Emerging Technologies: opportunities and pitfalls

Sunday, October 30th
Sergio Bernardini
Royal A & B

1952 2022 70th Anniversary
International Federation of Clinical Chemistry and Laboratory Medicine

Advancing excellence in laboratory medicine for better healthcare worldwide

ifcc.org

What means «Emerging»?

DE GRUYTER

Clin Chem Lab Med 2022; aop

Opinion Paper

Ronda F. Greaves*, Larry Kricka, Damien Gruson, Helen Martin, Maurizio Ferrari and Sergio Bernardini, on behalf of the IFCC Emerging Technologies Division

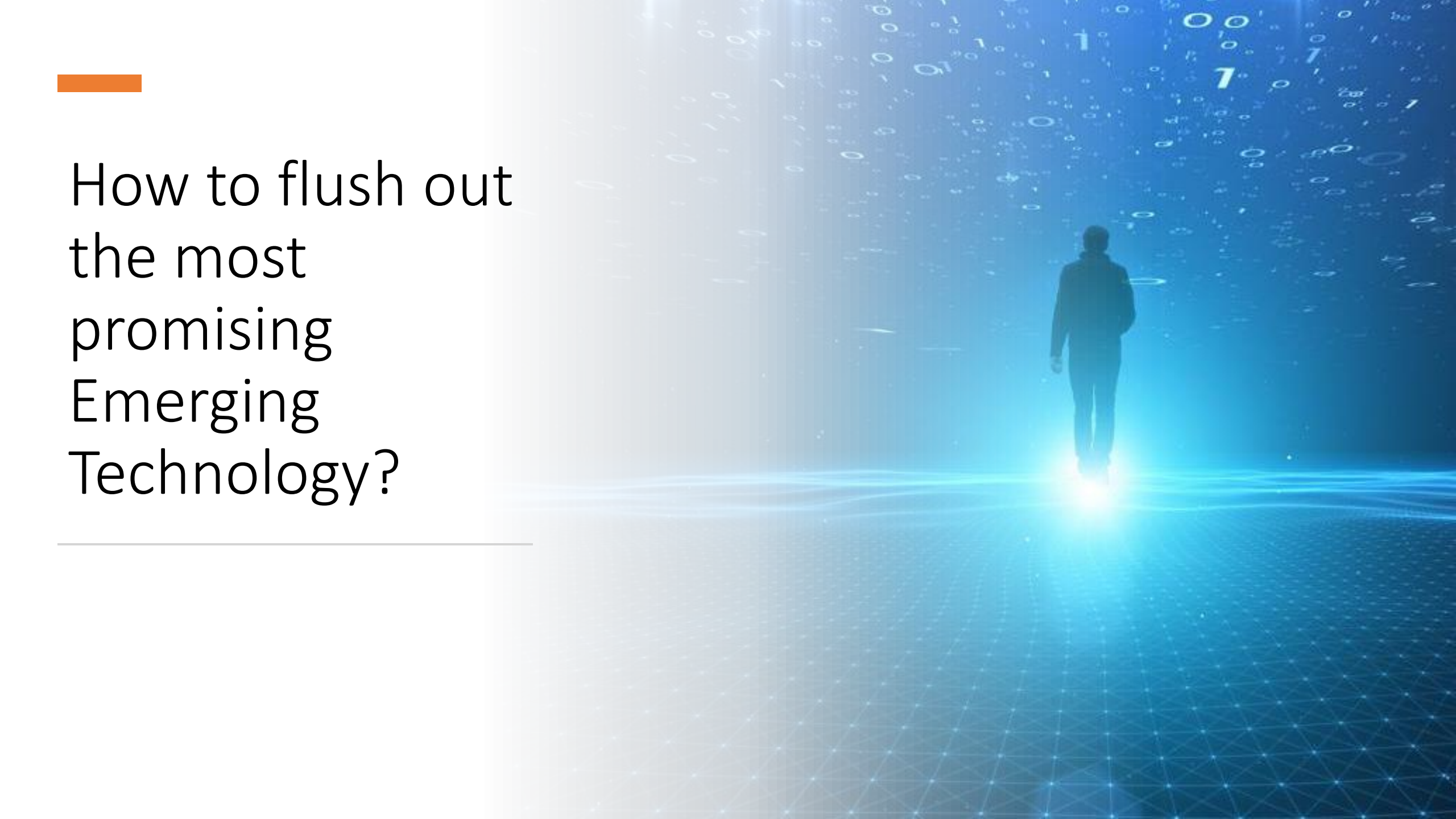
Emerging technology: a definition for laboratory medicine

- innovation
- relatively fast-growing
- future impact
- becoming apparent or prominent
- just beginning to exist
- uncertainty
- beginning to have economic success

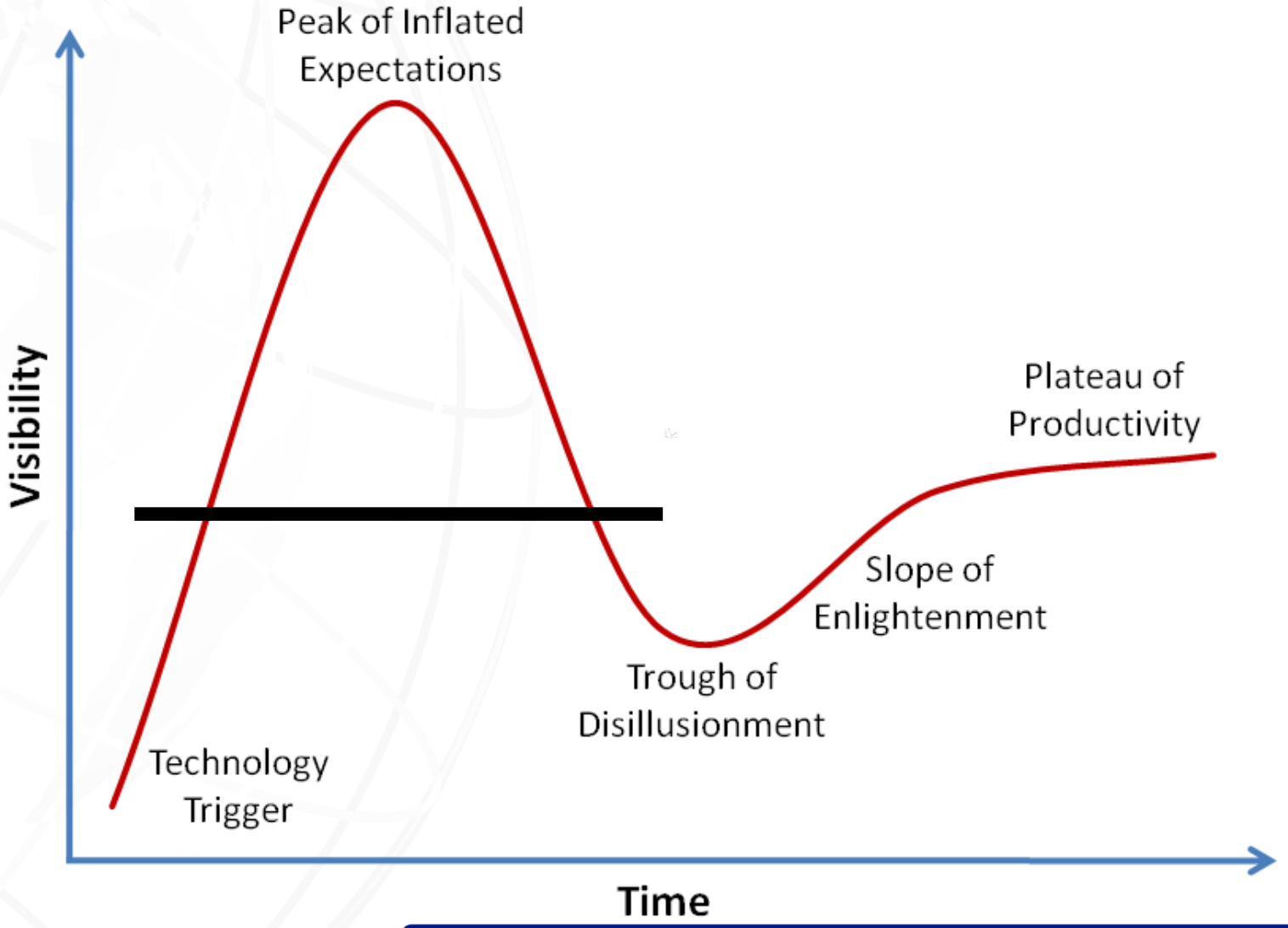
A radically novel and relatively fast-growing technology characterized by a certain degree of **coherence persisting over time** and potential to exert a considerable impact on the socio-economic domain(s) which is observed in terms of the composition of actors, institutions and patterns of interactions among those, along with the associated knowledge production processes. Its most prominent impact, however, lies in the future and so in **the emergence phase is still somewhat uncertain and ambiguous**"

Rotolo D.

How to flush out the most promising Emerging Technology?



Gartner hype cycle)



HEALTH TECHNOLOGY ASSESSMENT: "THE 6W"

WHAT

WHY

WHERE

WHEN

WHEREBY

WHO

HTA Core Model

1. Current use of the technology (implementation level)
2. Description and technical characteristics of the technology
3. Safety
4. Effectiveness
5. Costs, economic evaluation
6. Ethical aspects
7. Organizational aspects
8. Social aspects
9. Legal aspects

Health economic evaluations (HEEs)

Although LPs provide a unique expertise by combining medical and laboratory knowledge, their involvement in HEEs of laboratory tests is low. This implies that the specific laboratory expertise is frequently not considered in decision processes.

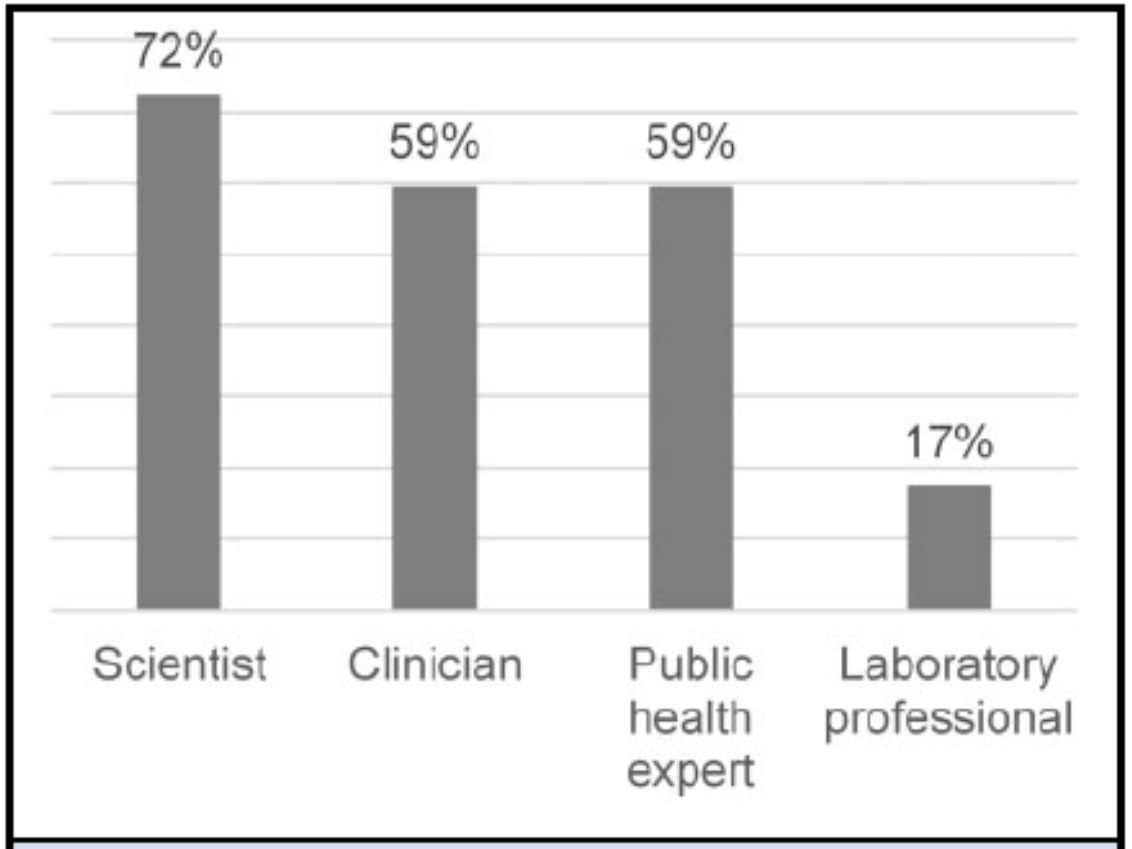
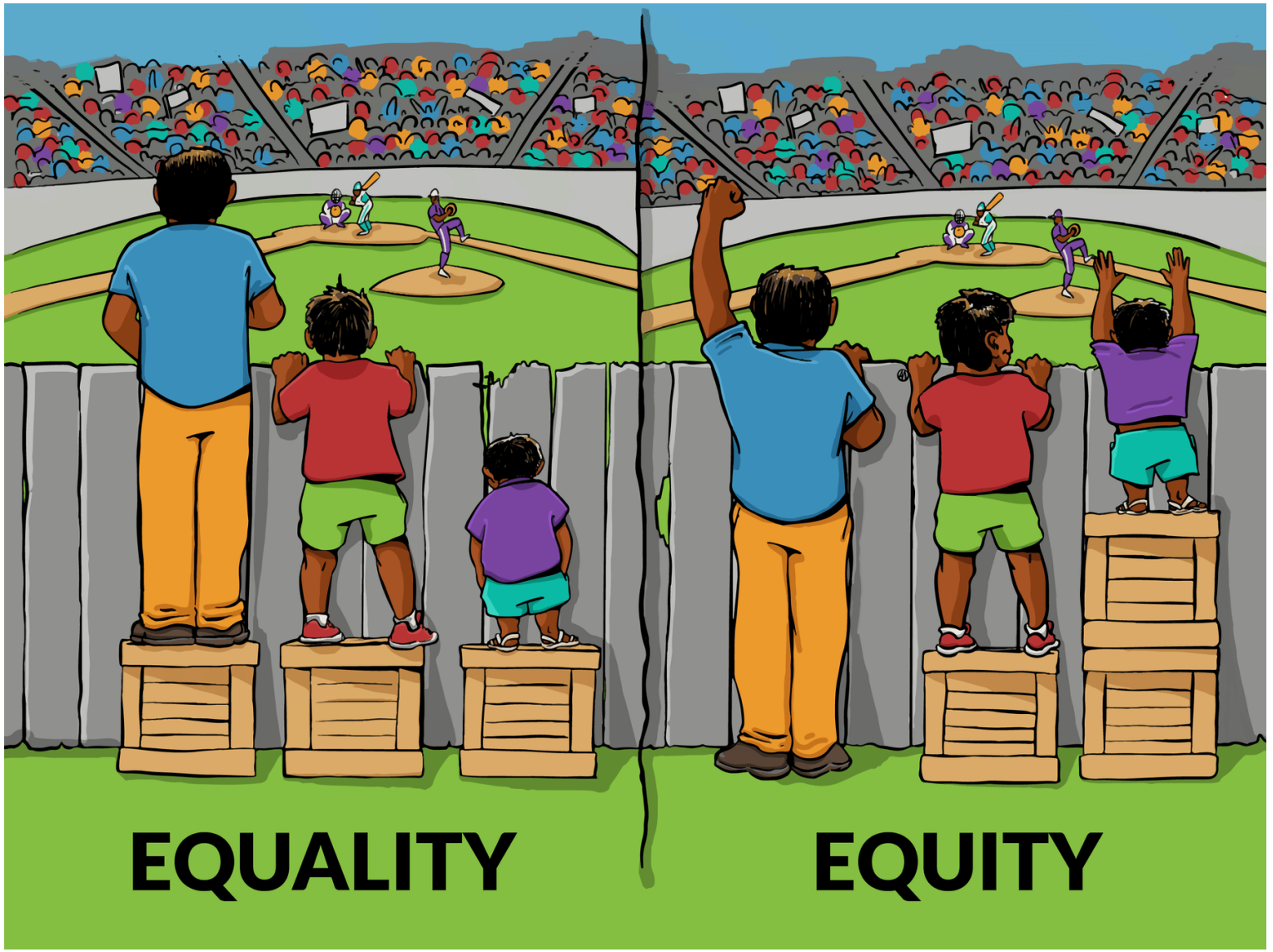


Fig. 2. Proportion of HEEs of laboratory tests authored by different professions (140 HEEs included).

Equity and globalization in Emerging Technologies implementation:
a matter for IFCC !

The best possible in each context !



Innovation creating Countries
(few and riches)

Innovation using Countries

Characteristics that make the difference in the adoption of Emerging technologies

clinical needs

healthcare models

Infrastructure e.g. water quality, electricity stability, health care process

current technologies available and options for support

ability to implement and sustain a new technology

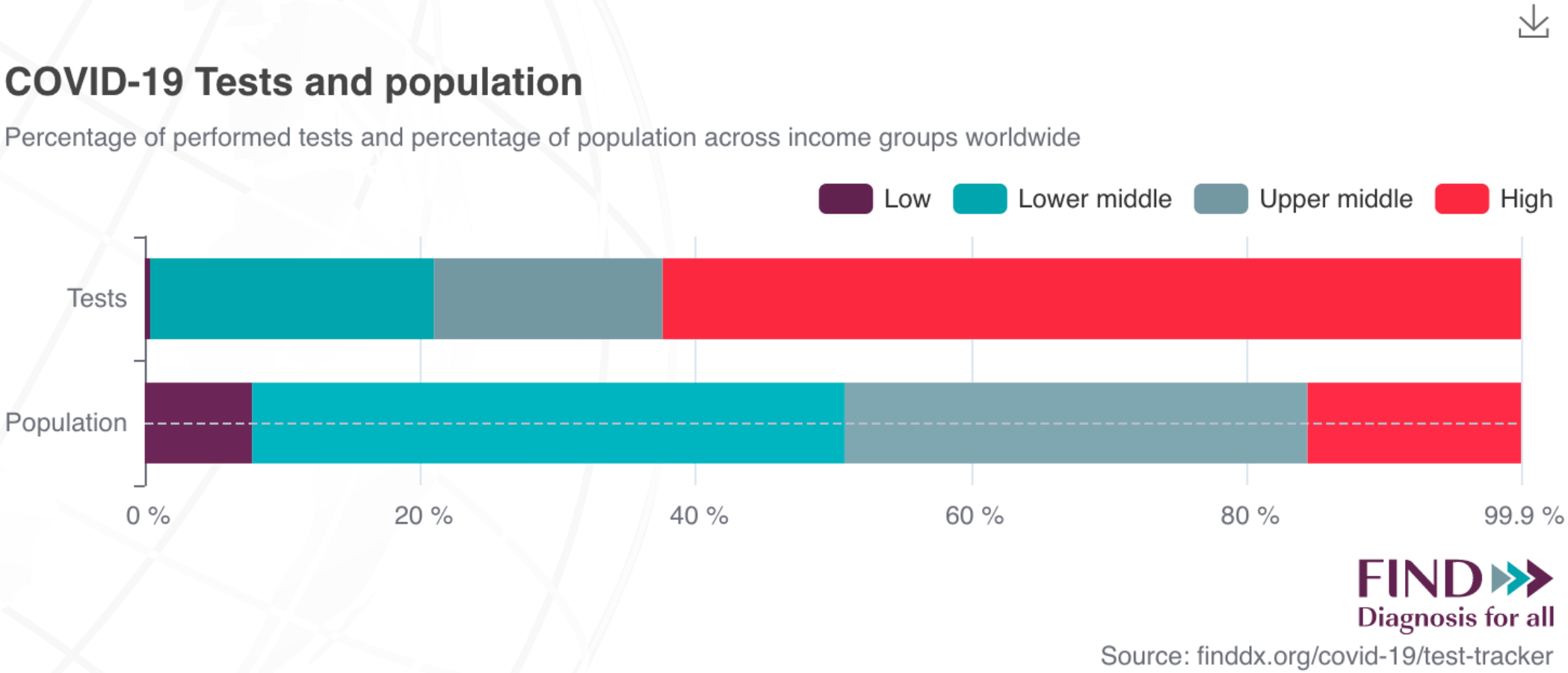
communication channels

time (influencing decision making and the rate of adoption)

cultural issues

socioeconomic circumstances

Just an example of Inequity…



NHS

The Topol Review

Preparing the healthcare workforce to deliver the digital future

An independent report on behalf of the Secretary of State for Health and Social Care

February 2019

Technological advances impacting healthcare and the magnitude of disruption.

	Technology (Digital Medicine, Genomics, AI & Robotics)	Proportion of workforce affected 2020 2025 2030 2035 2040
1.	Telemedicine	
2.	Smartphone apps	
3.	Sensors and wearables for diagnostics and remote monitoring	
4.	Reading the genome	
5.	Speech recognition and natural language processing (NLP)	
6.	Virtual and augmented reality	
7.	Automated image interpretation using AI	
8.	Interventional and rehabilitative robotics	
9.	Predictive analytics using AI	
10.	Writing the genome	

DIGITALIZATION of DATA and DATAFICATION

WHO and Digitalization

2005: “to consider drawing up a long-term strategic plan for developing and implementing eHealth services…

2013: “to consider developing … policies and legislativ mechanisms linked to an overall national eHealth strategy”.

2018: “ a global strategy on digital health, identifying priority areas including where WHO should focus its efforts”.

2020: “The global strategy on digital health 2020–2025

It’s matter of DATA !

Dataset too large to reside in a single computer system and to complex for relational database management systems which utilize Structured Query Language (SQL)

Data Fabric

"Often data remains siloed within applications, which means it's not being used as effectively as possible.

Data fabric integrates data across platforms and users, making data available everywhere it's needed.

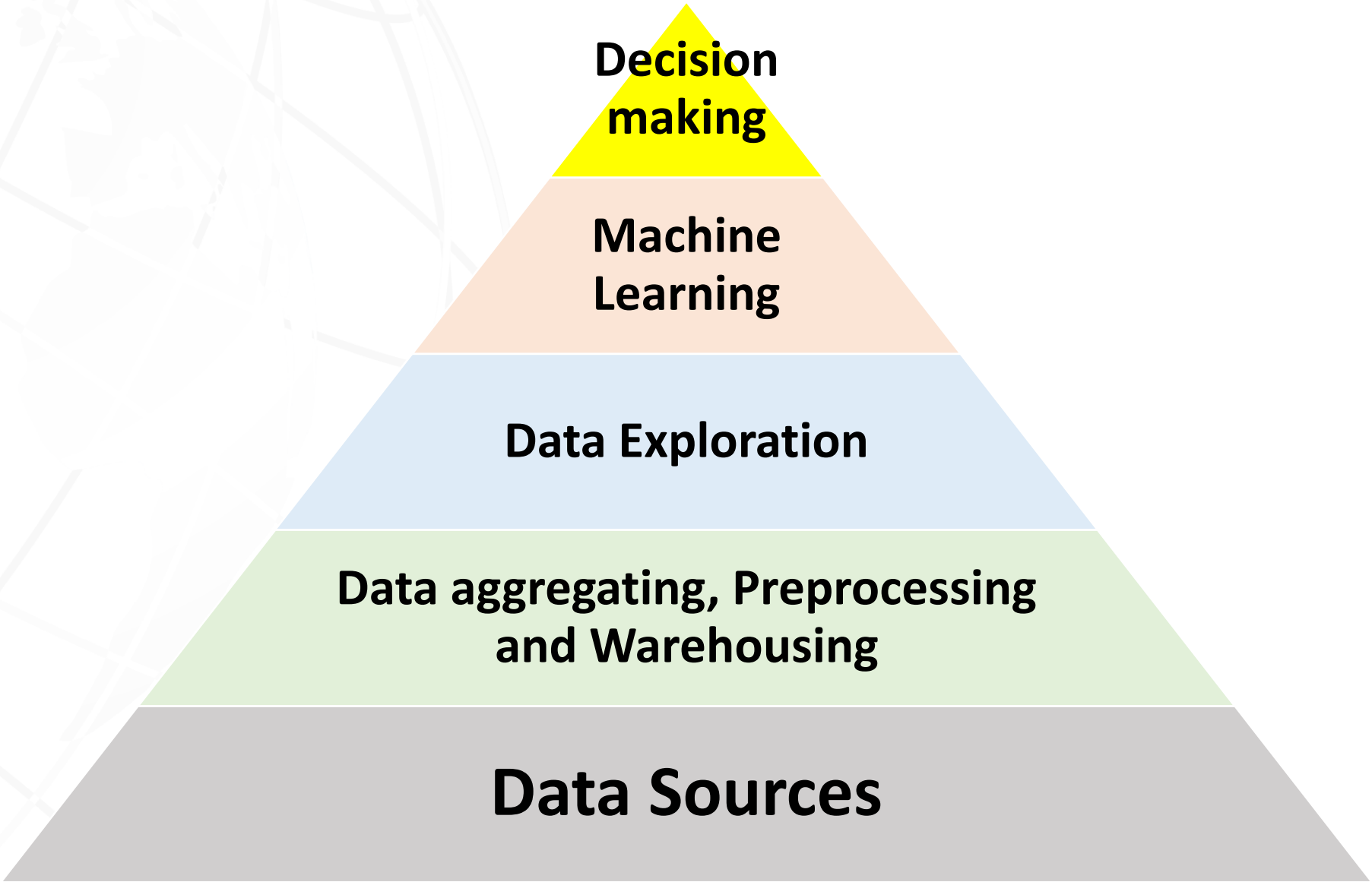
Gartner Top Strategic Technology Trends for 2022

The wisdom doesn't accumulate simply accumulating data

but

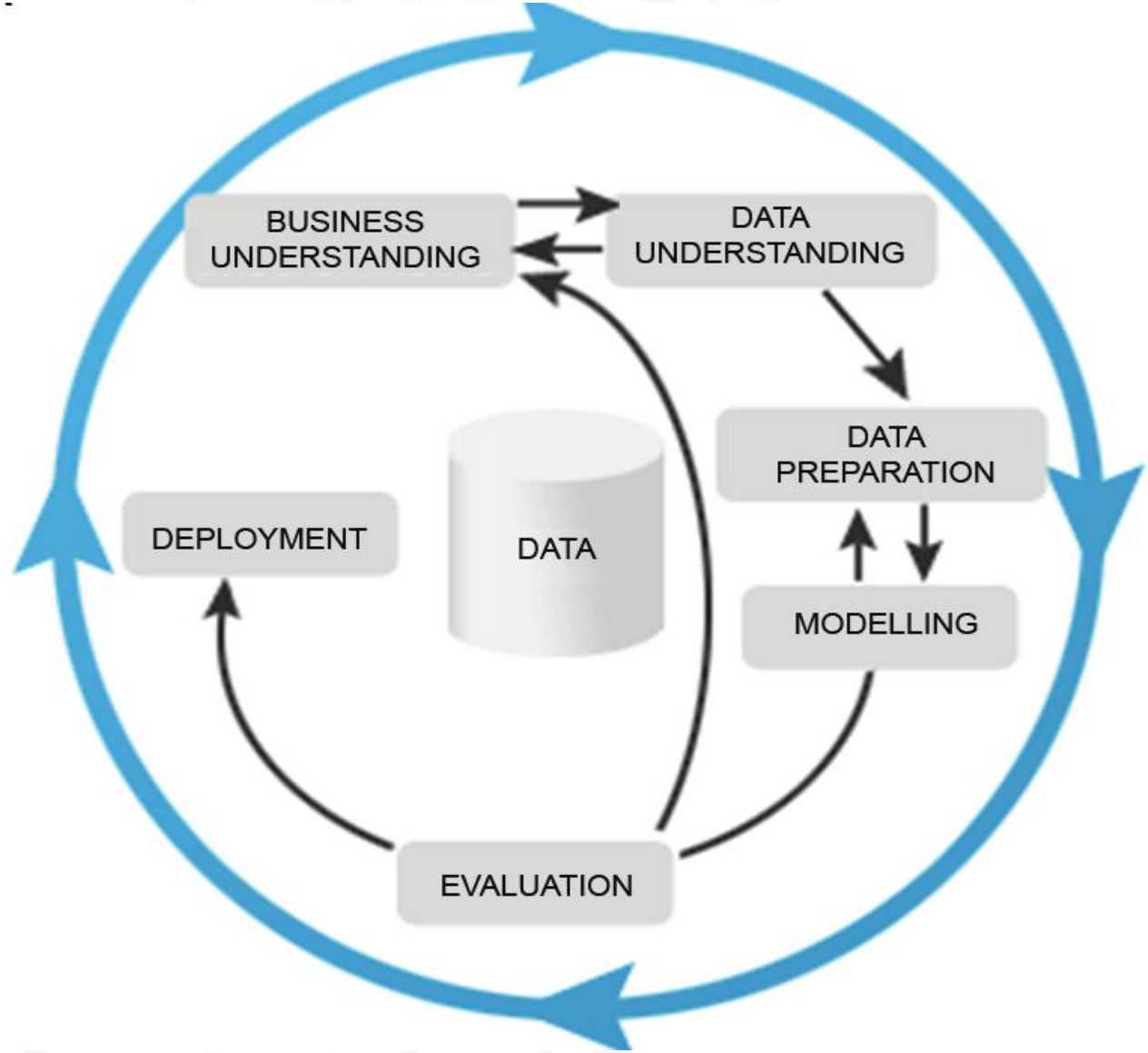
has to be extracted actively from data!
DATA MINING

The Data Science Pyramid is the tool to reach the wisdom

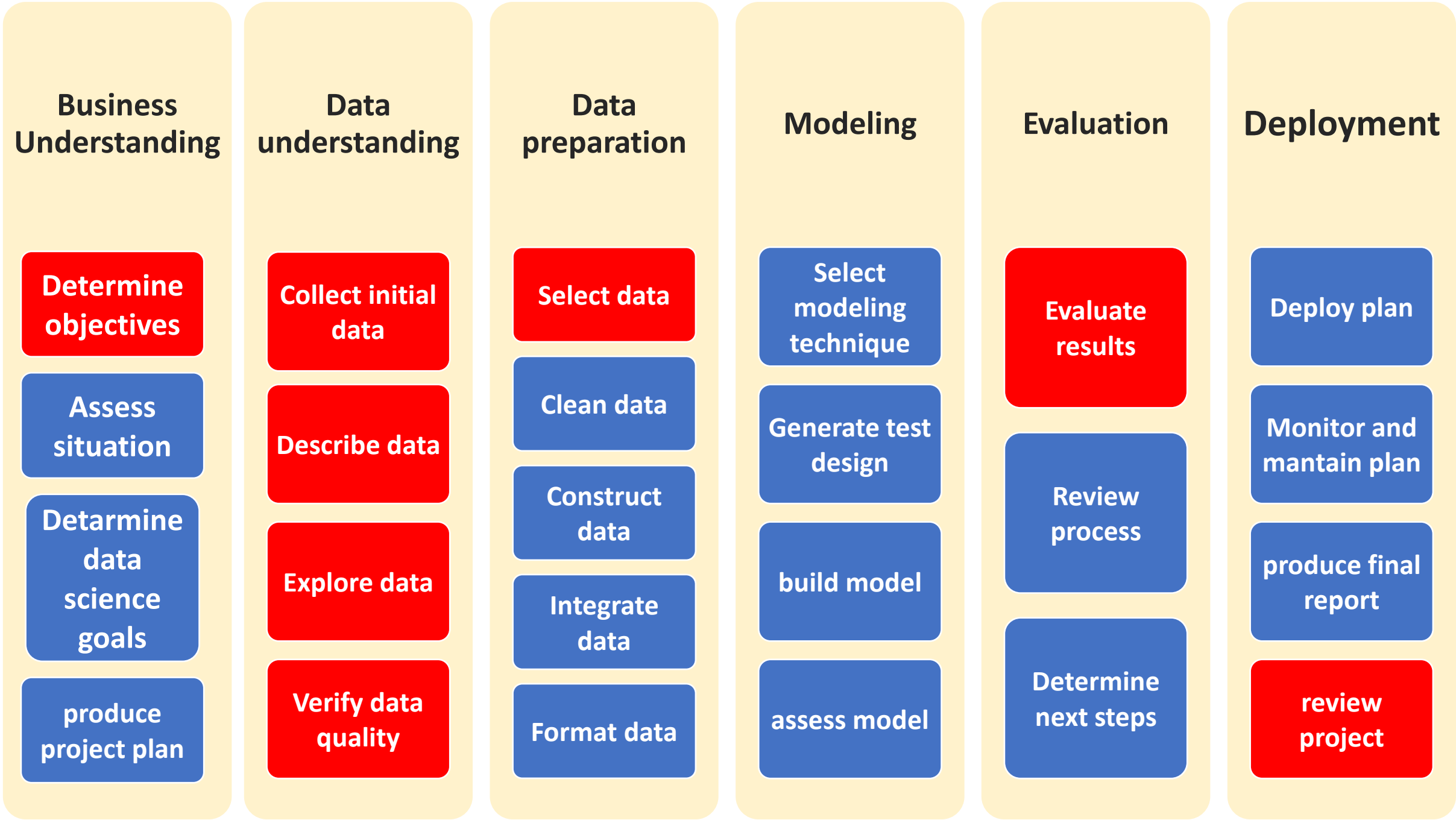


(Han, 2011)

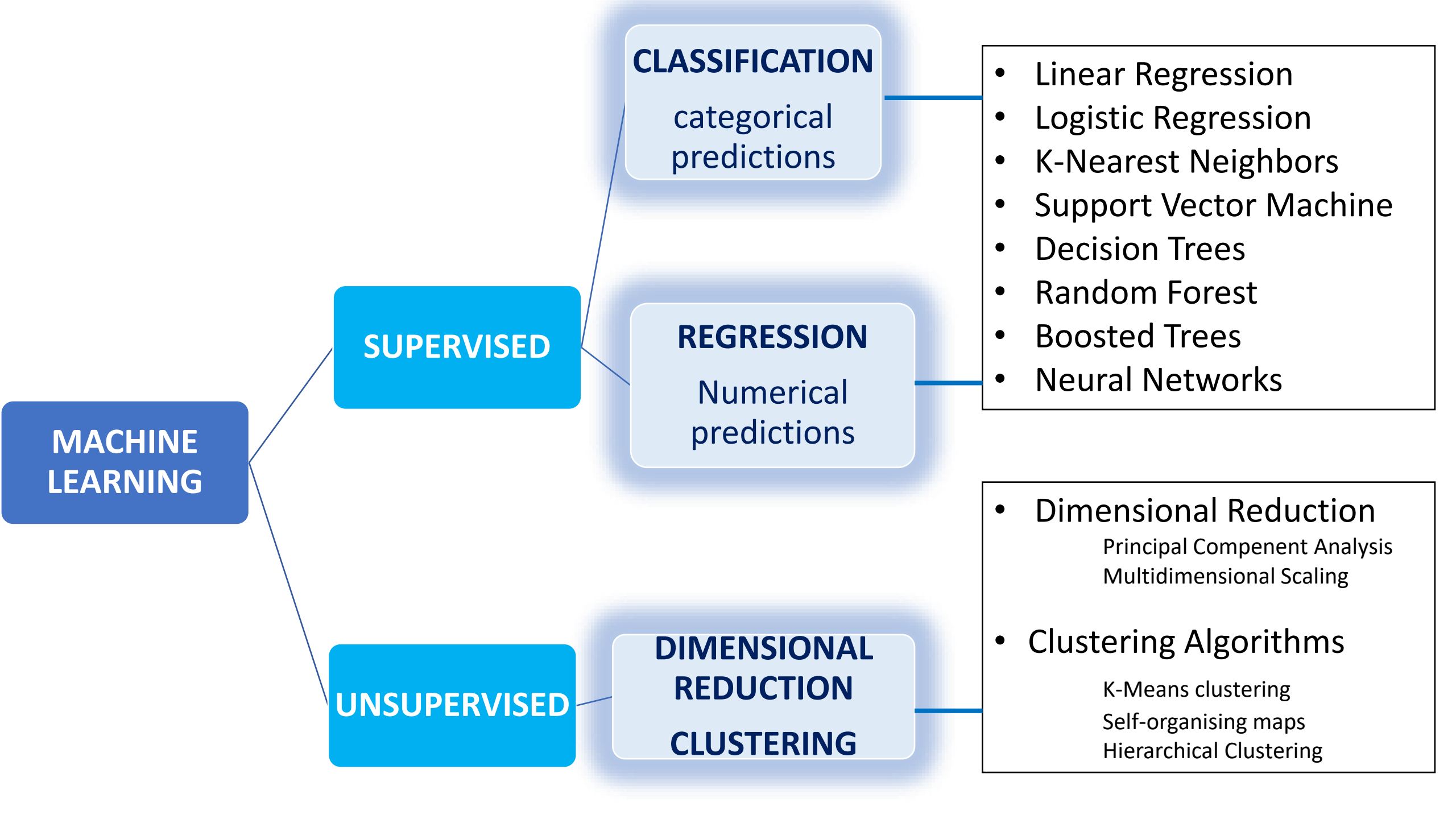
How to climb Data Science Pyramid ?



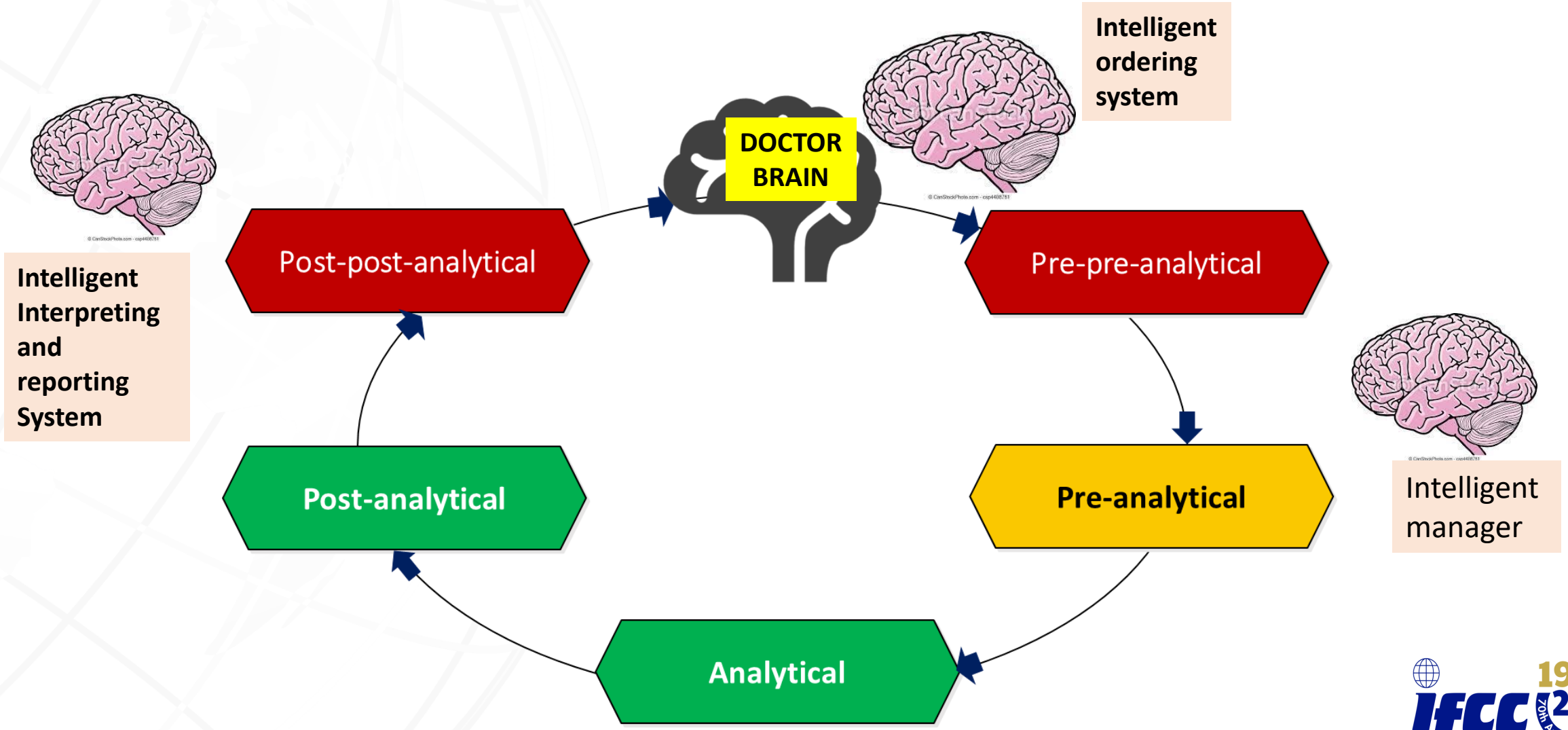
CRISP-DM
(Cross Industry Standard Process for Data Mining)


Business Understanding
Determine objectives
Assess situation
Detarmine data science goals
produce project plan
Data understanding
Collect initial data
Describe data
Explore data
Verify data quality
Data preparation
Select data
Clean data
Construct data
Integrate data
Format data
Modeling
Select modeling technique
Generate test design
build model
assess model
Evaluation
Evaluate results
Review process
Determine next steps
Deployment
Deploy plan
Monitor and mantain plan
produce final report
review project

Type of analytic	Focus	Tools	Question
Descriptive	Reporting	Statistic software Data visualization	What happened?
Diagnostic	Insight	Statistic software Data visualization	Why did it happen
Predictive	Forecasting	Statistic models Predictive modeling	What will happen
Prescriptive	Optimization	Predictive modeling Machine learning	What should I do?
Cognitive	Intelligence	Reinforcement learning Cognitive computing	What is the best that could happen?


MACHINE LEARNING
SUPERVISED
UNSUPERVISED
CLASSIFICATION
categorical predictions
REGRESSION
Numerical predictions
DIMENSIONAL REDUCTION
CLUSTERING
Linear Regression
Logistic Regression
K-Nearest Neighbors
Support Vector Machine
Decision Trees
Random Forest
Boosted Trees
Neural Networks
Dimensional Reduction
Principal Compenent Analysis
Multidimensional Scaling
Clustering Algorithms
K-Means clustering
Self-organising maps
Hierarchical Clustering

How the TTP might change?

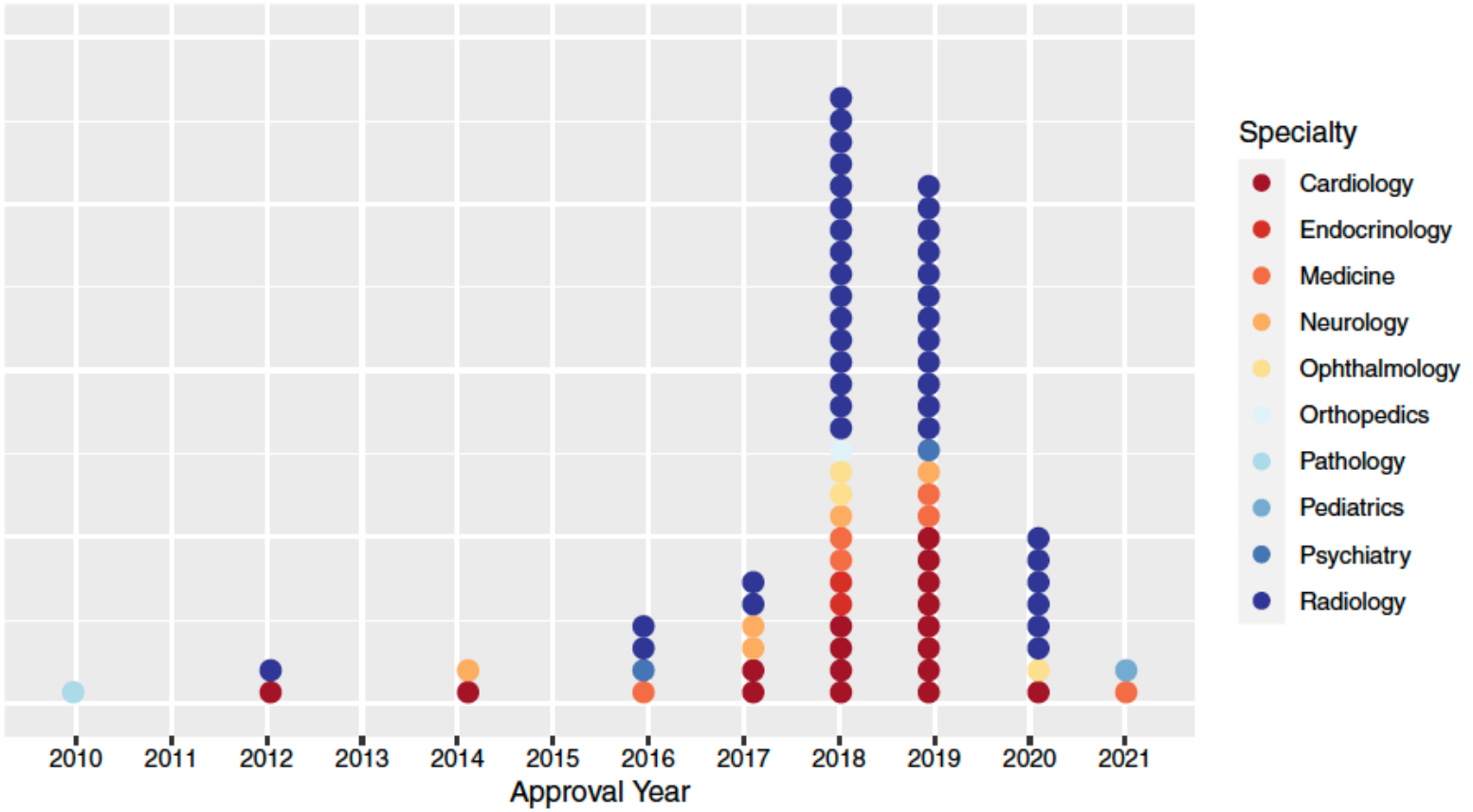


ML Applications

- Digital Cell Morphology
- Operational decision making
- Predict test results from other test values
- Expected diagnostic value from associate multivariate data
- Identifying at Risk populations
- Automated Review of instrument Data before reporting
- Interpreting workflow: normal/abnormal profile
- Integrate Care Pathway management

Artifical Intelligence-based Software as Medical Devices

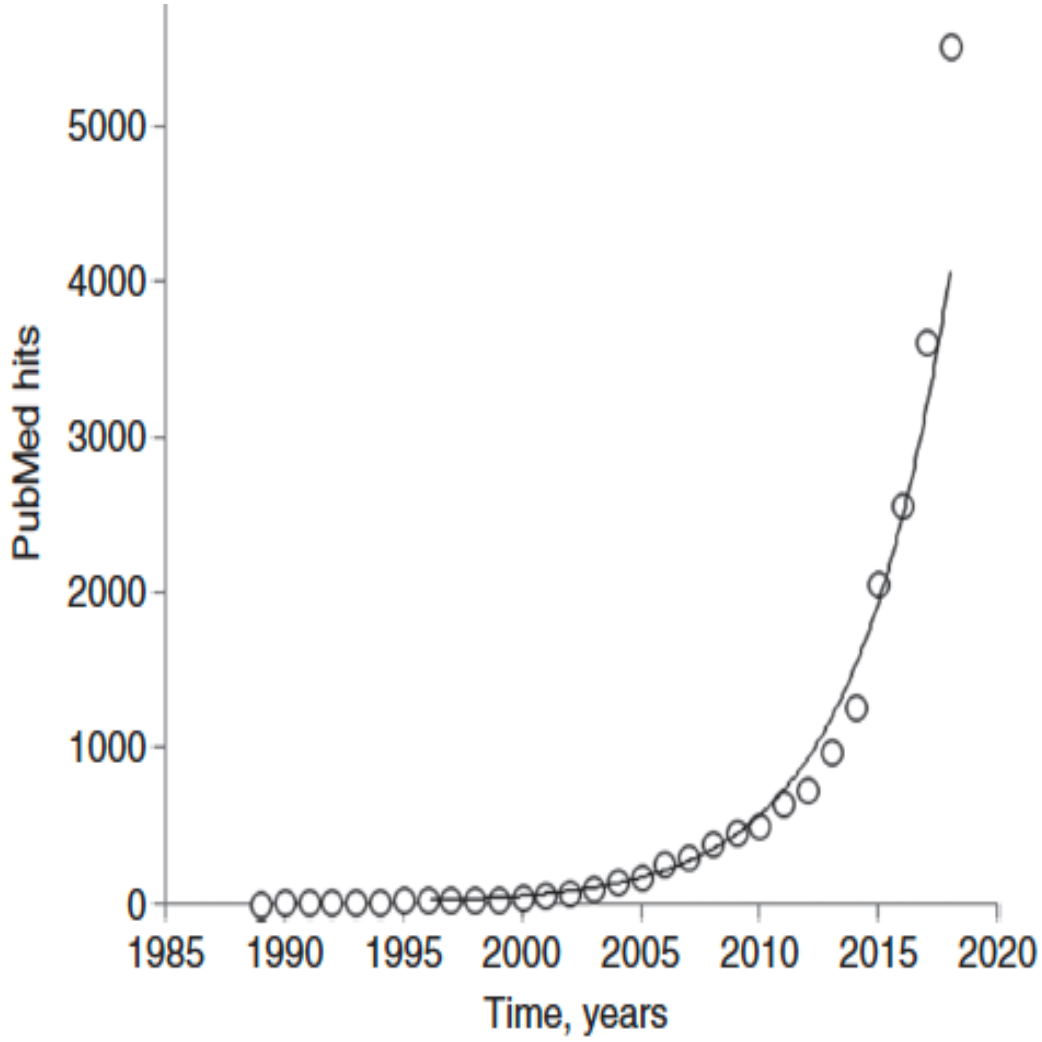
FDA-Approved Algorithms To Date



Database can be accessed at https://medicalfutur ist.com/fda-approved-ai-based-algorithms/

The "Replication Crisis"

Exponential escalation of PubMed hits using the keyword "machine learning".



Clinical Chemistry 68:3
392–395 (2022)

Opinion

How Can We Ensure Reproducibility and Clinical Translation of Machine Learning Applications in Laboratory Medicine?

Shannon Haymond[a,b,*] and Stephen R. Master[c,d]

ETD: Making the Point

June 9th, 2017; Athens

EB approved a new IFCC Functional Unit: "Emerging Technology Division"

October 20th, 2017; Durban

EB approved the Executive Committee members

March 11°, 2018; Rome

First meeting ETD-EC

Clinica Chimica Acta 495 (2019) 570–589

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journal homepage: www.elsevier.com/locate/cca

Opinion paper

Key questions about the future of laboratory medicine in the next decade of the 21st century: A report from the IFCC-Emerging Technologies Division

Ronda F. Greaves[a,b], Sergio Bernardini[c,*], Maurizio Ferrari[d], Paolo Fortina[e], Bernard Gouget[f], Damien Gruson[g], Tim Lang[h], Tze Ping Loh[i,j], Howard A. Morris[k], Jason Y. Park[l], Markus Roessler[m], Peng Yin[n], Larry J. Kricka[o]

Executive Committee

Name	Position	Term	Time of Office
S. Bernardini IT	Chair	2nd	2021 01 - 2023 12
P. Fortina US	Vice-Chair	2nd	2021 01 - 2023 12
R. Greaves AU	Secretary	2nd	2021 01 - 2023 12
D. Gruson BE	Member	2nd	2021 01 - 2023 12
M. Roessler DE	Corporate Member	2nd	2021 01 - 2023 12
P. Yan Liu CN	Corporate Member	1st	2023 01 - 2025 12
M. Ferrari IT	Consultant		
L. Kricka US	Consultant		
J. Park US	Consultant		
H.Martin AU	Consultant		

Emerging Technologies in Pediatric Laboratory Medicine (C-ETPLM)

Name	Position	Country	Term	Time in Office
T. Lang	Chair	UK	2nd	2021 01 - 2023 12
T.P. Loh	Member	SG	2nd	2021 01 - 2023 12
C. M. Mak	Member	CN	2nd	2022 01 - 2024 12
I. Papassotiriou	Member	GR	2nd	2021 01 - 2023 12
Y.B. de Rijke	Member	NL	1st	2021 05 - 2023 12
L. Kyriakopoulou	Member	CA	1st	2022 04 - 2024 12
K. Kohse	Consultant	DE		
S. Geaghan	Consultant	US		
R. Greaves	ETD EC Liaison	AU		

Emerging Technologies in Pediatric Laboratory Medicine (C-ETPLM)

Corresponding	Full and Affiliate Member Societies
Martha Lyon	Canadian Society of Clinical Chemists (CSCC)
Agnès Mailloux	Société Française de Biologie Clinique (SFBC)
Sojit Tomo	Association of Clinical Biochemists of India (ACBI)
Anita Devnath	Association of Medical iochemists of India (AMBI)
Elena Dumin	Israel Society for Clinical Laboratory Science
Atsushi Watanabe	Japan Society of Clinical Chemistry (JSCC)
Audrone Eidukaite	Lithuanian Society of Laboratory Medicine
Josephine Onakoya	Association of Clinical Chemists Nigeria (ACCN)
Anne-Lise Bjørke-Monsen	Norwegian Society of Medical Biochemistry
Ranya Abu Sair	Palestinian Medical Technology Association (PMTA)
Josep Miquel Bauçá	Sociedad Española de Medicina de Laboratorio (SEQCML)
Eresha Jasinghe	Association for Clinical Biochemistry, Sri Lanka
Fatma Taneli	Turkish Biochemical Society (TBS)
Joely Straseski	American Association for Clinical Chemistry (AACC)
Tran Thi Chi Mai	Vietnamese Association of Clinical Biochemists (VACB)

To identify, prioritize and coordinate projects to support the emerging science in pediatric laboratory medicine across the total testing process.

- ICPLM in Munich 2022 EUROMEDLAB 2021 MUNICH and in Rome 2023 WORLDLAB · EUROMEDLAB ROMA 2023
- Website documents
- Gap analysis / Scoping areas to develop educational solutions and other activities that will support developing countries especially. e.g. guidelines, best practice advice

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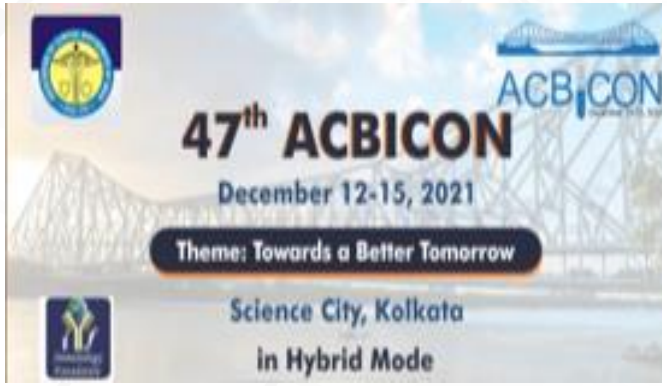
Committee on Mobile Health and Bioengineering in Laboratory Medicine

Name	Position	Country	Term	Time in Office
B. Gouget	Chair	FR	2nd	2021 01 - 2023 12
K. Kotani	Member	JP	2nd	2022 01 - 2024 12
J. Nichols	Member	US	2nd	2022 01 - 2024 12
F. Desiere	Member-Roche	DE	2nd	2022 01 - 2024 12
M. Heydlauf	Member-Siemens	US	2nd	2022 01 - 2024 12
D. Gruson	EC Liaison	BE		

Corresponding	Full and Affiliate Member Societies
Irena Korita	Albanian Society of Clinical biochemistry and Laboratory Medicine (ASoLaM)
Ramy Khalil *	Egyptian Association of Healthcare Quality and Patient Safety (EAHQPS)
Pradeep K Dabla	Association of Clinical Biochemists of India (ACBI)
Sanja Stankovic	Serbian Society for Clinical Laboratory Medicine and Science (SCLM)
Evgenija Homsak	Slovenian Association from Clinical Chemistry and Laboratory Medicine (SZKKLM)
Zihni Onur Uygun	Turkish Biochemical Society (TBS)
Neil Anderson	The Association for Clinical Biochemistry & Laboratory Medicine (ACB) UK
Juergen Becker	Quidel
Julien Wallemacq	Abbott
Alistair Gammie	Ortho-Clinical Diagnostics, Inc.

To promote the potential of e-health and m-health in laboratory medicine



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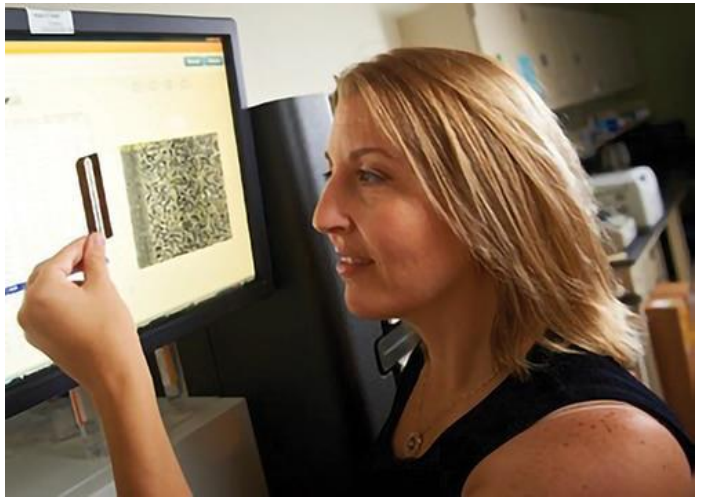
Guidance for the Implementation of Custom-made Genomic Panels

Name	Position	Country	Term	Time in Office
J. Morrissette	Chair	US	2nd	2022 01 - 2024 12
OO. Soriyan	Member	NG		
C. Paolillo	Member	US		
M. Ewalt	Member	US		
C. Santonocito	Member	IT		
M. E. Marmarelis	Member	US		
M. Carroll	Member	US		
M. Murthy	Member	BW		
YM Martei	Member	BW		
C. Davies	Member	US		
J. Segal	Member	US		
R. T. Sussman	Member	US		
C Rushton	Member	US		

Assist clinical laboratories in developing in-house NGS programs

- Genomics educational section
- Industries partners and Technologies of interest
- Common equipments for NGS assays
- Virtual and actual rapid genomics demonstration

- jemorris@pennmedicine.upenn.edu



Single Cell and Spatial Transcriptomics

Name	Position	Country	Term	Time in Office
AP South	Chair	US	1st	2021 01 - 2023 12
RJ Cho	Member	US		
P. Fortina	Member	US		

Provide a regularly updated perspective on the clinical diagnostic applications of single-cell and spatial transcriptomic technologies

- Work on a manuscript delineating the prerequisites required for the implementation of single cell in the clinical setting
- Review the current genomic testing platforms available in the clinic
- Investigation of new platforms for rapid single cell and spatial genomics
- Explore technologies for single cell somatic mutational profiling in tumor, inflammatory, and normal tissues

- Andrew.south@jefferson.edu

Artificial Intelligence and Genomic Diagnostics

Name	Position	Country	Term	Time in Office
LJ Kricka	Chair	US	1st	2021 01 - 2023 12
LM Baudhuin	Member	US		
R Carling	Member	UK		
A Ertel	Member	US		
P Fortina	Member	US		
T Hope	Member	US		
C McCudden	Member	CA		
JY Park	Member	US		
S Polevikov	Member	US		
D Satchkov	Member	US		

To develop a resource that will inform the IFCC community on developments and trends in the applications of artificial intelligence in clinical genomic.

- Survey on AI-driven software platforms for genomic analysis and interpretation
- Survey on the role of AI in genomic tests for detecting COVID-19
- AI glossaries
- Recommendations for data, source code, AI methods, and experiments in AI publications
- Documents collection on convergence of digital health, artificial intelligence with Universal Health Coverage, ethics and governance of AI, good ML practice, and the reproducibility and clinical translation of Ml applications
- Current awareness (AI Index Report, References Update…)

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International Federation of Clinical Chemistry and Laboratory Medicine

Metabolomics (WG-M)

Name	Position	Country	Term	Time in Office
E. Fux	Chair	DE	1st	2021 10 - 2023 12
A. Bendt	Member	SG		
D. Di Natale	Member	IT		
D. Friedecky	Member	CZ		
J. Ivanisevic	Member	CH		
M. Lenski	Member	FR		
J. Otvos	Member	US		

Corresponding	Full or Affiliate Member Societies
Qing Li	Chinese Society of Laboratory Medicine (CSLM)
Marie Lenski	Société Française de Biologie Clinique (SFBC)

To evaluate and monitor emerging trends of Research in the field of Metabolomics

- “Sensor array and gas chromatographic detection of the blood serum volatolomic signature of COVID-19” iScience 2021
- Manuscript in progress : “View of IFCC Working Group on Metabolomics: From research to clinical diagnostics & prognostics”
- Website in progress

elie.fux@roche.com

Method Evaluation Protocols (WG-MEP)

Name	Position	Country	Term	Time in Office
R. Greaves	Co-Chair	AU	1st	2022 05 - 2024 12
TP Loh	Co-Chair	SG	1st	2022 05 - 2024 12
B. Cooke	Member	AU		
C. Markus	Member	AU		
M. Tran	Member	VN		
R. Zakaria	Member	AU		
CS Ho	Consultant	CN		
M. Pieri	Corresponding Member	IT		

To provide high-level guidance and incorporate evidence-based procedures for method evaluation

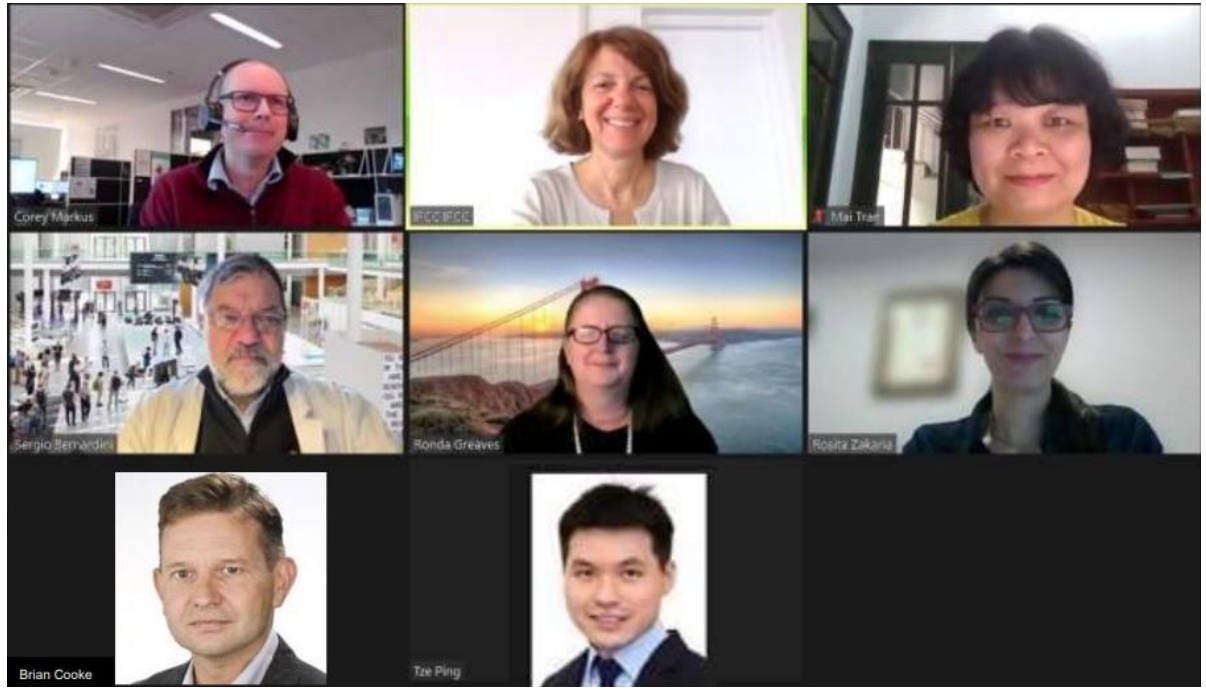
DE GRUYTER

Clin Chem Lab Med 2022; ■■■(■■■): 1–8

Opinion Paper

Tze Ping Loh, Brian R. Cooke, Corey Markus, Rosita Zakaria, Mai Tran, Chung Shun Ho and Ronda F. Greaves*

Method evaluation in the clinical laboratory; on behalf of the IFCC working group on method evaluation protocols



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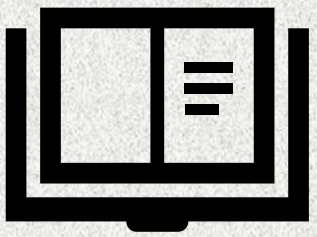
- tploh@hotmail.com

IFCC 1952 2022 70th Anniversary
International Federation of Clinical Chemistry and Laboratory Medicine



2020

Collaborative AI and Laboratory Medicine Integration in Precision Cardiovascular Medicine
Damien Gruson, Sergio Bernardini, Pradeep Kumar Dabla, Bernard Gouget, Sanja Stankovic
Clinica Chimica Acta, 509, October 2020, Pages 67-71

COVID-19: Armageddon before light?
Damien Gruson, Gabriel Ko, David Luu
eJIFCC Volume 31 n°2 – 2020

Artificial Intelligence – powered search tools and resources in the fight against COVID-19
Larry J. Kricka, Sergei Polevikov, Jason Y. Park, Paolo Fortina, Sergio Bernardini, Daniel Satchkov, Valentin Kolesov, Maxim Grishkov
eJIFCC Volume 31 n°2 - 2020

Key questions about the future of laboratory medicine in the next decade of the 21st century: A report from the IFCC-Emerging Technologies Division
Ronda F. Greaves, Sergio Bernardini, Maurizio Ferrari, Paolo Fortina, Bernard Gouget, Damien Gruson, Tim Lang, Tze Ping Loh, Howard A. Morris, Jason Y. Park, Markus Roessler, Peng Yin, Larry J. Kricka.
Clinica Chimica Acta, 495, 570-589 (open access).

Sustainability in Healthcare: perspectives and reflections around laboratory.
Aroa Molero, Michele Calabrò, Maguelone Vignes, Bernard Gouget, Damien Gruson
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Promoting BCLF identity in Belgrade with the e-nergized SMBS.
Gouget B. Gruson D., Bernardini S.
J Med Biochem 37: 1–5, 2019.

Loh TP, Ho CS, Hartmann MF, Zakaria R, Lo CWS, van den Berg S, de Rijke YB, Cooke BR, Hoad K, Graham P, Davies SR, Mackay LG, Wudy SA, Greaves RF. Influence of isotopically labeled internal standards on quantification of serum/plasma 17α-hydroxyprogesterone (17OHP) by liquid chromatography mass spectrometry. Clin Chem Lab Med. 2020 Sep 25;58(10):1731-1739. doi: 10.1515/cclm-2020-0318. PMID: 32697750

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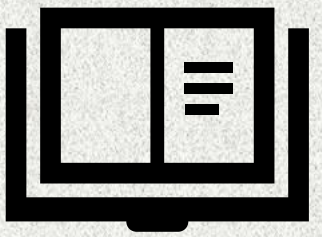

2021

Emerging technologies in paediatric laboratory medicine
C. Mak, I. Papassotiriou, J. Zierk, K. P. Kohse, R. F. Greaves, S. M. D. Geaghan, et al.
Journal of Laboratory Medicine 2021 Vol. 45 Issue 6 Pages 245-248. DOI: doi:10.1515/labmed-2021-0097.
https://doi.org/10.1515/labmed-2021-0097

Detection of Vitamin D Metabolites in Breast Milk: Perspectives and challenges for measurement by Liquid Chromatography Tandem-Mass Spectrometry*TC. Tuddenham, R. F. Greaves, A. E. Rajapaksa, J. D. Wark and R. Zakaria*
Clin Biochem 2021. Accession Number: 34419456 DOI: 10.1016/j.clinbiochem.2021.08.003

Newborn bloodspot screening in the time of COVID-19
F. Greaves, J. Pitt, C. McGregor, M. Wall and J. Christodoulou
Genet Med 2021 Vol. 23 Issue 6 Pages 1143-1150. Accession Number: 33442021 PMCID: PMC7804212 DOI: 10.1038/s41436-020-01086-6. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7804212/pdf/41436_2020_Article_1086.pdf

Serum Amyloid A Protein as a useful biomarker to predict COVID-19 patients severity and prognosis
Pieri, M. Ciotti, M. Nuccetelli, MA Perrone, MT Cali`, MS Lia, M. Minieri, S. Bernardini
International Immunopharmacology 95 (2021) 107512

Clinical validation of a second generation anti-SARS-CoV-2 IgG and IgM automated chemiluminescent immunoassay
Pieri, M. Nuccetelli, E. Nicolai, S. Sarubbi, S.Grelli, S. Bernardini
Journal of Medical Virology 2021;93:2523–2528.

NGS in more labs? IFCC group aims to ease the way
Interview to Dr. Jennifer Morrissette, IFCC working group chair
CAP Today

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In progress

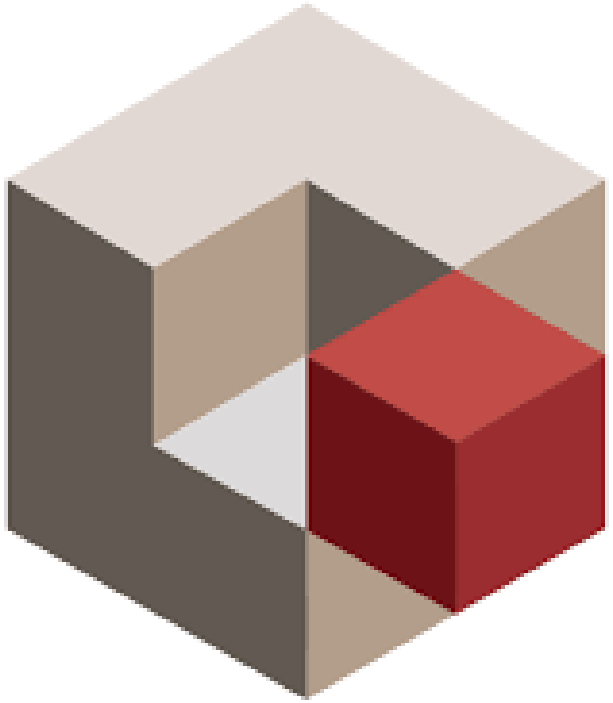
What to do as soon as after GC?

- WG- Health Technology Assessment
- WG-Neonatal bilirubin standardization (SD – ETD interphase)

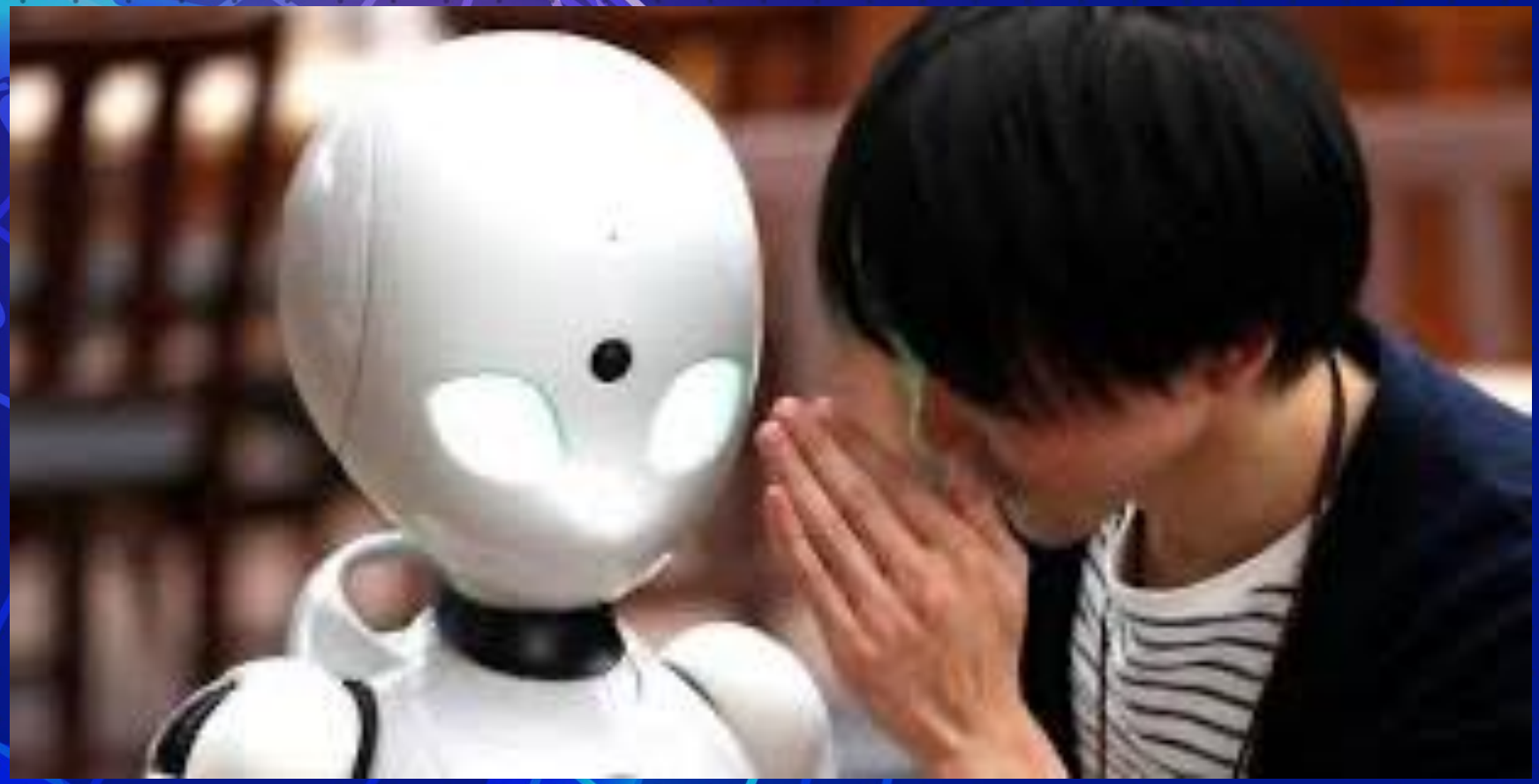
- Renewal of the membership by the end of 2023
- Involvement in ETD functional units:
  - Young Scientists
  - other NSs
  - IT Companies
  - Data Scientists
  - Clinicians

Ten cornerstones in ETD perspective

- Implement LP knowledge at the interface between digital technologies and Laboratory Medicine
- Contribute to define features of digital transformation of Lab Med
- Diffuse the benefits of digital health technologies in the IFCC Community equitably
- Allow IFCC to be part of the ecosystem of Health digital trasformations
- Encourage elements such as access to connectivity, data interoperability, and data security in IFCC members



- Harmonise data handling, protection and governance considering different cultural, political and societal influences in different countries
- Get in touch with big technology companies focused in health service and virtual models of care, to work in sinergy at Lab Med models
- Include in the TTP, data from real and virtual life digital trails
- Encourage data solidarity between IFCC National members
- Work in sinergy with others IFCC Divisions and functional units



THANKS!

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