CIMDR
China International Medical Device Regulatory Forum
中国医疗器械监督管理国际会议

战胜疫情 2020 再出发

11th China International Medical Device Regulatory Forum

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Plenary - 20 Nov. 2020

How Innovative Medical Technologies Can Contribute to Better Health

创新医疗科技，共建医疗保健

Nicole Denjoy

COCIR Secretary General and DITTA Chair

COCIR秘书长 DITTA主席

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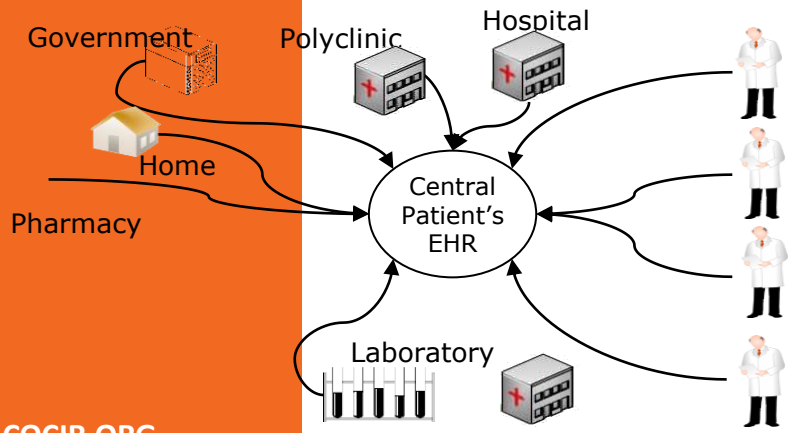
Introduction to COCIR 简介

- COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe　COCIR(**欧洲医用影像、电子医学与卫生信息技术行业协会**)，是一家非营利性贸易协会，成立于1959年，在布鲁塞尔和中国设有办事处，代表欧洲医疗技术行业。
- COCIR covers 4 key industry sectors:　COCIR涵盖4个主要行业领域
  - Medical Imaging 医学影像
  - Radiotherapy 放射治疗
  - Health ICT 卫生信息技术
  - Electromedical 电子医学
- Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle. 我们的行业引领先进技术的发展，提供覆盖整个生命周期的综合解决方案。



COCIR Membership COCIR成员

COCIR COMPANY MEMBERS:

Abbott 雅培 · ACCURAY · AGFA HealthCare · AGFA · Alcon · alert · align · invisalign | iTero · BARCO · BAYER · BD · Canon CANON MEDICAL · Carestream · Dentsply Sirona · Elekta · EOS imaging · Epic · esaote · FRESENIUS MEDICAL CARE · FUJIFILM · GE · HITACHI Inspire the Next · HOLOGIC · tba · IBM · 强生(中国)医疗器材有限公司 Johnson & Johnson Medical (China) Ltd. · KONICA MINOLTA · Medtronic 美敦力 Further.Together · nova motum · PHILIPS · Roche · SAMSUNG · SIEMENS Healthineers · stryker · varian · WeHealth Digital Medicine · ZEISS

NATIONAL TRADE ASSOCIATIONS MEMBERS:

.AGORIA BELGIUM	SNITEM FRANCE	bvitg GERMANY	ZVEI: GERMANY
ETOSZ Association of Health Technology Suppliers and Medical Device Manufacturers HUNGARY	CONFINDUSTRIA Dispositivi Medici ITALY	apormed PORTUGAL	FHI Medical Technology THE NETHERLANDS
FME Powered by Dutch Technology THE NETHERLANDS	Vereniging van Organisaties voor ICT in de Zorg THE NETHERLANDS	femin Federación Española de Empresas de Tecnología Sanitaria SPAIN	Swedish Medtech SWEDEN
TIP GÖR DER TURKEY	AXREM UNITED KINGDOM		

WWW.COCIR.ORG

COCIR at International Level COCIR在国际层面

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

DITTA - 全球诊断影像、医疗信息技术与放射治疗贸易协会

1. Importance of clinical data and how Digital can contribute to RWD?

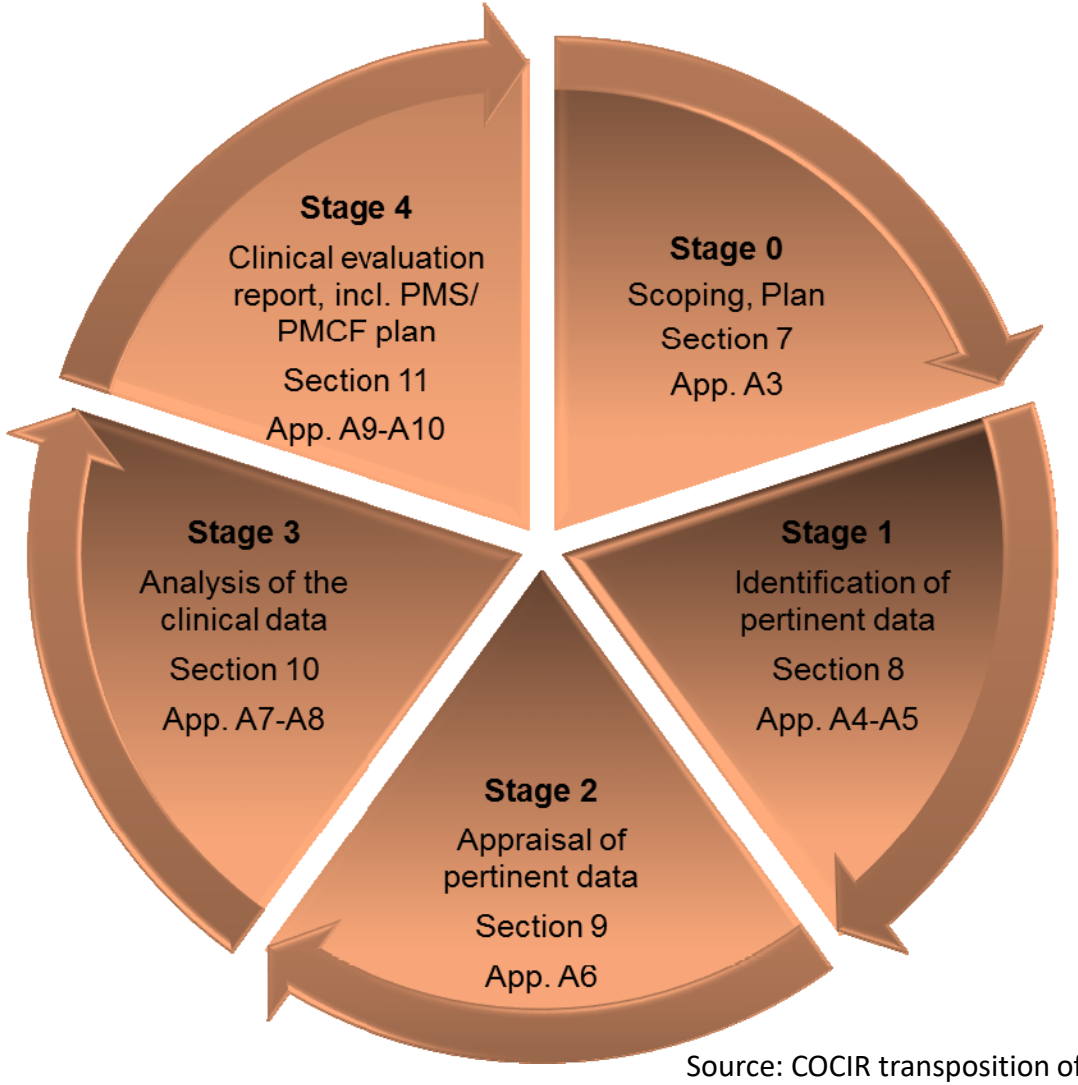
临床数据的重要性及数字化将如何助力真实世界数据?

Importance of clinical data in the context of MDR
欧盟医疗器械法规框架下临床数据的重要性

Clinical evaluation 临床评价

- a methodologically sound ongoing procedure
  - to collect, appraise and analyse **clinical data** pertaining to a medical device 一套包含收集、评估和分析医疗器械相关临床数据的程序
  - and to analyse whether there is **sufficient clinical evidence** to confirm compliance with relevant GSPR for safety and performance 同时分析是否有足够的临床证据佐证其安全和性能符合相关GSPR(通用安全及性能要求)

- when using the device according to the **manufacturer's instructions for use** 当器械按照制造商的说明书使用时



Source: COCIR transposition of MEDDEV 2.7/1 rev. 4 to MDR
MEDDEV 2.7/1 rev. 4 转化为 MDR, by COCIR

Available guidance on clinical evaluation & investigations under MDR 已发布的MDR框架下临床评价临床试验导则

Guidance on sufficient **clinical evidence** for legacy devices 老器械充足临床证据指南
Guidance on **Equivalence** 实质等同指南
Clinical Evaluation Assessment Report **(CEAR)** 临床评价报告(CEAR)
Post-Market Clinical Follow-Up Report **(PMCF)** 上市后临床跟踪报告(PMCF)
Safety reporting in **Clinical Investigations** 临床试验中的安全报告
Summary of Safety and Clinical Performance **(SSCP)** 安全及临床性能总结(SSCP)
Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of **Medical Device Software** 医疗器械软件临床评价(MDR)/性能评价(IVDR)指南

Gap: Guidance on **Clinical Evaluation** (transposition of MEDDEV 2.7 / 1 rev. 4)
尚在制定中：临床评价指南(由MEDDEV 2.7 / 1 rev. 4转化)

Use of Real World Data 真实世界数据应用

- by healthcare systems to better leverage real world evidence to improve patient outcomes and processes – enabled by technology solutions 通过技术解决方案，医疗系统更好地利用真实世界证据提升患者的治疗效果和治病流程
- By manufacturers for the development and validation of (Artificial Intelligence-based) health and medical device software 由制造商开发和验证（基于人工智能的）健康和医疗器械软件
- by regulatory authorities (especially in vigilance and market surveillance activities) 通过政府监管（特别是警戒和市场监督活动）
- by HTA bodies, payers, and procurers for assessing the value of health innovations for market access 由医疗技术评估机构、支付者和采购者评估医疗创新的市场准入价值

How Digital Health can help in RWD 数字健康助力RWD

- Changing boundaries of what is considered health data 改变健康数据的边界
  - Electronic health records 电子健康档案
  - Genomic data 基因组数据
  - Input from wearables 源于可穿戴器械的数据
  - Nutrition 营养状况
  - Lifestyle / Socio-economic conditions 生活方式/社会经济条件
  - Living environment (water, soil,…) 生活环境(水、土壤...)
  - Reported outcomes 成果报告
- Digital health provides the opportunity to collect, combine and share data, leading to insights and innovations improving patient outcomes 数字健康提供了收集、合并和共享数据的机会，产生见解和创新，从而改善患者的治疗效果

How digital health can help in RWD 数字健康助力RWD

- Establishing a European Health Data Space 建设欧洲健康数据空间
  - Data governance framework 数据治理框架
    - ❖ Access and use of data 数据获取与使用
  - Data quality 数据质量
    - ❖ Interoperability 交互性
    - ❖ Standardisation 标准化
    - ❖ FAIR principles 公平原则
  - Infrastructure 基础设施
    - ❖ System architecture 系统架构
    - ❖ Cross-border exchange 跨界交流
  - Capacity building 能力构建
  - Skills 技能

2. COVID-19: Industry initiatives in cybersecurity: reference to IMDRF workshop and to initiatives from our industries on cybersecurity by design

COVID-19:行业针对网络安全的举措:参考IMDRF研讨会及医疗器械产业在根于设计的网络安全方面的倡议

COVID-19: what are our industries doing?
新冠疫情：我们行业做了什么？

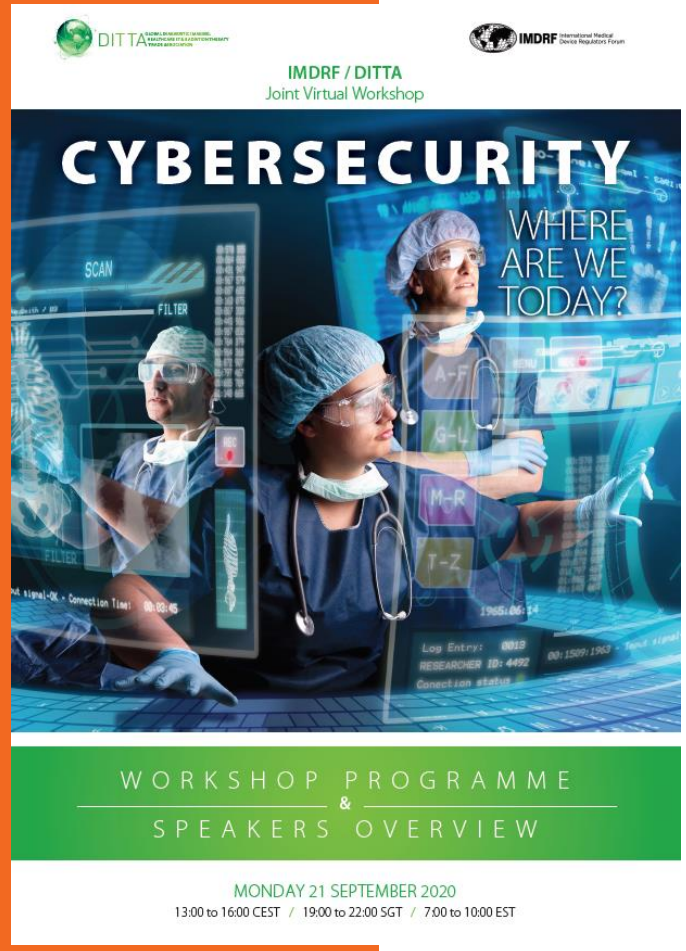
- Dynamic involvement of our industries with re-organization to respond to demands
  我们的行业积极参与重组以响应需求
- Supply priority medical devices for COVID-19 patients 优先为疫情患者提供医疗器械
- Ensure manufacturing plants can work and re-adjust their production to respond to the demands from governments and hospitals 维持正常生产活动并按政府和医院需求作出调整
- Ensure engineers/workers have protective equipment and can move safely cross-border to ensure installation and well functioning of equipment in hospitals and at home 保障工程师和工人的防护设备与安全出境，确保设备在医院和家中正常运转
- Share best practices and show the importance of Digital Health 分享经验，呈现数字健康的价值

Industry Innovations 行业创新

- Industries continue to innovate to provide priority medical devices 行业坚持创新，提供先进的医疗器械
  - Ventilators 呼吸机
  - Imaging equipment 医学影像设备
  - Oxygen equipment 氧合设备 （例如，ECMO, 体外膜肺氧合）
  - Etc 等等
- In addition and because of the increasing importance of Digital Health, COCIR is communicating event more on the following strategic elements: 同时，由于数字健康的重要性日益攀升，COCIR正在就以下战略要素进行更多交流
  - Cybersecurity (ensuring cybersecurity by design) 网络安全(保证根于设计的网络安全)
  - Artificial Intelligence (refer to concrete AI solutions available on the market) 人工智能(指市场上现有的AI解决方案)
  - Health Data Space 健康数据空间
  - Need for implementation and scaling up of EHR solutions and ensure interoperability 实现并扩大电子健康档案，确保其互通性

IMDRF / DITTA virtual workshop on CYBERSECURITY – 21 Sept. 2020

DITTA组织的网络安全研讨会 - 2020年9月21日IMDRF会议期间



Goals 目的:

- Discuss the implementation of the IMDRF cybersecurity guidance in different jurisdictions 讨论IMDRF网络安全指南在不同国家/地区监管机构的实施情况
- Learn from healthcare providers on steps towards ensuring their facility is secure 向医疗保健提供者学习确保其设施安全
- Learn what the medical device industry is doing to make devices more secure and prevent cyber attacks 了解医疗器械行业在提升器械安全性与防止网络攻击的经验

Attendance: 500 registered participants - 322 attendees (regulators, auditing organisations, healthcare providers, scientific societies and industries) 500人注册，322人参会(监管、审计机构、医疗保健提供者、科研机构以及行业代表)

Speakers: 18 from 6 jurisdictions (Singapore, USA, Canada, EU/Germany/Belgium, Japan, South Korea) 发言人:18位来自6个司法管辖区的专家(新加坡、美国、加拿大、欧盟/德国/比利时、日本、韩国)

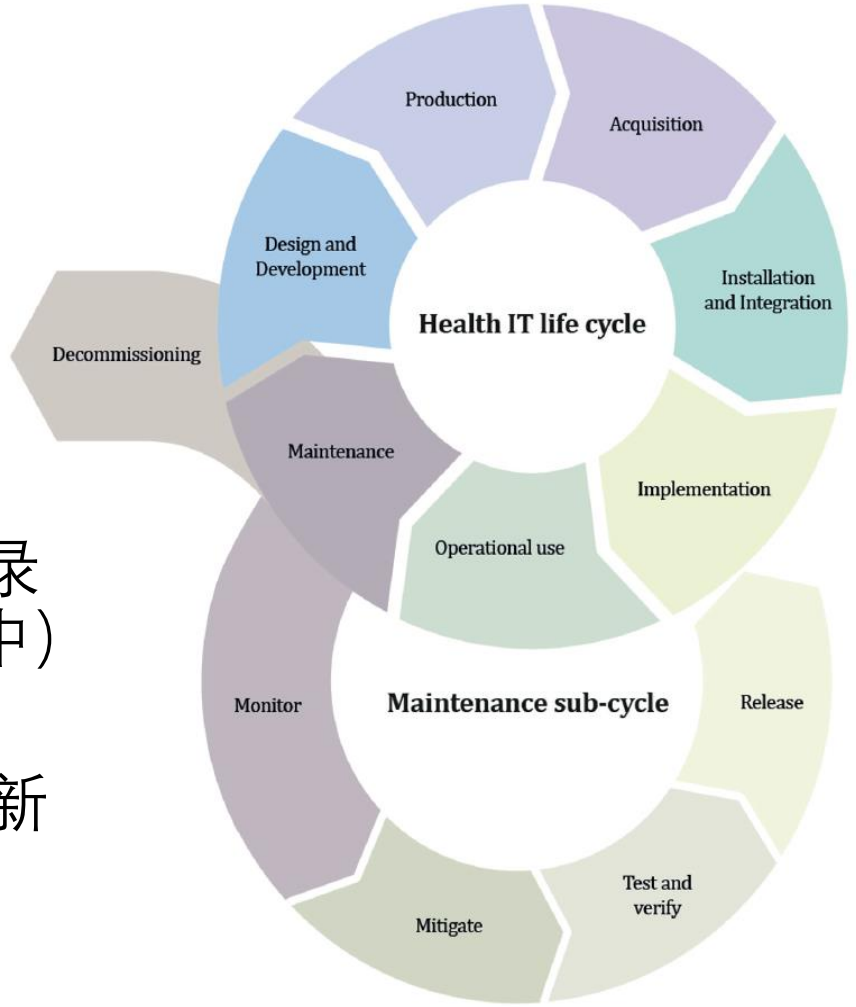
Key Take-Aways: 关键信息

- All actors (regulators, healthcare providers, HCPs, industry) in the medical device regulatory system consider cybersecurity a priority and take active steps to ensure safety and security of devices 医疗器械监管系统中的所有参与者(监管机构、医疗保健提供者、行业)都将网络安全视为优先事项，并采取积极措施确保设备安全
- Published IMDRF cybersecurity guidance is an excellent first step towards global convergence IMDRF发布的网络安全指南是迈向全球融合的绝佳第一步
- Further work is necessary on, for example, the practical implementation of security for legacy/transitional devices and shared responsibility at international level 有必要进一步开展工作，例如，切实落实老设备和过渡性设备的安全，以及在国际层面分担
- Cybersecurity is a shared responsibility across healthcare stakeholders 网络安全是医疗利益相关方的共同责任

Link: https://www.globalditta.org/media-centre/events/article/imdrf-ditta-joint-virtual-workshop-cybersecurity-where-are-we-today.html

Cybersecurity By Design 根于设计的网络安全

- The manufacturer is responsible to address cybersecurity during the entire product life cycle. 制造商有责任在整个产品生命周期内负责网络安全问题
- The expected intended operational environment of use has to be clearly documented (e.g. in the IfU). 必须明确记录使用的预期实操环境（例如：在说明书中）
- Newly identified threats and remediation scenarios have to be communicated. 沟通新出现的风险以及补救方案



ISO 81001-1

Sharing of information 信息共享

- Information sharing must be bidirectional 保证双向信息共享
- Security information through accompanying documentation such as but not limited to Instructions for Use, Instructions for Administrators and Network administrator guides 通过附带文档提供安全信息，包括但不限于使用说明、管理员说明和网络管理员指南
- Information published on the manufacturers website or part of procurement process: 在制造商网站上的公开信息或采购过程的一部分：
  - Security and Privacy whitepapers 安全与隐私白皮书
  - MDS2 documents MDS2文档(医疗器械安全制造商披露声明)
  - System security status / patch information 系统安全等级/补丁信息
  - Security notifications 安全性通知
  - Other security relevant information 其他相关信息

Need for remote audits under MDR

MDR 框架下远程审核的需求

COCIR Recommendation

Need for remote audits under the MDR in times of COVID-19

Background information

The Medical Device Regulation (MDR) enters into force on 26 May 2021. To place a new device or a device that has under-gone a significant change on the European market after that date, MDR certification must be in place – requiring an audit by a Notified Body. Annex IX 3.3 of the Regulation stipulates that "audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors".

Problem statement

The current COVID-19 pandemic causes travel and other restrictions leading to delays of initial MDR certification audits, as Notified Body auditors do not have access to the physical premises of the manufacturer. Many audits have been postponed until the end of 2020 or even 2021. Some companies are even still waiting for the exact audit date from their Notified Body. **There is thus a high likelihood that not all COCIR member companies will have achieved MDR certification by the end of May 2021, even though they are ready and have prepared everything for MDR compliance.**

Some Notified Bodies have already announced that changes to devices certified under the Medical Device Directives (MDD) are not possible anymore after November 2020. In addition, when production has been planned according to EU MDR, there are often limited possibilities to step back to MDD production (due to supplier capacity, parts availability, documentation to be reworked, etc.).

In conclusion, if the current situation continues, we expect delays in product launches (or even shortages) for certain imaging, electromedical, radiotherapy and software devices next year. This is especially concerning as the pandemic situation is worsening and it is not clear if all re-scheduled audits will actually take place as planned. **If no solution is found, we see a direct threat to the availability of innovative medical devices to European healthcare systems and to the competitiveness of the medical device industry in Europe.**

Recommendation

In these extraordinary circumstances, urgent action is needed to allow **conducting initial MDR certification audits remotely** by using the latest Information and Communication Technologies[1]. **COCIR calls on the Medical Device Coordination Group (MDCG) to expand the current guidance[2] on remote audits to all (not only essential for COVID-19) devices under MDR.** A condition may be introduced that the on-site audit must take place at the next surveillance audit.

[1] See also March 2020 guidance issued by the International Accreditation Forum (IAF) that proposes alternative auditing methods in extraordinary circumstances. The IAF also published a statement with specific guidance for COVID-19.
[2] April 2020 Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions: https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_4_nb_audits_covid-19_en.pdf

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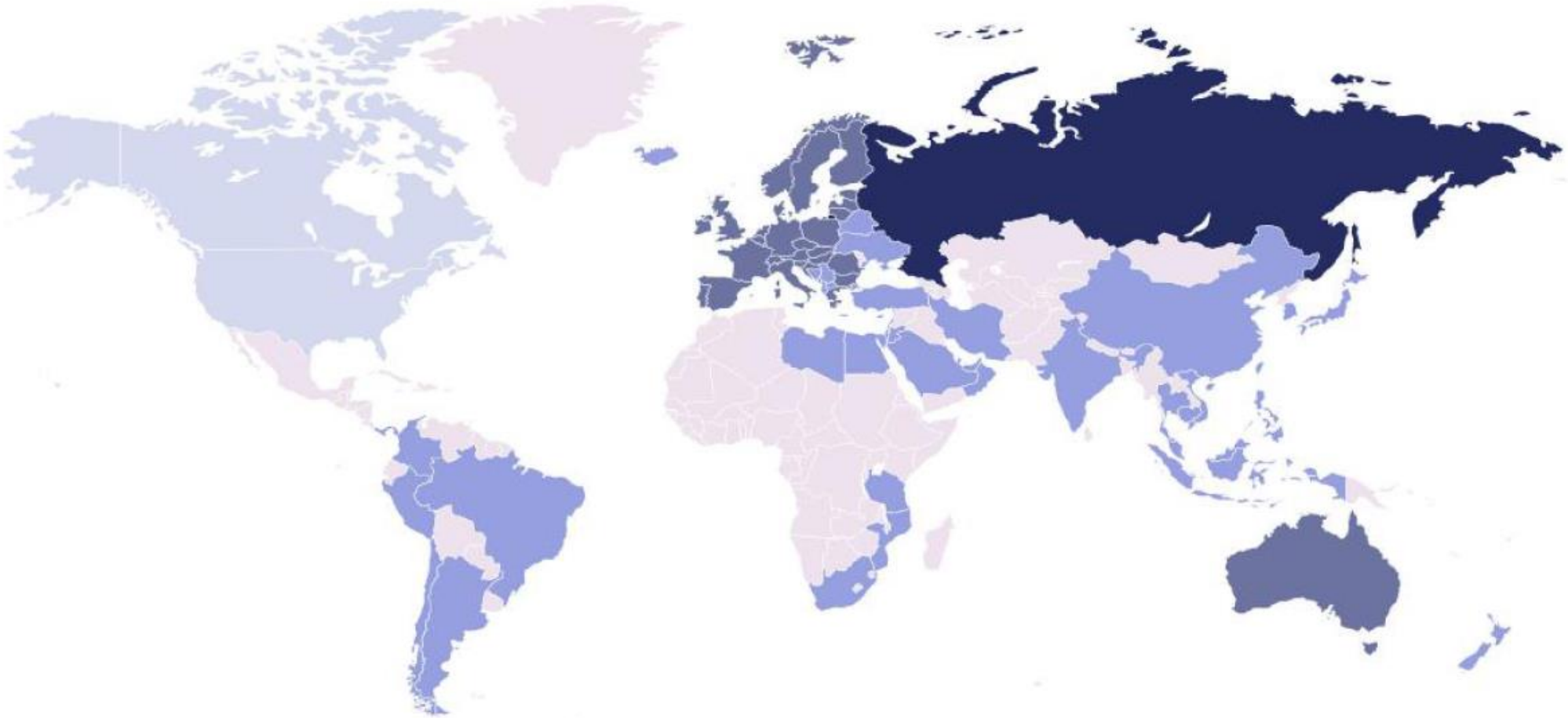
- several Notified Bodies will not update existing MDD certificates anymore —些公告机构不再更新MDD证书
- COVID-19 is delaying MDR audits due to (travel) restrictions 由于新冠疫情的旅行限制，MDR审核被推迟
  - many audits postponed until between November this year to even early next year (or even not scheduled at all) 许多审核推迟到今年11月，甚至明年年初(有的仍暂无计划)。
- limited possibilities to step back to MDD production 回到MDD框架下生产的可能性有限
- **need for remote/virtual audits 需要进行远程/虚拟审核**
  - Recommendation: expand current guidance (MDCG 2020-4) on remote audits to all (not only essential for COVID-19) devices under MD

  建议：将目前关于远程审核的指导文件(MDCG 2020-4)扩大到MDR下的所有(不仅对COVID-19至关重要)器械

Qualification of software as a medical device 作为医疗器械的软件



3. Better access to innovative MDs to contribute to better healthcare: welcome fast track regulatory framework in China and importance of AI
优化创新医疗器械准入，共建医疗保健：支持中国建立快速通道监管框架，以及人工智能的重要性

Fast Track Regulatory Framework in China
(针对创新医疗器械)中国的快速通道监管框架

- To encourage innovation of medical devices, China NMPA established Procedure for Innovative Medical Device Program*, which helps for innovative products speed to market – CMDE provides
  为鼓励医疗器械创新，国家药品监督管理局实施《创新医疗器械特别审批程序》，帮助创新产品快速进入市场。国家药品监督管理局医疗器械技术审评中心提供
  - consulting services and technical comments during the whole process; 全过程的咨询服务和技术意见
  - Priority of reviewing; 优先审评
  - Disclosure of review report. 公开审评报告

In 2019, EUCCC-COCIR China got accepted by NMPA as one of the total seven innovation service stations, the only one among all foreign Chambers/Associations.
2019年，中国欧盟商会被医疗器械技术审评中心纳入七个创新服务站点之一

** Two documents issued by CMDE: <Process for Innovative Medical Device Program>, and <Standard Operation Procedure for Innovative Medical Device Program>*

Importance of AI – What's going on in China

Artificial Intelligence Medical Device Innovation and Cooperation Platform 人工智能医疗器械创新合作平台

- The Platform was jointly launched by 14 organizations including CMDE (under NMPA) (Executive Institution), the China Academy of Information and Communications Technology (CAICT, under MIIT), and International Health Exchange and Cooperation Center (IHECC, under NHC), etc.

  该平台由国家药品监督管理局医疗器械技术审评中心、工信部下属中国信息通信研究院、国家卫生健康委员会下属国际卫生交流与合作中心等14家机构联合创立。

- 12 Work Teams are performing from perspectives like technical regulation, data governance, cybersecurity, standardization research, clinical evaluation, etc.

  12个工作组从技术法规、数据治理、网络安全、标准化、临床评价等角度着手。

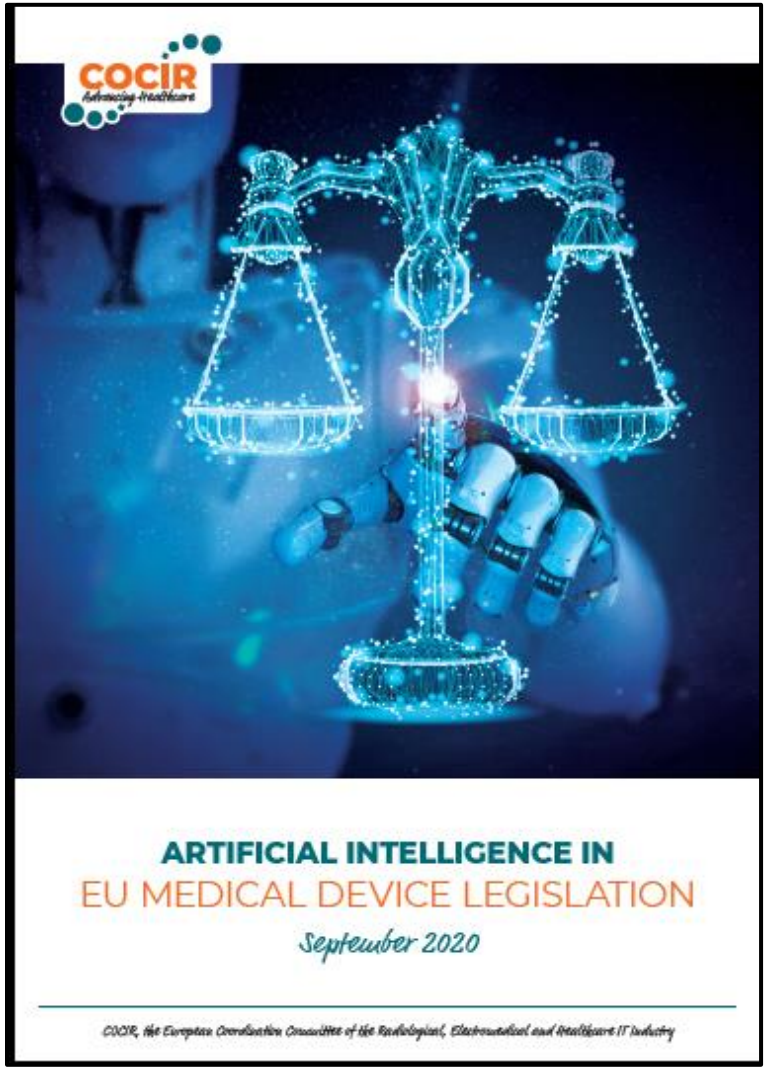
Chinese Measures on Cybersecurity Review 中国网络安全审查相关举措

- In April 2020, The Cyberspace Administration of China ("CAC"), together with 11 other authorities, has jointly issued the *Measures for Cybersecurity Review Product Risk Evaluation Report* 2020年4月，国家网信办会同其他11个部门联合发布了《网络安全审查办法》

China's *Data Security Law* is under developing 中国《数据安全法》正在制定

- Industries pay much attention to Connection between this law and Cybersecurity Law, Definition of Data and Important Data, Control of 'Data Activities' and Testing, Evaluation and Review of Data, Export Control of Data
  各行各业都在关注本法与《网络安全法》的关系、数据和重要数据的定义、"数据活动"的控制和数据的测试、评估和审查、数据的出口控制。

Artificial Intelligence-based Medical Devices



- IMDRF New Work Item on **Artificial Intelligence** (definitions & terminology)

  IMDRF关于人工智能的新工作项目(定义和术语)

- Development of **horizontal EU framework** for Artificial Intelligence
  欧盟工作框架的发展
- COCIR sees no need for novel regulatory frameworks for AI-based devices in Healthcare, because the **requirements of EU MDR are adequate**

  COCIR认为无需为医疗保健中基于人工智能的设备建立新的监管框架，欧盟MDR的要求已经足够

COCIR
Advancing Healthcare

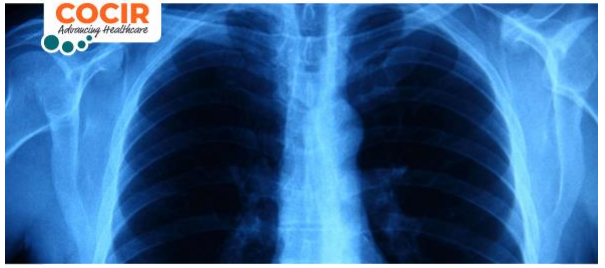
| *Artificial Intelligence in Healthcare*

人工智能在医疗方面应用

COCIR ARTIFICIAL INTELLIGENCE USE CASE 01

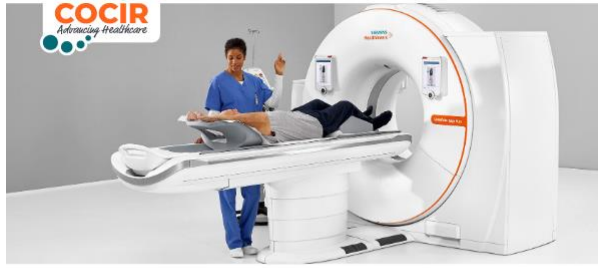
AI IN CHEST IMAGING

COCIR ARTIFICIAL INTELLIGENCE USE CASE 02



AI FOR PNEUMOTHORAX (PTX) DETECTION & IMPROVED WORKFLOW PRODUCTIVITY

COCIR ARTIFICIAL INTELLIGENCE USE CASE 03



AI IN PATIENT POSITIONING FOR COMPUTED TOMOGRAPHY IMAGING

COCIR ARTIFICIAL INTELLIGENCE USE CASE 04

AI WOMEN'S HEALTH ULTRASOUND

COCIR ARTIFICIAL INTELLIGENCE USE CASE 05

SNAKEBITE & SNAKE IDENTIFICATION VIA MOBILE DEVICES

COCIR ARTIFICIAL INTELLIGENCE USE CASE 06

TELEDERMATOLOGICAL SCREENING SOLUTION VIA MOBILE DEVICES

COCIR ARTIFICIAL INTELLIGENCE USE CASE 07

AI IN CHEST IMAGING

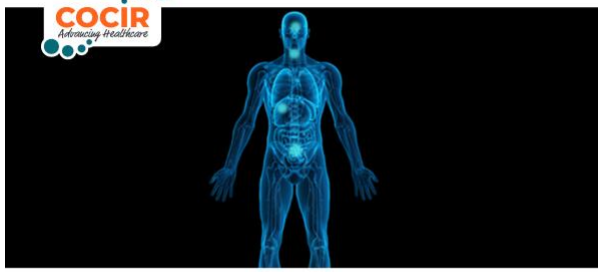
COCIR ARTIFICIAL INTELLIGENCE USE CASE 08

AI IN ADAPTIVE RADIOTHERAPY

COCIR ARTIFICIAL INTELLIGENCE USE CASE 09

AI IN MAMMOGRAPHIC BREAST DENSITY

COCIR ARTIFICIAL INTELLIGENCE USE CASE 10



AI BASED RADIOTHERAPY TREATMENT PLANNING SOLUTION

More COCIR AI Use Cases to follow

更多AI使用案例请关注COCIR出版物关于数字健康的主题 – www.cocir.org

COCIR publications on digital health topics - www.cocir.org

COCIR
Advancing Healthcare