
<http://www.insightcrime.org/news-briefs/counterfeit-drugs-kill-1-million-annually-interpol>
- For the period 2011–14, FDA announced that there were 456 instances of drugs in shortage, a circumstance that can cause adverse outcomes for patients, including substitutions (alternate drugs) or modifications to treatment. Drug shortages result in nearly \$230 million in additional costs annually for hospitals because of the higher costs of substitute drugs. Source: Pew Charitable Resource Trust
<http://www.pewtrusts.org/en/research-and-analysis/reports/2017/01/drug-shortages>
- The lack of guidance and ineffective track and trace with globalization of the food supply are making consumers sick and creating a \$55Bn food safety problem.
Source: Fortune magazine - <http://fortune.com/food-contamination/>
- The limitations on outreach for a larger and more inclusive population for patient engagement for clinical trials inhibits the potential for a comprehensive and more effective clinical trials.
 - Only 3% of adult cancer patients have ever participated in a trial
 - 80% of clinical trials fail to meet their patient enrollment timelines and up to 50% of research sites enroll one or no patientsSource: National Center for Biotechnology Information
<https://www.ncbi.nlm.nih.gov/books/NBK50895/>
- The rise in globalization, outsourcing, and e-retailing have significantly complicated the modern supply chain creating a loss of control and visibility thereby creating a market for counterfeit medical devices
 - \$7MM worth of intra-aortic pumps had to be recalled after defective components were found to be fake
Source: <https://www.smcs-risk.com/1843-2/>
 - Over 8% of medical devices in circulation are fake and only 20% of countries have strict regulations to prevent the development and spread of counterfeit medical products. Source: MIMS
<https://today.mims.com/topic/medical-industry-newest-problem-counterfeit-medical-devices>