Project: IEEE P802.15 Working Group for Wireless Personal Area Networks (WPANs)

Submission Title: [Dependability Based on Regulatory Science for Medical Devices]
Date Submitted: [14 May, 2014]
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Abstract: [Dependability can be systematically taken care by regulatory science in which risk or predictable damage and drawback of new invented systems such as medical devices and benefit or improvement and advantage of the systems by using scientific numerical evaluation, and then regulation can be made by common understanding the risk and the benefit considering remained uncertainty and cost for implimentation. Dependable wireless systems can be designed and sold by guarantee based on regulatory science for wide variety of life critical applications such as medicine, disaster, dependable sensing and controlling cars, buildings, smart grids, and smart city. Using this theoretical concept of regulatory science, specifications of MAC and PHY may be discussed to make s wireless system much more reliable, secure, fault tolerant, robust against undesired factors.]

Purpose: [The discussion on use cases and applications will lead definition and requirement of current ongoing research and development on dependable wireless networks.]

Dependability Based on Regulatory Science for Medical Devices

14th May, 2014 Big Island

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Agenda

1. Background of Regulatory Science
2. Definition of Regulatory Science
3. Example of Regulatory Science
4. Concluding Remakes

Dependablity in Wireless Networks

- **Meanings of Dependability:**
  - In Wikipedia, **"Dependability"** is a value showing the reliability of a person to others because of his/her integrity, truthfulness, and trustfulness, traits that can encourage someone to depend on him/her. The **wider use of this noun is in Systems engineering.**
  - **For us, "Dependability in network"** means to guarantee lowest performance enough high in a sense of highly reliable, safe, secure, fault tolerant, robust services in any predictable and even unpredictable worse environments.
- **Demand for Dependable Networks:**
  - Need for **Highly Reliable, Robust Communications for Controlling**
  - Transition from Human centric communications **to Machine / Device Centric (M2M) communications for controlling**.
  - Highly reliable, safe, secure and robust communications for **M2M Controlling** is necessary.

1. Background of Necessity of Regulatory Science

Necessary Procedure for Practical Global Business and Social Services of BAN

Step 1: **Investigation of Demand and Future Vision** for Ideal Medical Healthcare

Step 2: **Research and Education** of Necessary Technology (Technical Innovation) for BAN

Step 3: **Development and Prototyping** of Practical BAN

Step 4: **Standardization** of BAN for Global Medical and Other Business

Step 5: **Business Modeling and Promotion** of BAN

Step 6: **Regulation Making and Compliance Test** for BAN as a Medical Device

Step 7: **Education of Regulatory Science** for Risk Management and Harmonization for Medical ICT(ex. BAN) and Other Trans-disciplinary Fields.

Procedure in Compliance Testing Body in Japan (PMDA)

Current Compliance Testing Procedure

Development of Medical Device

Collection and analysis of data
Filling of Application

PMDA

Review

Re-presentation Application and data

Building Regulatory Science

PMDA

Review

Approval＜Reject

⇨ Desired Compliance Testing Procedure

Development and improvement of a Device

Building Regulatory Science

Unification of development and RS

shorten time for compliance testing

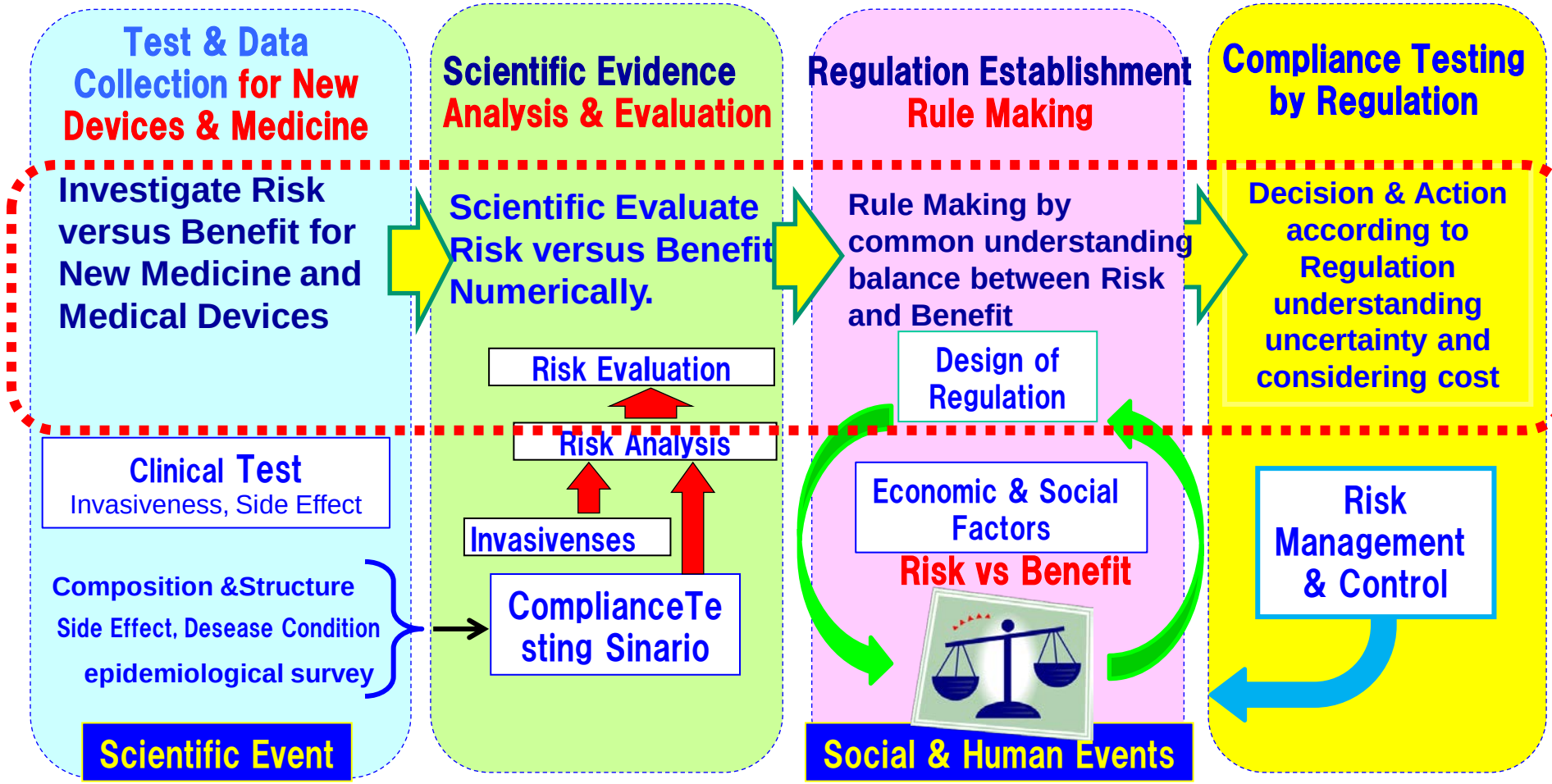
PMDA

Review

A problem "Device Lag" i.e. too long time for regulatory certification

Key solution : regulatory science

2. Regulatory Science for Clinical Approval of Medical Devices and Medicine



- *Speed up procedure of regulatory compliance test of medical devices by Regulatory Science.*
- *Not only patients but also manufactures can be protected for saving life and business by Regulatory Science.*

General Classification and Application Types of Medical Devices for Regulatory Compliance

Higher Benefit & Risk

Class in Japan	Global Class	Classification according to risk for body	Compliance Test	Testing Body
Ordinary medical devices	Class I	Extremely low risk for human body even in case of broken	Submission only	Self test
Managed medical devices	Class II	Relatively low risk for human body in case of broken or unpredictable cases	Registration	RCB*1
Highly managed medical devices	Class III	High risk for human body in case of broken or unpredictable cases	Regulatory Compliance Test Approval	PMDA*2
	Class IV	Very high risk for human body and dangous in case of broken or unpredictable case		

*1 RCB(Registered Certified Body): 3rd Party Approval

*2 PMDA(Pharmaceuticals and Medical Devices Agency, Japan): Government Regulator like FDA in USA

General Classification and Application Types of Medical Devices for Regulatory Compliance in USA by FDA CDRH

- **Class I** - no application required
- **Class II** – We review for Substantial Equivalence to another cleared device by a 510K application.
- **Class III** – Devices with higher risk and require a Pre-Market Application **(PMA)**
- **Humanitarian Device Exemption (HDE)** for rare diseases or conditions.

3. Example of Regulatory Scientific Approach

Study on Measuring SAR Considering BER Performance for Medical BAN's Regulatory Compliance Testing

Kohno Laboratory, Yokohama National University
Master Student
Ms. Yumi Ozaki

3.1 Human Impact and BER

SAR(Specific Absorption Rate) is an energy absorption value in a human body by electro-magnetic field.

$$SAR = \frac{\sigma}{\rho} E^2 [W/kg]$$

σ : Inductive Ratio of Human Body[S/m]
ρ : Density of Human Cells[kg/m^3]
E : Inducted Electoric Fiels in Body[V/m]

SAR must be an index of electromagnetic field in a human body.

Permissible Value Based on Safety Guideline	Permissible Upper Limit Under control	Permissible Upper Limit in Non under control
SAR in average overall body[W/kg]	0.4	0.08
SAR in specific parts (Head and Human Core)[W/kg]	10	2

If temperature of deep body core increases 1℃, a human body will have serious damage.

3.2 Human Impact VS, BER

Pennes's Thermal Propagation Equation

$$c\rho\frac{\partial T}{\partial t} = \nabla\cdot(\kappa\nabla T) + A_0 + Q_v - b(T-T_b) \Rightarrow \kappa\nabla^2 T + \rho SAR - \rho\rho_b c_b F(T-T_b)$$

1st term; Thermal Propagation

2nd Term; Thermal Radiation to keep proper temperature

3rd Term; Thermal Volume by Millimeter wave

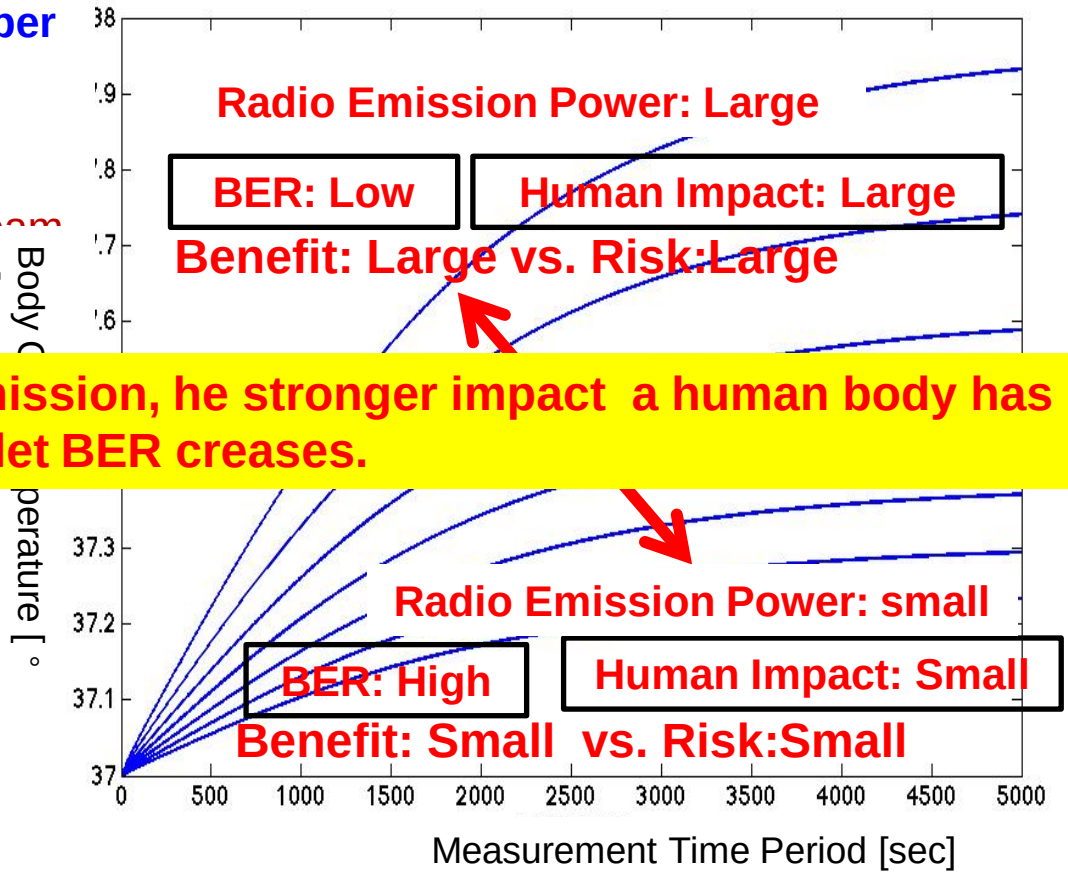
4th term; Thermal Change due to Blood Stream

EIRP of Emission Power P_t and Antenna Gain G_t for a distance R

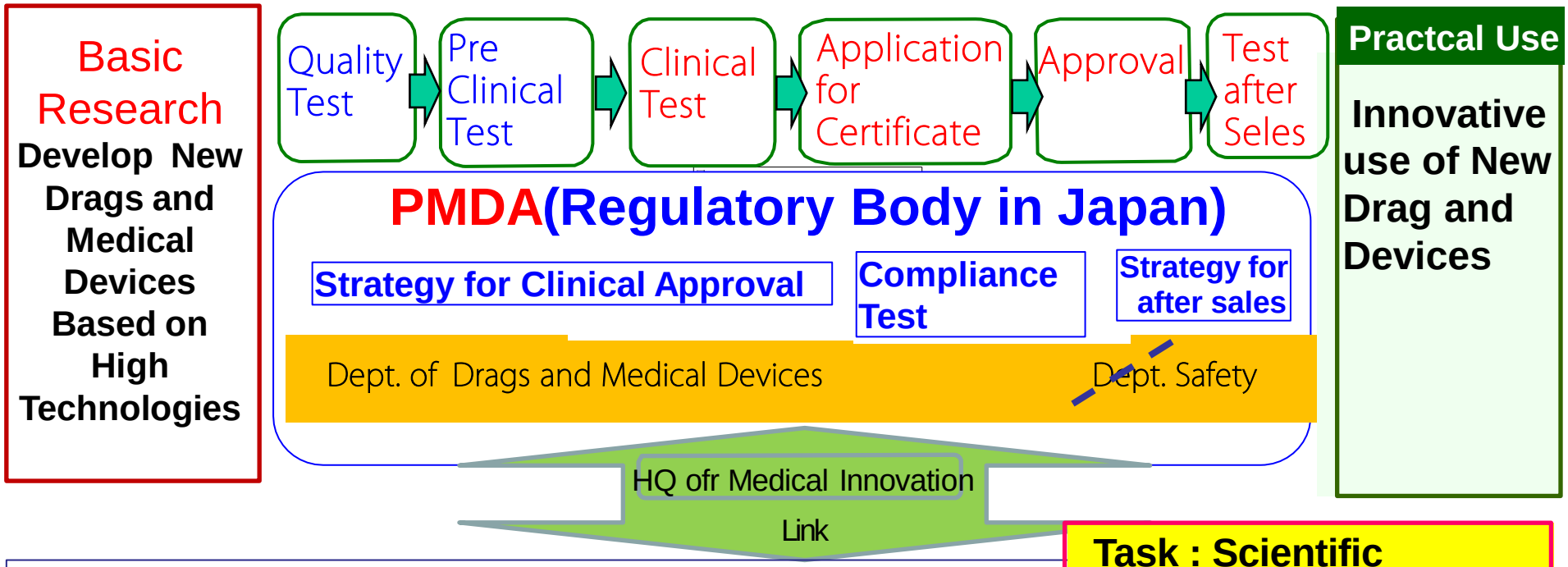
$$E = \frac{\sqrt{49P_tG_t}}{R}$$

$$SAR \propto Pt \propto E^2$$

Then, radio emission power or SAR must be a numerical parameter to evaluate risk versus benefit of radio medical devices.



Medical Innovation by PMDA in Japan

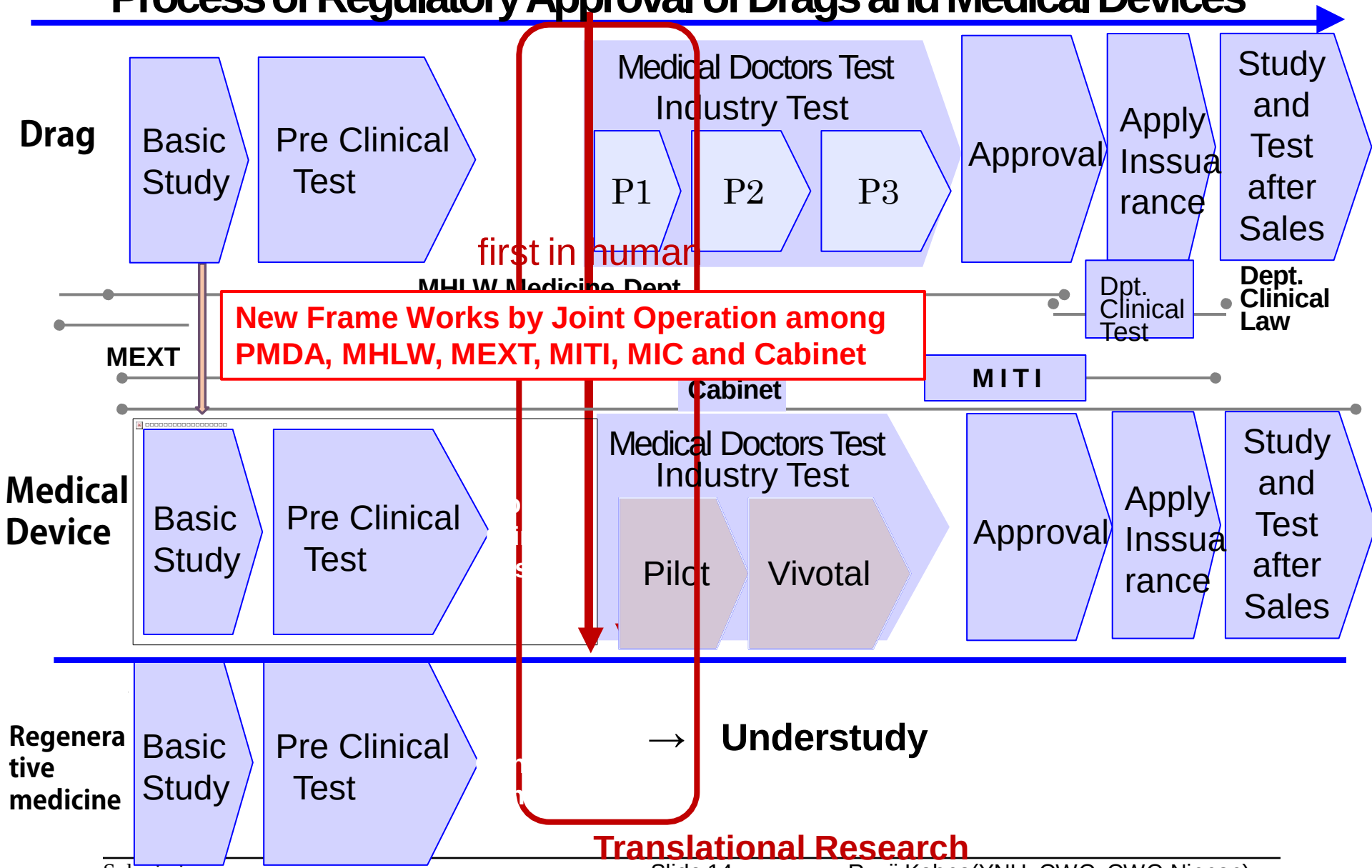


Founding Regulatory Science Committee

Analyze Risk and Benefit of Newly Invented Drags and Medical Devices with Numerical Parameters, Making Regulation and Approving them

Committee Members from
Academia, Universities

Process of Regulatory Approval of Drags and Medical Devices



4. Concluding Remarks

1. Dependability of communication network systems can be discussed by using a concept of regulatory science to guarantee performance based on a balance between risk and benefit considering remained uncertainty and cost.

2. One of the key issues is how to define a common numerical parameter to evaluate risk and benefit for the system.

3. Another issue is how to break down to design rule and to define MAC and PHY specification of dependable wireless systems.

4. One approach is to make application matrix of dependability with classification referring classes of medical devices.