Status of the Regulation on the Standalone Medical Device Software in Japan

2012 Nov. 3rd in AHWP Taipei

Susumu Takahashi
JIRA International Committee, Chair

- JIRA
  - Japan Medical Imaging and Radiological Systems Industries Association
  - Radiological systems, Health IT systems
  - Founding member of DITTA
    - DITTA
      - The Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association
      - Global voice for diagnostic imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers
      - Legally incorporated under US law since May, 2012

Today's Point

1） Latest Legal Status **of the Stand alone MD Software in Japan (finally came out)**
（ CABINET DECISION : July 10th 2012 ）

Good News !!

2） **How Health Software should be ensured the Safety in health domain ? <Many Stakeholders>**

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1） Handling of the Standalone Software
on existing Pharmaceutical Affairs Law (JPAL) : On going situation

■Standalone software is NOT a “medical device”
■Embedded software which is intended to operate the medical device is regulated as unbroken part of the Hardware (MD).

2) Cross-national Comparison on the Standalone Software Regulation

	SW Embedded in hardware	Standalone SW as medical device	Standalone SW as non-medical device
Japan	○	×	×
EU	○	○	○
US	○	○	○
Canada	○	○	○

Challenge to Standalone MD Software

- Safety of Medical Procedures using Health Software (Global trend)

  (Example)

  - Preceding use of tablet PC / Smartphone in clinical site by doctors

- Increasing demand to global regulatory harmonization

■ JIRA's Basic Stance on the Standalone Software (history)

Sep. 18th, 2010 Presentation : the basic stance to the handling of Software
@ APEC Life Science Innovation Forum

Apr. 13th, 2012 News release : the basic stance on the handling of Software

■ New Legal Status on the Stand alone MD Software in Japan

CABINET DECISION : July 10th 2012
POLICY ON REGULATORY AND INSTITUTIONAL REFORM
(including the medical device)

Good News !!

規制・制度改革に係る方針

平成24年7月10日
閣　議　決　定

行政刷新会議の下の「規制・制度改革委員会」における規制・制度改革に関する検討の結果を踏まえ、別紙のとおり、「規制・制度改革に係る方針」を定める。

POLICY ON REGULATORY AND INSTITUTIONAL REFORM

CABINET DECISION
July2012

HEREBY ADOPTED is“Policy on Regulatory and Institutional Reform”as attached,
based upon the results of the examination conducted on regulatory and institutional reform by“the Committee on Regulatory and Institutional Reform” established under the Government Revitalization Unit (GRU).

Outline of CABINET DECISION : July 10th 2012
POLICY ON REGULATORY AND INSTITUTIONAL REFORM
(Only Medical Device)

(No.4) Review of the system based upon the characteristics of medical devices

＜ Separation of drugs and medical devices on JPAL ＞

→establish a new“chapter”on medical devices, and to change the title of the Law

(No.5) Acceleration of approval review process for medical devices

→ Eestablish a new approval/certification system utilizing private certification bodies covering medical devices

(No.6) Rationalization and acceleration of approval procedures for partially changed medical devices

→expand the scope of partial change medical devices do not require approval

(No.7) Enhancement of international harmonization and streamlining of QMS audits

→the revision on the QMS Ministerial Order improving the harmonization with international standards

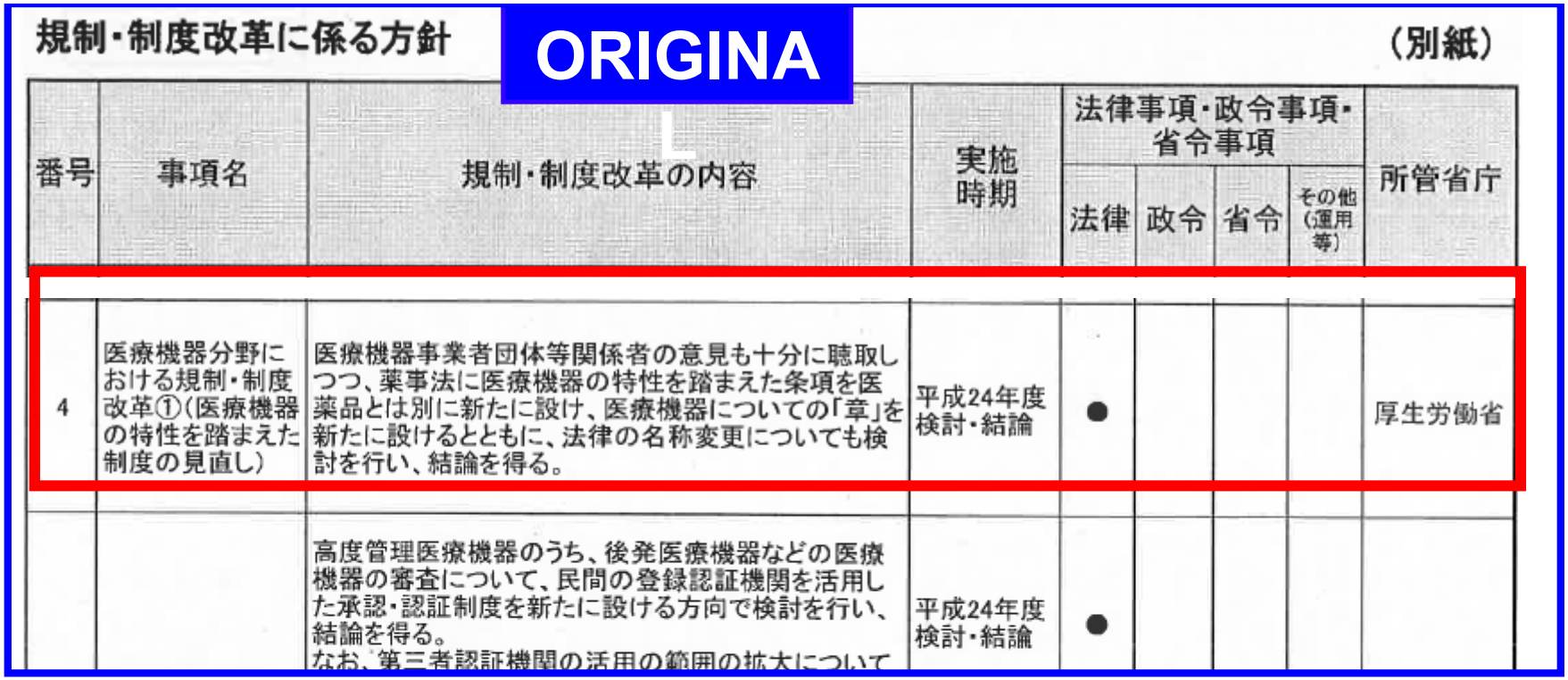
(No.8) Improvement of “certification” system on medical devices

(No.9) Omission of package insert “Tempu-Bunsyo” of medical devices

(No.10) Clarifying the position of stand-alone medical software in laws and regulations

→Stand-alone computer-aided diagnosis software shall be classified as medical device

＊ Other reference numbers (No.1 – No.3 and others) are not medical domain.



規制・制度改革に係る方針

ORIGINA

（別紙）

番号	事項名	規制・制度改革の内容	実施時期	法律事項・政令事項・省令事項				所管省庁
				法律	政令	省令	その他（運用等）	
4	医療機器分野における規制・制度改革①（医療機器の特性を踏まえた制度の見直し）	医療機器事業者団体等関係者の意見も十分に聴取しつつ、薬事法に医療機器の特性を踏まえた条項を医薬品とは別に新たに設け、医療機器についての「章」を新たに設けるとともに、法律の名称変更についても検討を行い、結論を得る。	平成24年度検討・結論	●				厚生労働省
		高度管理医療機器のうち、後発医療機器などの医療機器の審査について、民間の登録認証機関を活用した承認・認証制度を新たに設ける方向で検討を行い、結論を得る。 なお、第三者認証機関の活用の範囲の拡大について	平成24年度検討・結論	●				

(No.4) Review of the system based upon the characteristics of medical devices

The Ministry of Health, Labour and Welfare(MHLW) shall examine issues and decide on actions to be taken to establish new clauses in the Pharmaceutical Affairs Law, separately from clauses on pharmaceuticals, based upon the characteristics of medical devices, to establish a new“chapter”on medical devices, and to change the title of the Law, taking fully into account opinions from relevant stakeholders such as industrial associations on medical devices.

→Timeline:

Examine issues and decide on actions to be taken in FY 2012

Measures to be taken(Law, Cabinet Order, Ministerial Order and Other Measures) : Law

Responsible Ministry: MHLW

ORIGINAL

(No.10) Clarifying the position of stand-alone medical software in laws and regulations

The Ministry of Health, Labour and Welfare(MHLW) shall examine issues and decide on actions to be taken on the status of stand-alone medical software under laws and regulations, including clarification that stand-alone computer-aided diagnosis software shall be classified as medical device.

→Timeline : Examine issues and decide on actions to be taken in FY2012.

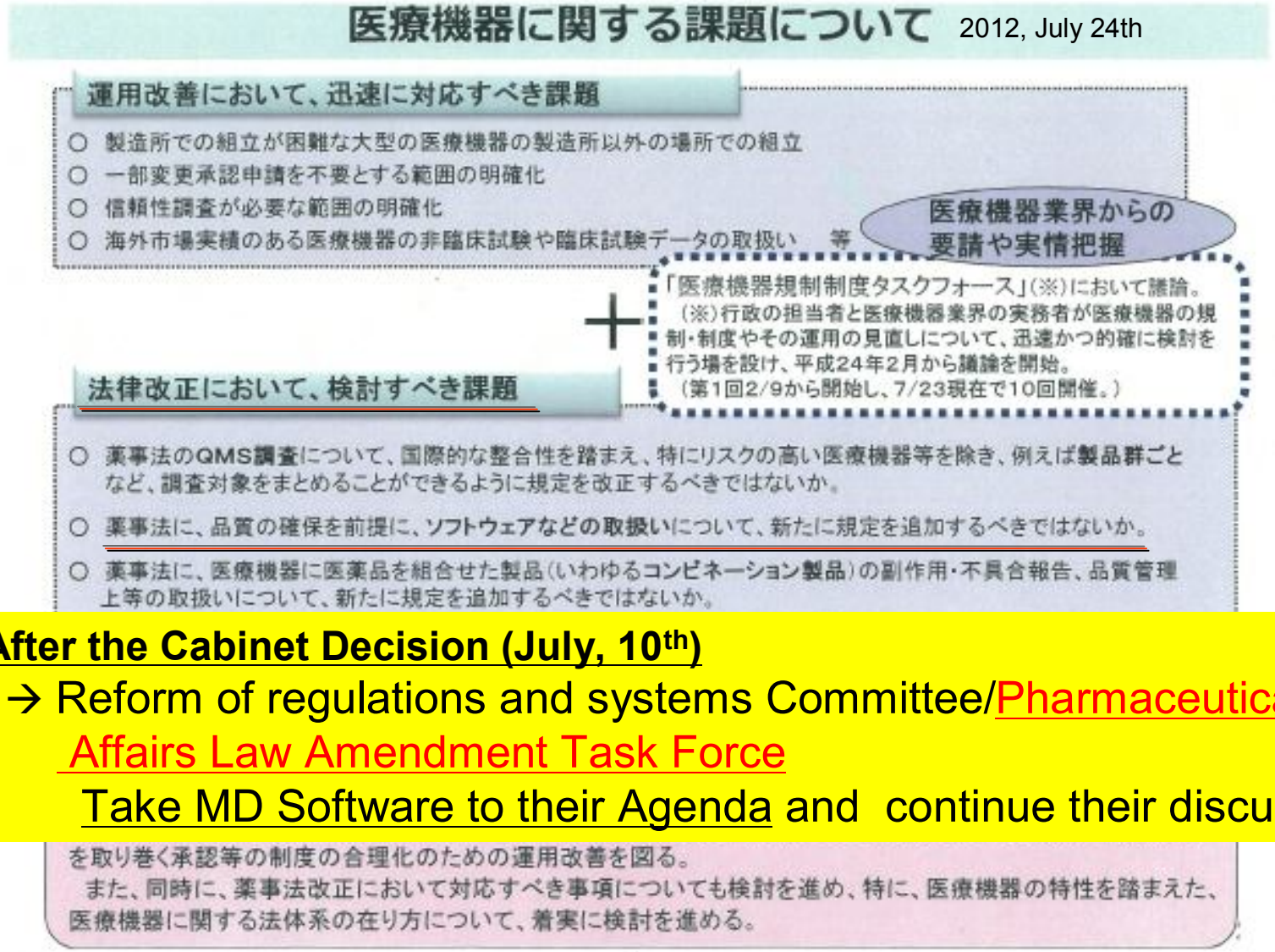
Measures to be taken(Law, Cabinet Order, Ministerial Order and Other Measures):Law

Responsible Ministry: MHLW

番号	事項名	規制・制度改革の内容	実施時期	法律事項・政令事項・省令事項			その他	所管省庁
	に係る添付文書の省略）	得る。						
10	医療機器分野における規制・制度改革⑦（医療用ソフトウェア等の法令上の位置付けの明確化）	単独で診断支援機能等を有するソフトウェア等が「医療機器」であることを明らかにすることなど、医療用ソフトウェア等の法令上の位置付けについて検討を行い、結論を得る。	平成24年度検討・結論	●				厚生労働省

What's Going on AFTER the CABINET DECISION

第10回医療機器・体外診断薬の薬事規制に関する定期意見交換会　厚生労働省医薬食品局医療機器審査管理室



After the Cabinet Decision (July, 10th)

→ Reform of regulations and systems Committee/Pharmaceutical Affairs Law Amendment Task Force

Take MD Software to their Agenda and continue their discussion.

Today's Point

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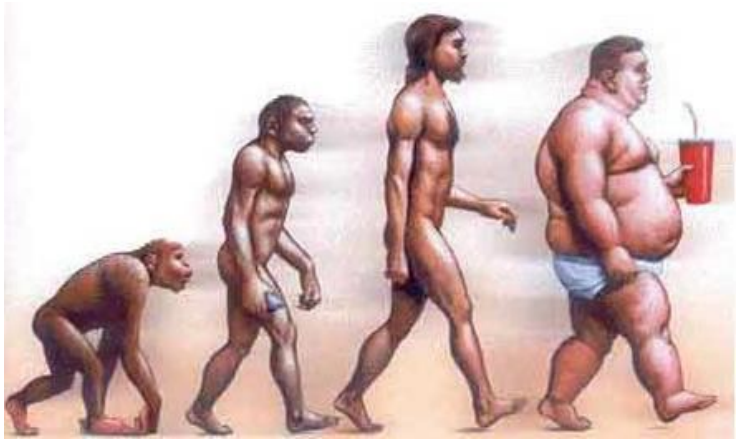
How Software should be regulated in Health domain?



« Apps » are increasing.

- Software provides great capabilities and value .
- Software can minimize human error in clinical process .
- Software's defect cause the significant effect on the patients.

Many Stakeholders in the Health Software (Medical and Non-medical Domain) !

■ Consistent direction to guarantee safety on them is required

→ Standardization work on software in the context of Health Software (ISO TC215/IEC TC62)

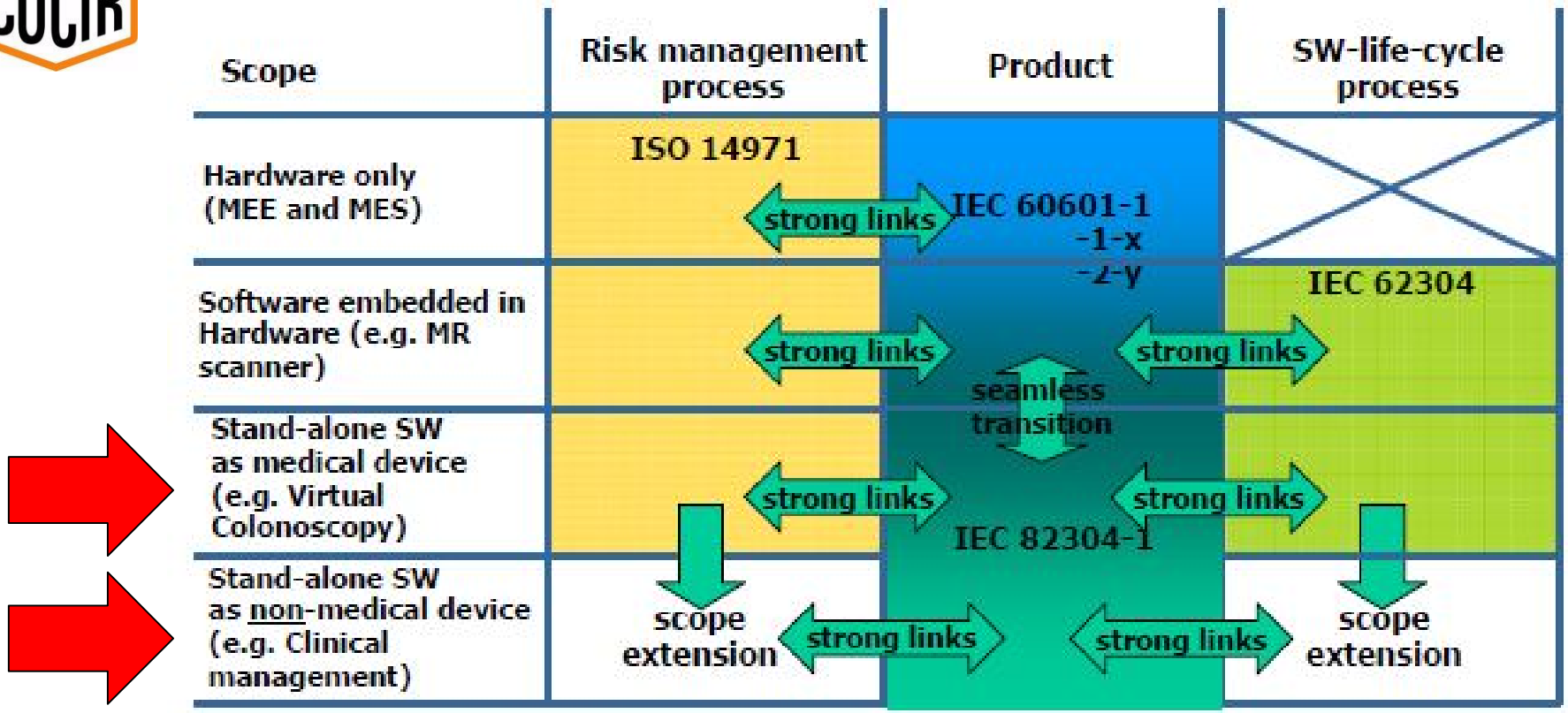
→ We need cross-sectional discussion among associations

3J Joint WG on Standalone Software 2012 in Japan

★Industry effort to provide consultation

■ Standardization work on software in the context of Health Software (ISO TC215/IEC TC62)

Make Use of the Scope to Solve the Requirements of Many Stakeholders



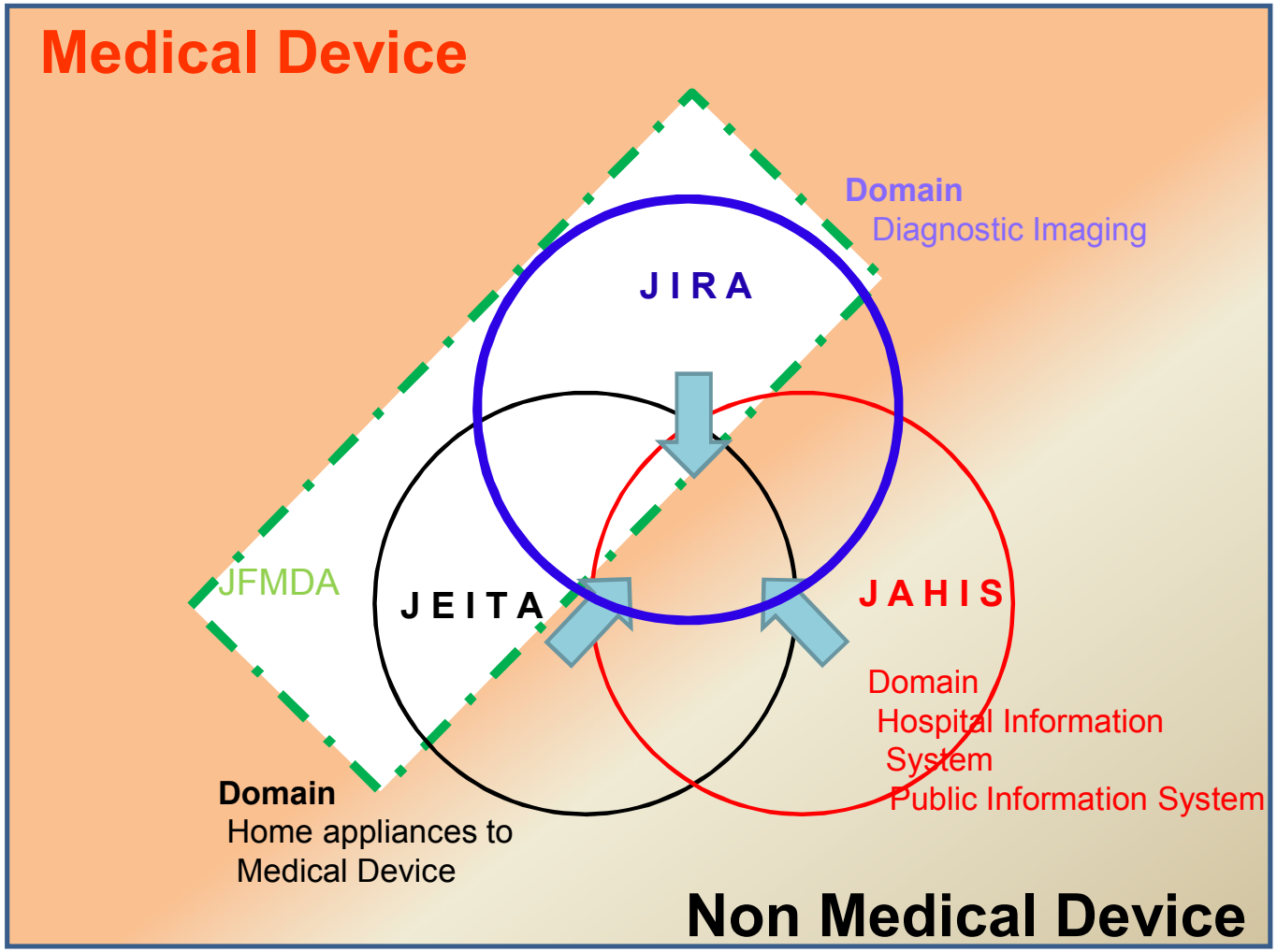
※ ISO-TC215-WG4_N0518 By COCIR ***Wolfgang Leetz***

JIRA/JAHIS/JEITA (3 J) joint WG on Standalone MD Software

-JAHIS: Japanese Association of Healthcare Information System Industry

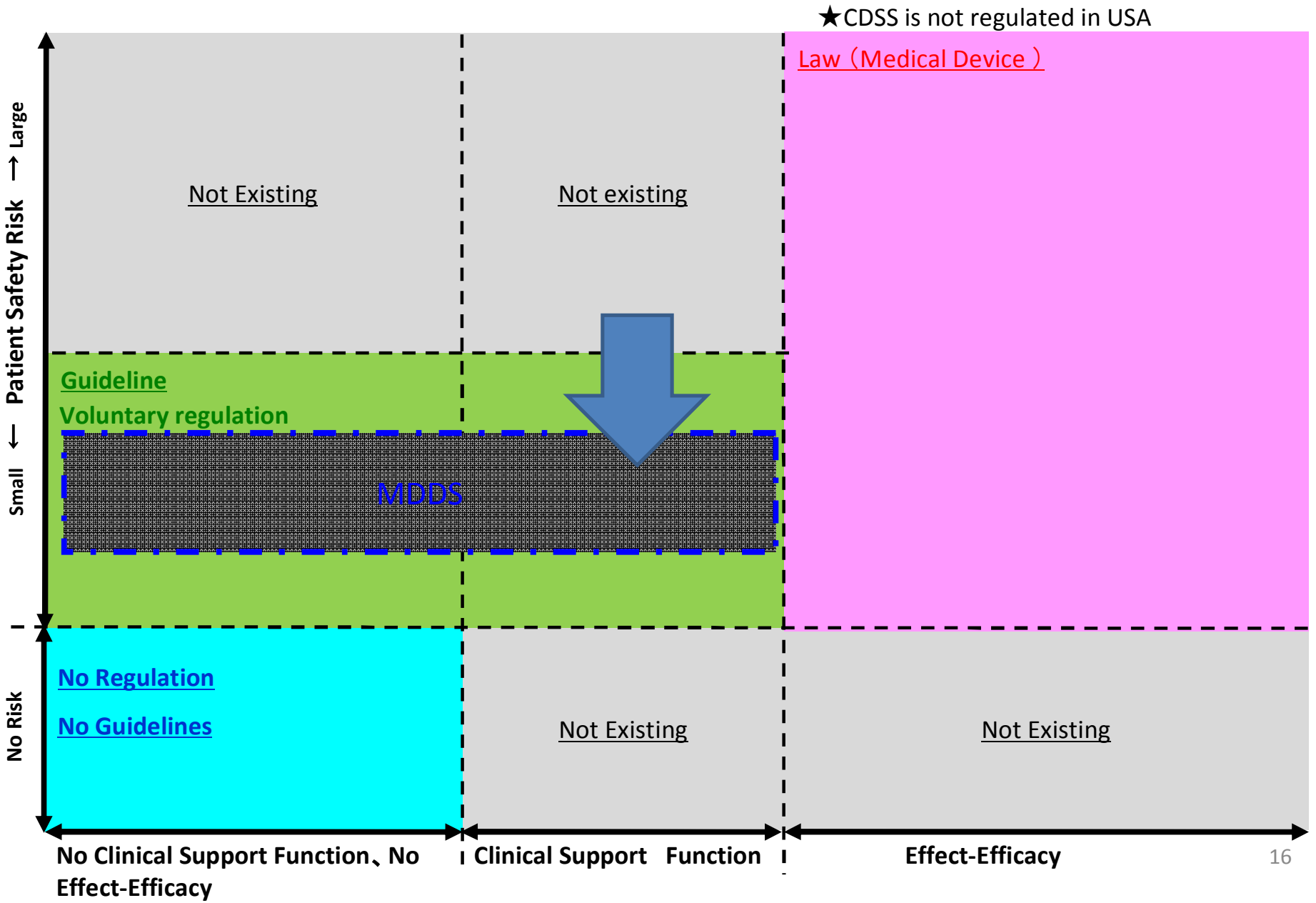
-JEITA: Japan Electronics and Information Technology Industries Association

Goal : make recommendations on the range of the regulations on Software

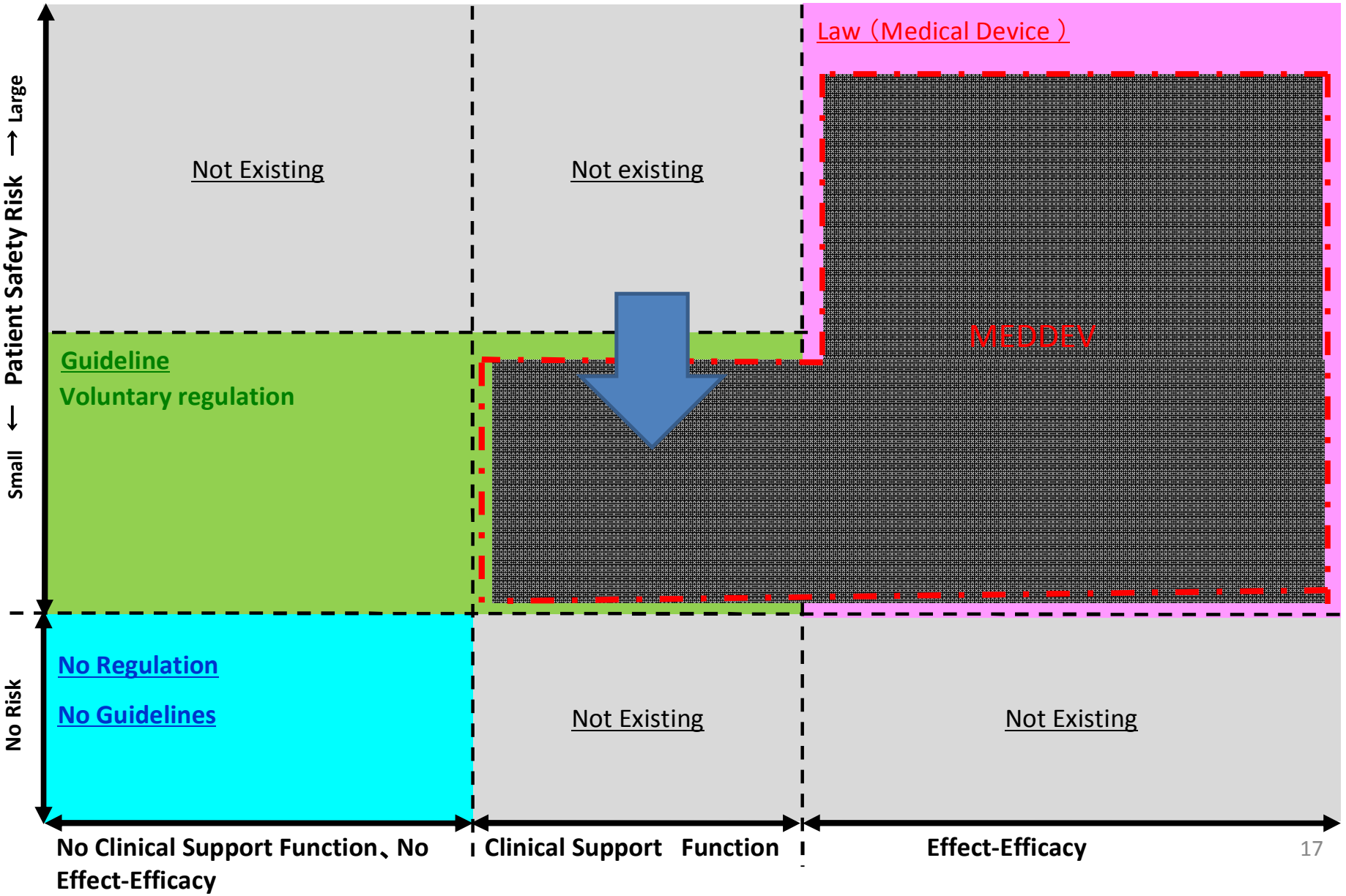


End

Region of Regulation on Health Related Software : USA MDDS

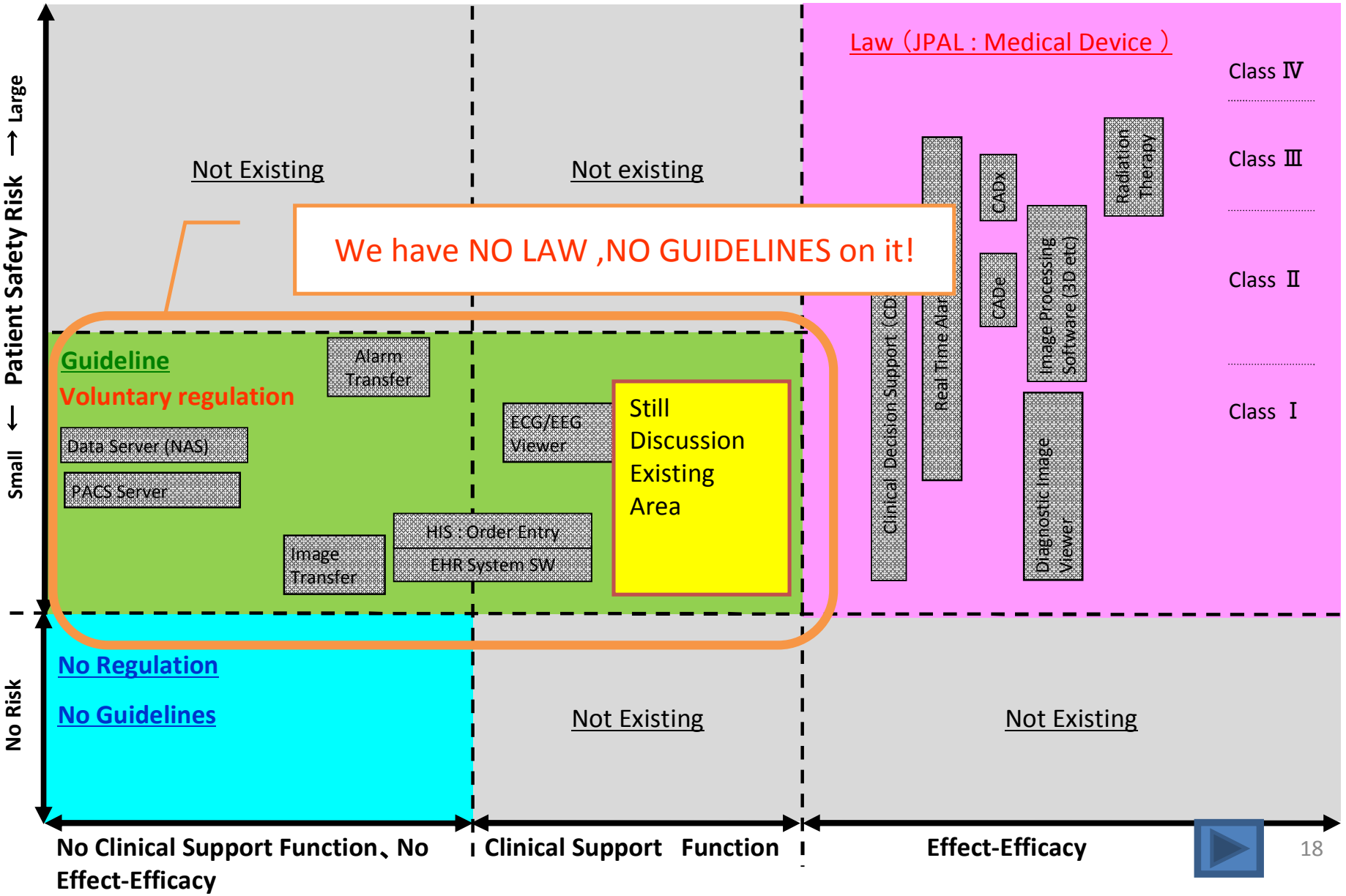


Region of Regulation on Health Related Software : EU MEDDEV



Region of Regulation on Health Related Software : JAPAN (3J Consensus)

【Standalone Software Mapping Example according to the Function (Not Fixed)】

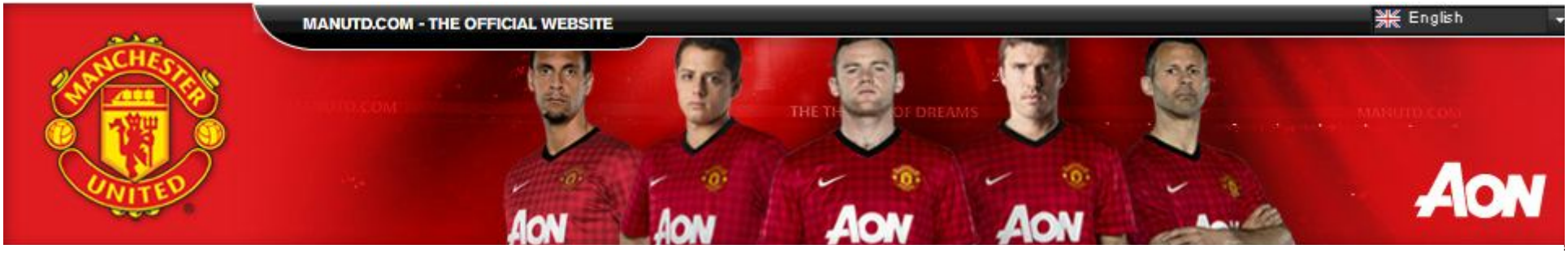


Challenges

- Discussions on the range of the Health / Medical Software Regulations with its Risk Management.

  → Point is to insure the Safety on Health / Medical Software.

Headache : Post market (Especially, How customization by users should be regulated ?)



Reds announce Toshiba deal

Manchester United has announced an agreement with Toshiba Medical Systems to become its Official Medical Systems Partner, the first partnership of its kind to be developed with a UK football club.

Thank you for your attention