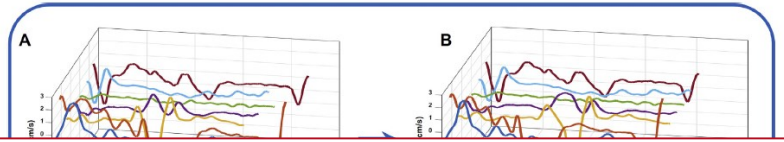
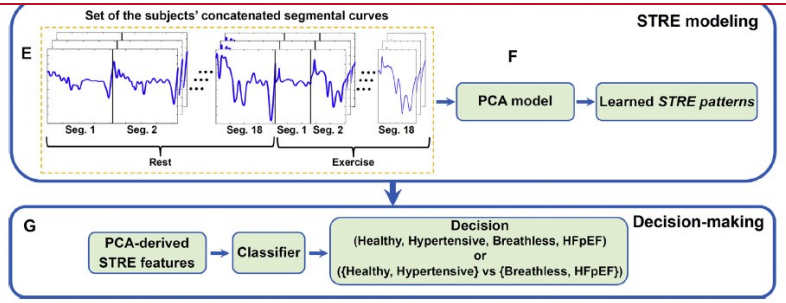
Piotr Szymański, MD, FESC
Chair, Regulatory Affairs Committee

Diagnosis of Heart Failure With Preserved Ejection Fraction: Machine Learning of Spatiotemporal Variations in Left Ventricular Deformation

Mahdi Tabassian, PhD, Imran Sunderji, MD, Tamas Erdei, MD, PhD, Sergio Sanchez-Martinez, MSc, Anna Degiovanni, MD, Paolo Marino, MD, Alan G. Fraser, MD, and Jan D'hooge, PhD,
Leuven, Belgium; Cardiff, United Kingdom; Barcelona, Spain; and Novara, Italy



Machine learning of spatiotemporal variations of LV strain rate during rest and exercise could be used to identify patients with HFpEF and to provide an objective basis for diagnostic classification



https://doi.org/10.1016/j.echo.2018.07.013

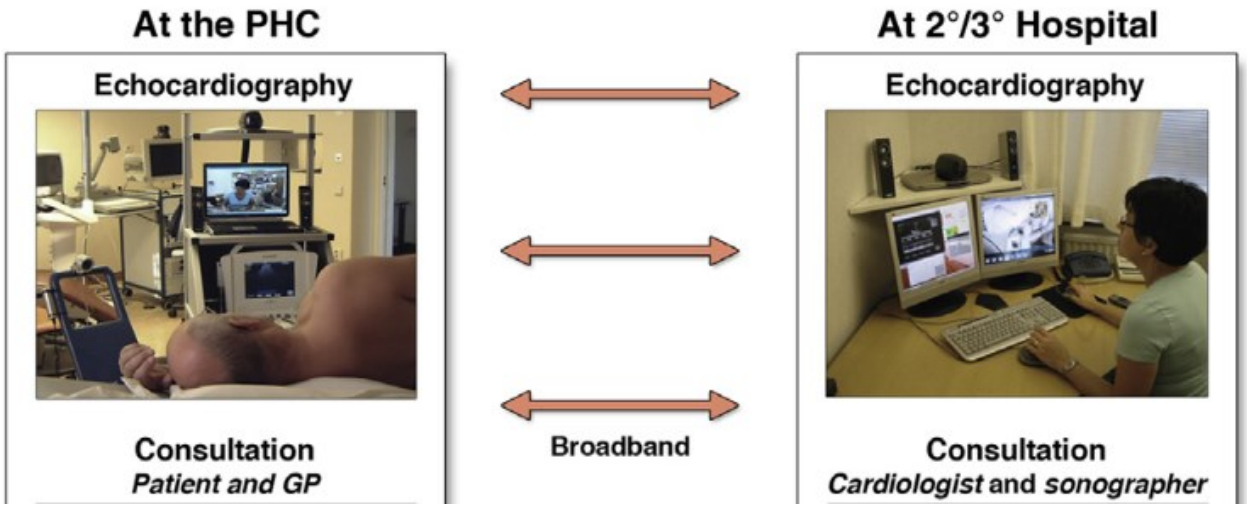
Robot-Assisted Echocardiography

CONCEPTS ON THE VERGE OF TRANSLATION

Robot-Assisted Remote Echocardiographic Examination and Teleconsultation

A Randomized Comparison of Time to Diagnosis With Standard of Care Referral Approach

Kurt Boman, MD, PhD,* Mona Olofsson, BSc,* Peter Berggren, MD,† Partho P. Sengupta, MD,‡ Jagat Narula, MD, PhD‡



J Am Coll Cardiol Img 2014;7:799–803


esa
SPACE FOR INTELLIGENT HEALTH
How space contribute to disruption and innovation in the health ecosystem
DOWNSTREAM GATEWAY
Space for Earth
Digital Workshop | 3 November 2020 | 9:00 – 16:00 CET

The objective of the workshop:

- Debate the technological needs and requirements deriving from policies from the institutional, financial and technical point of view
- Understand the innovative applications, opportunities, and transformative potential of AI and digitalisation in the Health Care system
- Present how Space sector is contributing toward ESA action to support the new challenges of the Health Care system
- Present ESA future roadmap in support to the innovative and holistic projects in Health Care on Earth and in Space

& Who we are
What we do

100,000

scientists, clinicians, nurses & allied professions

What is the ESC?

- A **volunteer led**, not-for-profit medical society
- Our members are **health care professionals**
- A source of **high quality**, evidence-based **science**
- Ensures **objectivity, transparency** and **integrity**

The ESC operates a strict Declaration Of Interest (DOI) policy. Some 2,000 ESC volunteers are required to complete an annual DOI. This policy can be reviewed at www.escardio.org/DOI

How the ESC Works

- The ESC is governed by an elected Board
- The ESC's activities are overseen by **dedicated committees**
- **5,000 cardiology experts contribute to ESC activities**
- The ESC employs **200 staff**, managed by a Chief Executive Officer

Understand the opportunities...”

Why the ESC exists

Cardiovascular disease remains the world’s, biggest killer

17.9 million deaths globally
(31% of all deaths)*

80% of premature heart disease and stroke is preventable*

CVD costs the EU economy an estimated 210 billion Euros per year*

11 million new cases of CVD in 47 ESC member countries**

**World Health Organization*
***ESC Atlas of Cardiology*

Why the ESC exists

Understand the opportunities…”

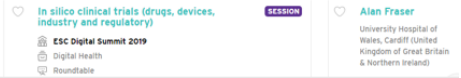
The complexity of modern medicine

ESC

- Genome — 3.2 $\times 10^9$ base pairs / varying 0.15% (<5 $\times 10^6$ sites)
- Transcriptome — Messenger RNA <20,000 genes / >1000 microRNAs
- Proteome — Proteins 30,057 / peptide sequences 293,700
- Metabolome — 2,272 human metabolic pathways (*reactome.org*)
- Microbiome — 38 $\times 10^{12}$ bacteria (cf. 30 $\times 10^{12}$ human cells)
- Physiome — …

Nature 2015;526:68 / JACC 2016;68:2577 / Nature 2014;509:575 / PLoS Biology 2016;14:e1002533

- Epigenetics, age, gender, lifestyle, social influences, comorbidities ..
- >13,000 diseases / >55,000 disease codes [ICD 11, WHO 2019] / >6,000 rare
- ~20,000 pharmaceutical products / ~500,000 medical devices / ~40,000 tests



How the ESC Works

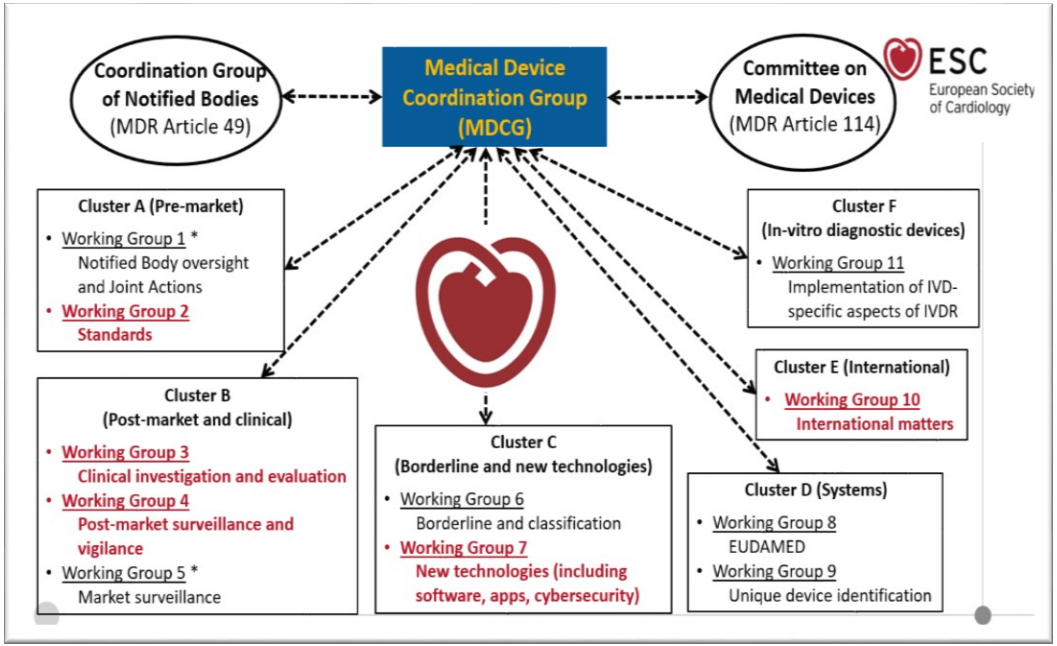
- The ESC is governed by an elected Board
- The ESC's activities are overseen by **dedicated committees**
- 5,000 cardiology experts contribute to ESC activities
- The ESC employs **200 staff**, managed by a Chief Executive Officer

ESC - Regulatory Affairs Committee

Better & safer medical devices in CVD

Provide high-level expertise to regulators for policy about cardiovascular devices: at EU **Medical Device Coordination Group** and its Working Groups

Significantly contribute to **EU Expert Panels assessing high-risk medical devices:** *56 cardiologists appointed as panel members and advisers*



ESC - Regulatory Affairs Committee

Take advantage of the digital revolution

- Provide expertise as a member of the **EU e-health Stakeholder Group**
- Contribute expert views for the development of the new European Health Data Space
- Promote EuroHeart to the European Institutions as key tool to provide real time data and evidence in CVD
- Contribute to the preparation of a Code of Conduct on GDPR and secondary use of health data
- Explore with EMA how EuroHeart could support regulatory decisions and randomized clinical trials
- Contribute to EMA Guideline on registry-based studies

EuroHeart

European Commission

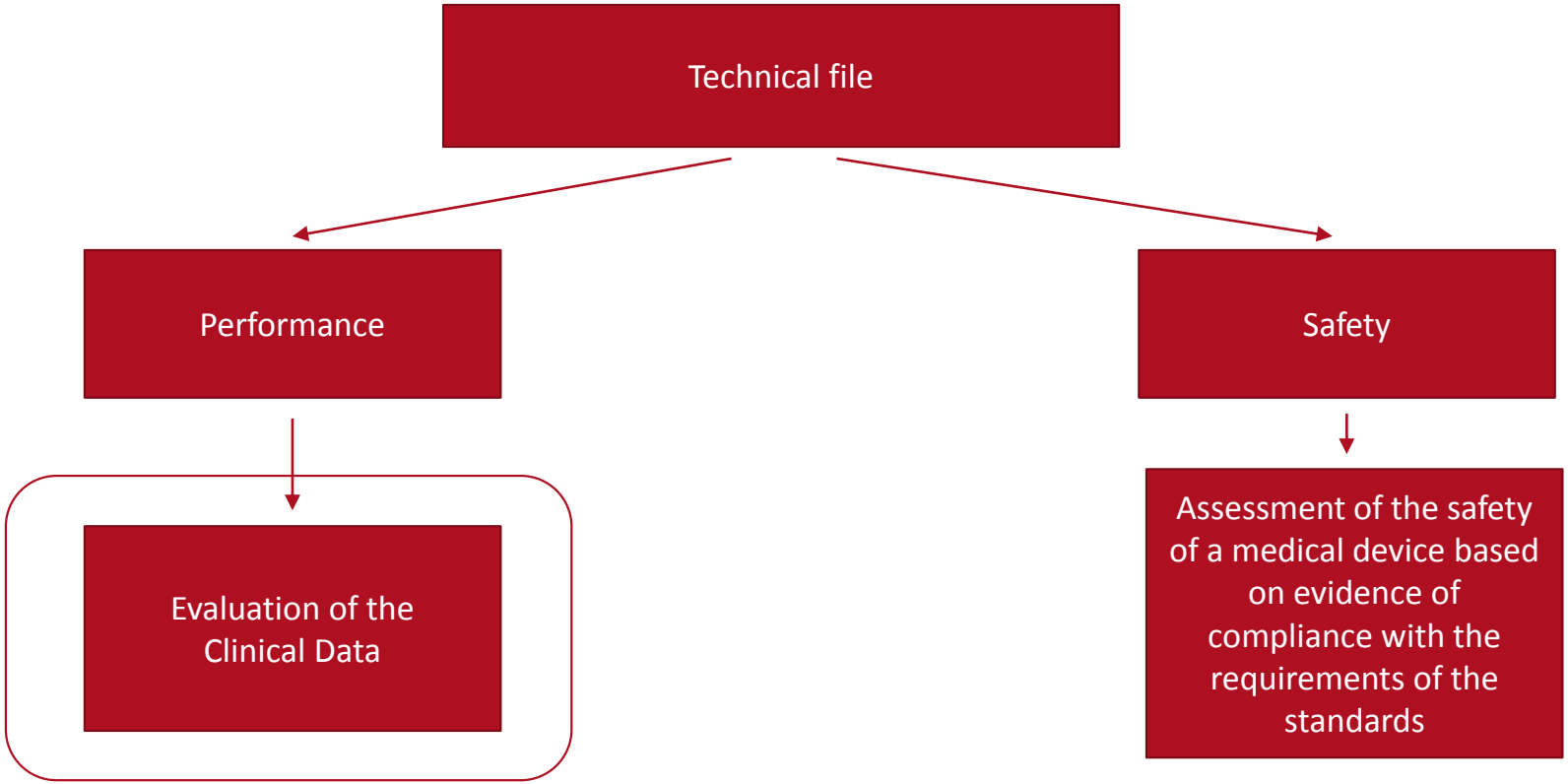
European Health Data Space

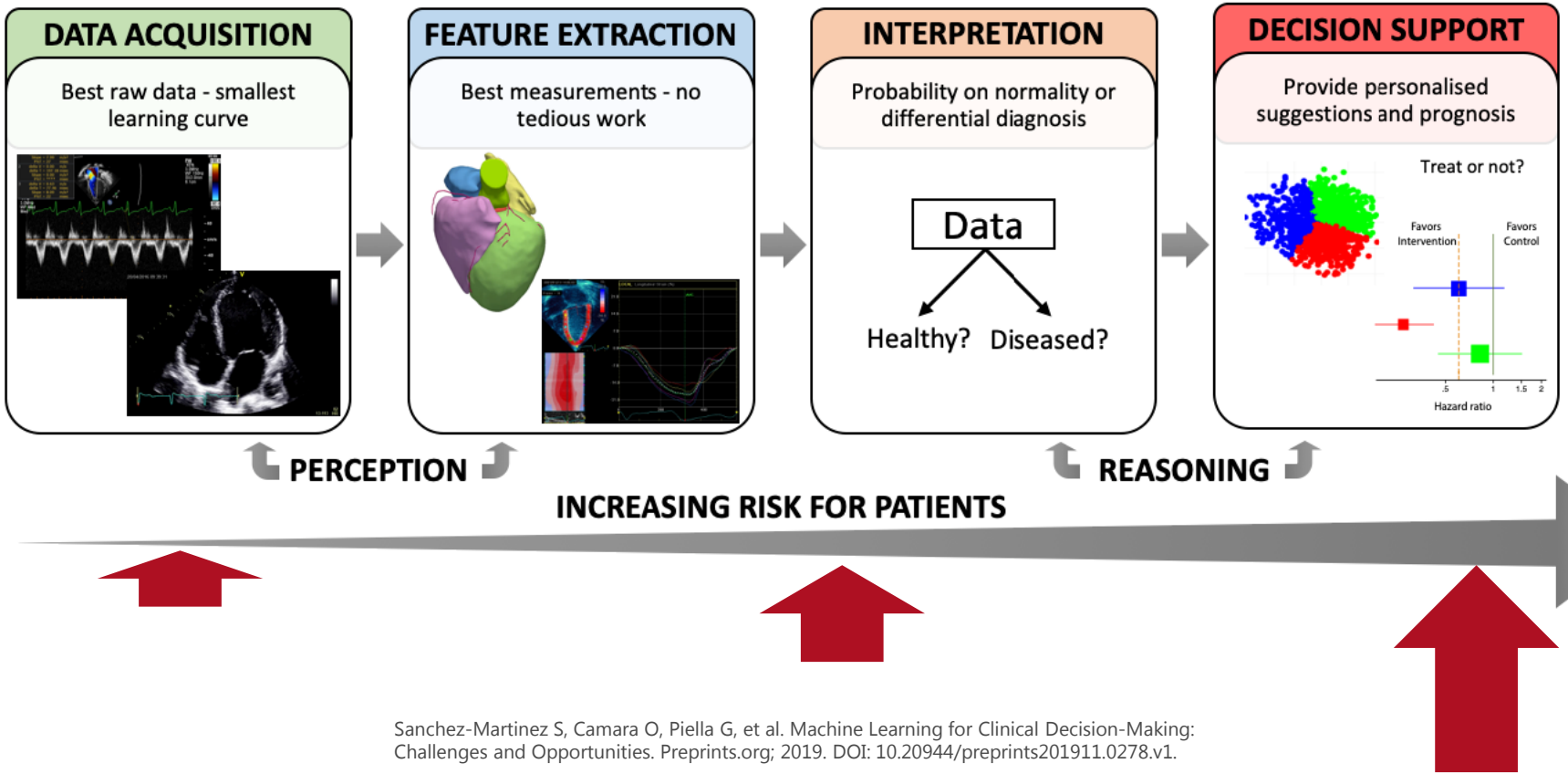
Contribution ID: 7f677b1e-eeb0-47be-af4c-10e2fc94221d
Date: 12/06/2020 14:37:28

Consultation on the White Paper on Artificial Intelligence - A European Approach

Fields marked with * are mandatory.

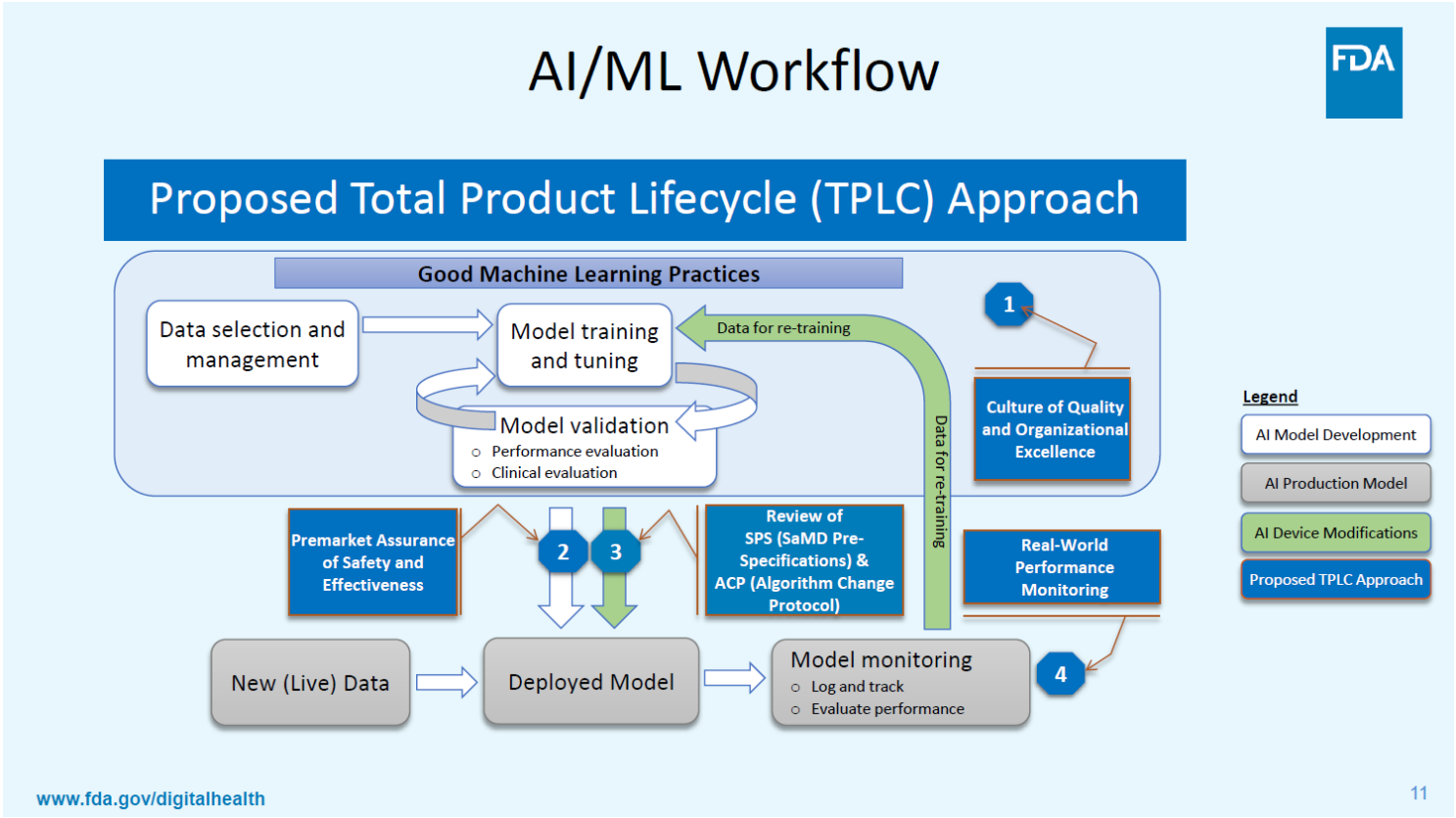
How does a notified body assess the performance and safety of a AI based medical device





Sanchez-Martinez S, Camara O, Piella G, et al. Machine Learning for Clinical Decision-Making: Challenges and Opportunities. Preprints.org; 2019. DOI: 10.20944/preprints201911.0278.v1.

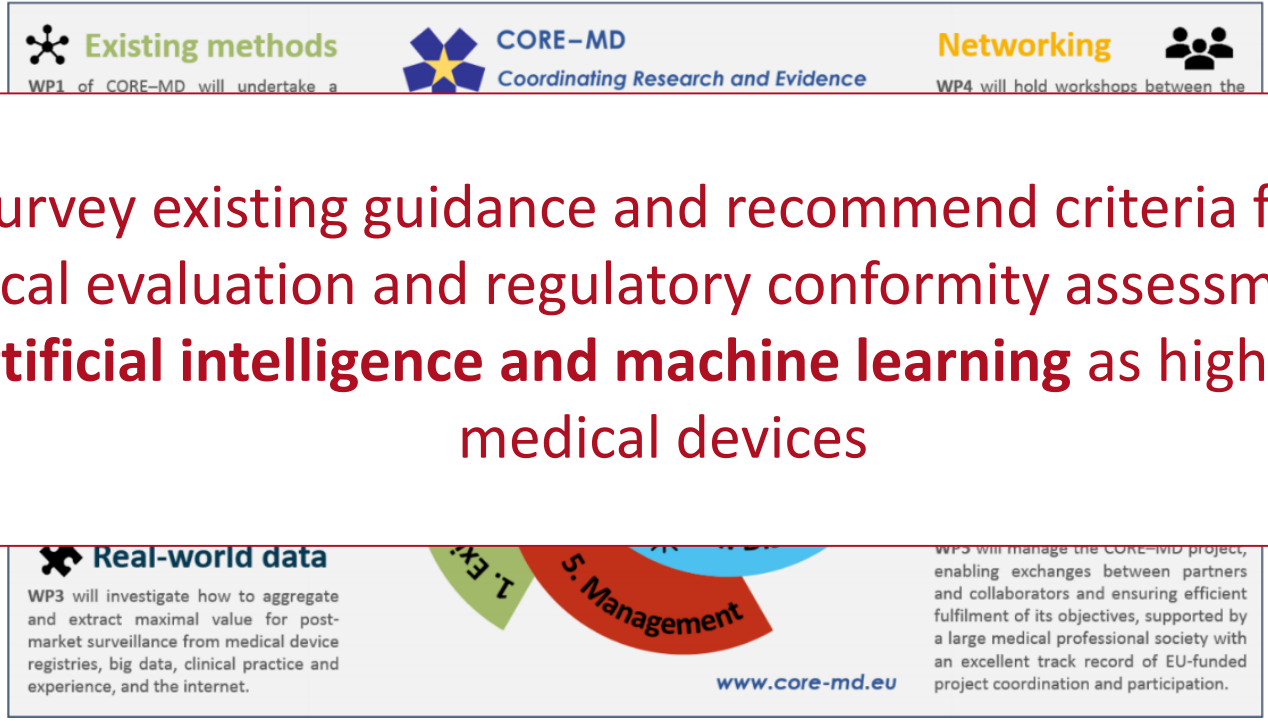
FDA proposed regulatory framework for AI/ML



CORE–MD

Coordinating Research and Evidence for Medical Devices

Translating expert knowledge into advice for EU regulatory guidance, and building expertise in regulatory science in the clinical community



to survey existing guidance and recommend criteria for the clinical evaluation and regulatory conformity assessment of **artificial intelligence and machine learning** as high-risk medical devices

Horizon 2020 Call: H2020-SC1-BHC-2018-2020
ID: SC1-HCO-18-2020
Type of action: Coordination and Support Action

ESC - Regulatory Affairs Committee

Improving the regulatory framework for clinical trials

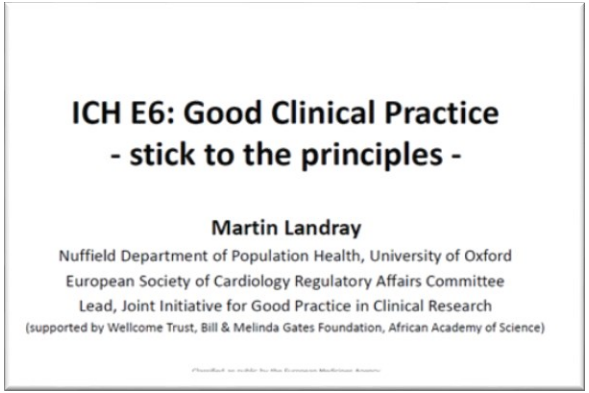
- Collaboration with the **Good Clinical Trials Collaborative** initiative in calling for an urgent revision of guidance for the conduct of clinical trials
- Member of the **EMA ICH Expert Working Group** tasked with updating the Good Clinical Practice (GCP) guideline (ICH E6)
- Learn from **experience during COVID-19** on pragmatic approach in clinical trials
- Work with the **BioMedical Alliance**

Biomedical Alliance in Europe

Reducing bureaucracy in clinical trials: now is the time!

Joint statement by medical societies and patient advocates

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



Guidelines for clinical trials

for interventions involving AI

RESEARCH METHODS AND REPORTING

OPEN ACCESS

Check for updates

Guidelines for clinical trial protocols for interventions involving artificial intelligence: the SPIRIT-AI Extension

Samantha Cruz Rivera,[1,2] Xiaoxuan Liu,[2,3,4,5,6] An-Wen Chan,[7] Alastair K Denniston,[1,2,3,4,5,8] Melanie J Calvert,[1,2,6,9,10,11] On behalf of the SPIRIT-AI and CONSORT-AI Working Group

For numbered affiliations see end of the article.

Correspondence to:
A K Denniston,
Institute of Inflammation and Ageing, College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK,
a.denniston@bham.ac.uk

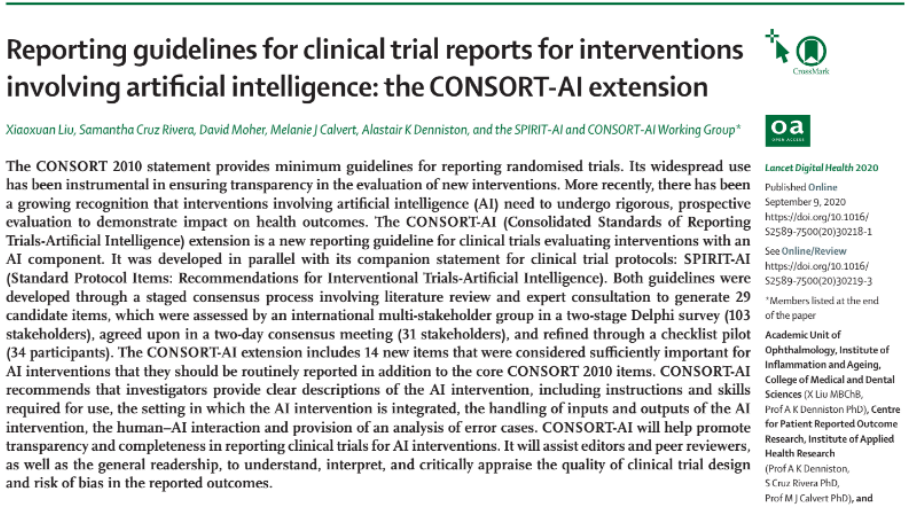
Cite this as: *BMJ* 2020;370:m3210
http://dx.doi.org/10.1136/bmj.m3210

Accepted: 4 August 2020

The SPIRIT 2013 (The Standard Protocol Items: Recommendations for Interventional Trials) statement aims to improve the completeness of clinical trial protocol reporting, by providing evidence-based recommendations for the minimum set of items to be addressed. This guidance has been instrumental in promoting transparent evaluation of new interventions. More

investigators provide clear descriptions of the AI intervention, including instructions and skills required for use, the setting in which the AI intervention will be integrated, considerations around the handling of input and output data, the human-AI interaction and analysis of error cases.

SPIRIT-AI will help promote



Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension

*Xiaoxuan Liu, Samantha Cruz Rivera, David Moher, Melanie J Calvert, Alastair K Denniston, and the SPIRIT-AI and CONSORT-AI Working Group**

The CONSORT 2010 statement provides minimum guidelines for reporting randomised trials. Its widespread use has been instrumental in ensuring transparency in the evaluation of new interventions. More recently, there has been a growing recognition that interventions involving artificial intelligence (AI) need to undergo rigorous, prospective evaluation to demonstrate impact on health outcomes. The CONSORT-AI (Consolidated Standards of Reporting Trials-Artificial Intelligence) extension is a new reporting guideline for clinical trials evaluating interventions with an AI component. It was developed in parallel with its companion statement for clinical trial protocols: SPIRIT-AI (Standard Protocol Items: Recommendations for Interventional Trials-Artificial Intelligence). Both guidelines were developed through a staged consensus process involving literature review and expert consultation to generate 29 candidate items, which were assessed by an international multi-stakeholder group in a two-stage Delphi survey (103 stakeholders), agreed upon in a two-day consensus meeting (31 stakeholders), and refined through a checklist pilot (34 participants). The CONSORT-AI extension includes 14 new items that were considered sufficiently important for AI interventions that they should be routinely reported in addition to the core CONSORT 2010 items. CONSORT-AI recommends that investigators provide clear descriptions of the AI intervention, including instructions and skills required for use, the setting in which the AI intervention is integrated, the handling of inputs and outputs of the AI intervention, the human–AI interaction and provision of an analysis of error cases. CONSORT-AI will help promote transparency and completeness in reporting clinical trials for AI interventions. It will assist editors and peer reviewers, as well as the general readership, to understand, interpret, and critically appraise the quality of clinical trial design and risk of bias in the reported outcomes.

Lancet Digital Health 2020
Published Online
September 9, 2020
https://doi.org/10.1016/S2589-7500(20)30218-1
See Online/Review
https://doi.org/10.1016/S2589-7500(20)30219-3

*Members listed at the end of the paper

Academic Unit of Ophthalmology, Institute of Inflammation and Ageing, College of Medical and Dental Sciences (X Liu MBChB, Prof A K Denniston PhD), Centre for Patient Reported Outcome Research, Institute of Applied Health Research (Prof A K Denniston, S Cruz Rivera PhD, Prof M J Calvert PhD), and

ESC – Regulatory Affairs Committee
Take advantage of the digital revolution

- Provide expertise as a member of the EU e-health Stakeholder Group
- Contribute expert views for the development of the new European Health Data Space
- Promote **EuroHeart** to the European Institutions **as key tool to provide real time data and evidence in CVD**

EuroHeart

EuroHeart

European Unified Registries for Heart Care Evaluation and Randomised Trials

The Mission of EuroHeart is:

1. To develop an international collaboration that provides common definitions of QoC indicators and the availability of an IT infrastructure for continuous online registration of high quality and harmonised patient data, supporting improvement of care and outcomes in patients with common cardiovascular diseases.
2. To provide an international infrastructure for cost-effective safety surveillance of new drugs and devices and registry-based randomized controlled trials in a general patient population across multiple geographies.

EuroHeart
European Unified Registries for Heart Care Evaluation and Randomised Trials

The full spectrum of cardiology

Unifying knowledge, expertise and understanding of CVD

Acute Cardiovascular Care Association

EAPC European Association of Preventive Cardiology

HFA Heart Failure Association

ACNAP Association of Cardiovascular Nursing & Allied Professions

EAPCI European Association of Percutaneous Cardiovascular Interventions

ESC Councils

EACVI European Association of Cardiovascular Imaging

EHRA European Heart Rhythm Association

ESC Working Groups

frontiers in Astronomy and Space Sciences

MINI REVIEW
published: 23 August 2016
doi: 10.3389/fspas.2016.00027

Weightlessness and Cardiac Rhythm Disorders: Current Knowledge from Space Flight and Bed-Rest Studies

Enrico G. Caiani[1]*, *Alba Martin-Yebra*[1,2], *Federica Landreani*[1], *Juan Bolea*[2,3], *Pablo Laguna*[2,3] and *Pierre Vaïda*[4]

[1] *Dipartimento di Elettronica, Informazione e Bioingegneria, Politecnico di Milano, Milan, Italy,* [2] *Instituto de Investigación en Ingeniería de Aragón (I3A), Universidad de Zaragoza, Zaragoza, Spain,* [3] *Centro de Investigación Biomédica en Red en Bioingeniería, Biomateriales y Nanomedicina, Zaragoza, Spain,* [4] *École Nationale Supérieure de Cognitique, Institut Polytechnique de Bordeaux, Université de Bordeaux, Bordeaux, France*

Isolated episodes of heart rhythm disorders have been reported during 40 years of space flight, triggering research to evaluate the risk of developing life-threatening arrhythmias induced by prolonged exposure to weightlessness.

OPEN ACCESS

Edited by:
Jack Van Loon,
Vrije Universiteit Amsterdam,
Netherlands

risk the astronaut health, due to limited options of care on board the International Space Station. Starting from original observations, this mini review will explore the latest research in this field, considering results obtained both during space flight and on Earth, the latter by simulating long-term exposure to microgravity by head-down bed rest maneuver in order to elicit cardiovascular deconditioning on normal volunteers.

Risk of Spaceflight Induced Cardiovascular Disease

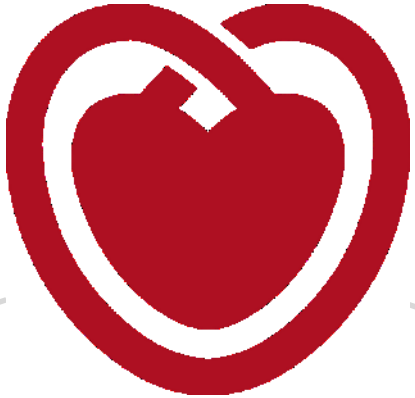
- Cardiac function - cardiac deconditioning
- Circadian activity of the CV system
- Arrhythmic risk
- Cardiotoxicity (radiation protection)

Summing up, the ESC is…

The reference and authority for cardiology in Europe

Quality science and best practice

Independent real-life data



Unbiased scientific expertise

A voice for cardiology

A uniting force for the cardiology community

Thank you