QMIC QUANTITATIVE MEDICAL IMAGING COALITION

NIST–NIBIB SYMPOSIUM ON MEDICAL METROLOGY AND STANDARDS
September 24, 2026

The Quantitative Medical Imaging Coalition (QMIC)

A collaborative nonprofit advancing the science and implementation of quantitative imaging (QI) — to transform personalized medicine.

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Disclosures:

- None.

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Why QMIC? What are some of the issues?

- All clinical images are n-D datasets (where n>1) —

  → not just "pictures."

  Difficult concept for many to accept.

- In biology, typically a noisy, blurry dataset

  We need to understand the sources of noise.

- Quantitative imaging (QI) involves extracting the specific voxel data subsets of interest ("segmentation")

  QI typically requires an AI tool to do that extraction.

- Although the concept has matured over 25 years,

  clinical acceptance has been slow.

QMIC's work is timely and urgent because …

The imaging community is at an inflection point shaped by three converging forces:

Measurements now drive care

Imaging-derived measurements guide treatment eligibility and monitor response — so measurement accuracy directly affects patients.

Standardization infrastructure is missing

Global imaging ecosystem lacks the standardization infrastructure the clinical laboratory world established decades ago.

AI is only as good as the data

AI tools now offer unprecedented capability to extract quantitative information — but these tools are only as reliable as the underlying data.

QMIC: Founding & Timeline

- Successor to RSNA/QIBA & QUIC
  - But expanded scope covering the entire imaging chain.
- incorporated March 2025
- Coalition by design: Built as a multi-stakeholder coalition from the start, not a single professional-society effort.
- Neutral convener: Positioned as a trusted, neutral third-party to convene collective efforts across groups (E.g., Federal, industry, professional societies)

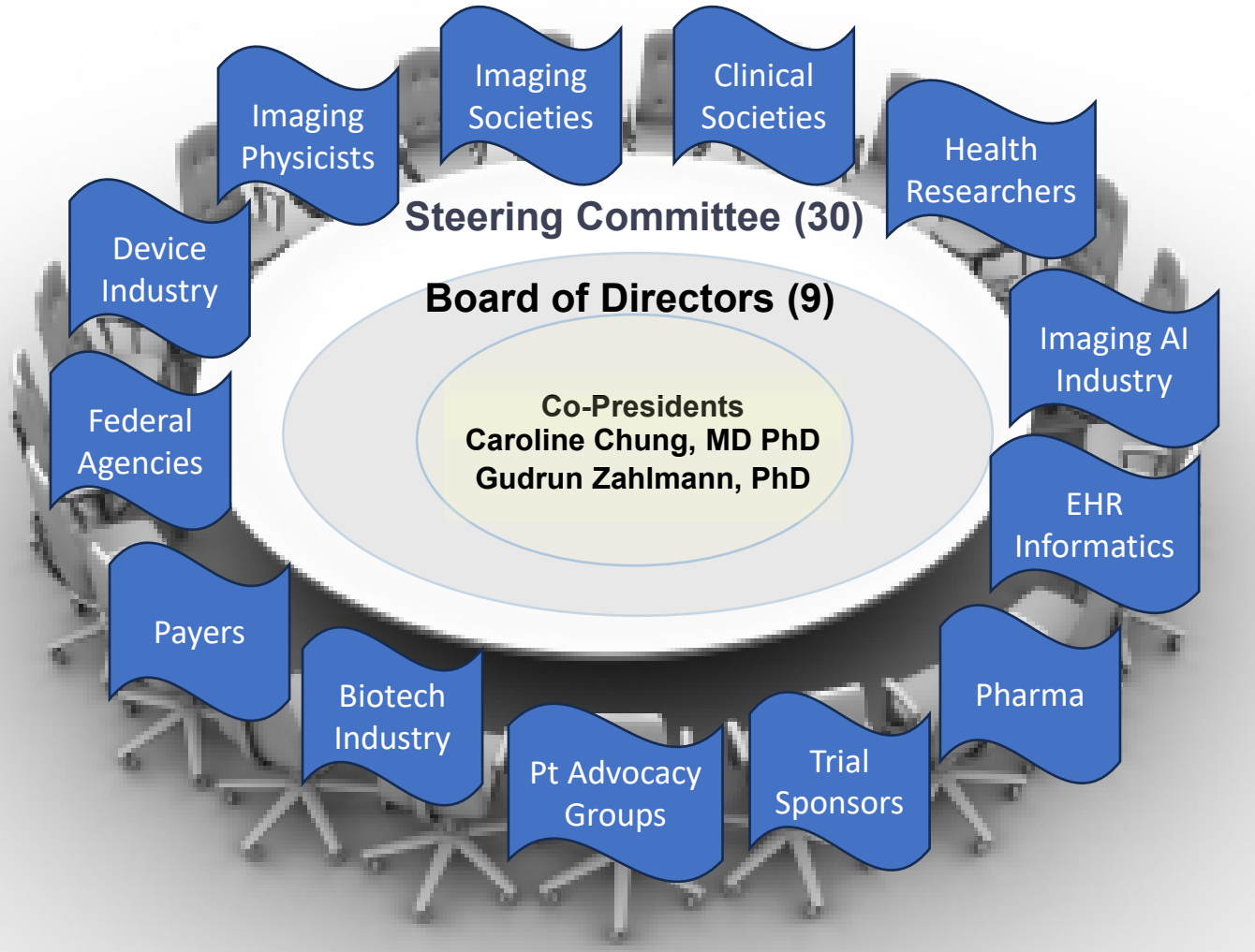
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QMIC Mission and Goals

- ***Mission:*** ***advance the science and implementation of quantitative imaging in clinical practice and clinical trials.***
- ***Goals:*** **From a foundation of rigorous measurement science (metrology) –**
  - **Develop QI, including quantitative imaging biomarker (QIB), guidelines.**
  - **Enable rigorous implementation of QI guidelines in clinical practice and clinical research.**
  - **Collaborate with education programs that foster the application of QI.**

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QMIC: One coalition, three governance layers, multiple contributors.



QMIC Standards and Guidance Documents

Biomarker Committees (BCs)

Each BC formally collaborates with a relevant clinical society.

QMIC Guidance Documents

International standardization papers that define how a quantitative imaging measurement should be made, reported, and interpreted.

QMIC: Future Directions, In Progress …

Conformance models

Develop conformance models — streamlined testing procedures and phantom-based QA protocols.

Centers of excellence

Designate centers of excellence / proficiency for QI implementation.

Funding

Assess funding sources to sustain the work.

Research collaboration

Pursue research collaborations and funding to advance the science.

What is a QMIC Guidance Document?

- A standards document that describes a specific performance Claim and how it can be achieved.
- Structure:
  - Clinical context
  - Compliance/Conformance requirements
  - Claim
  - Details/Specifications/Checklists
  - Assessment procedures

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What is a QMIC Guidelines Claim?

- Defines the quantitative performance claims of the guideline, including
  - [+/- bias],
  - precision (repeatability),
  - [+/-reproducibility],
  - longitudinal change detection, and
  - conditions required for those claims to hold.

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Examples of QMIC Claim Statements

CROSS-SECTIONAL CLAIM: **There is a 95% probability that the measured *< insert QIB name here >* ± *< insert precision value here >* encompasses the true value.**

PET SUV example,

"There is a 95% probability that the measured SUV_{max} ± 15% encompasses the true SUV_{max}."

LONGITUDINAL CLAIM: **There is a 95% probability that the measured change in *< insert QIB name here >* ± *< insert precision value here >* encompasses the true change.**

CT Tumor example,

"There is a 95% probability that the measured change in mass volume ±30% encompasses the true change in mass volume."

Example Claims:
CT Small Lung Nodule (SLN) detection

"Conformance with this Profile by all relevant staff and equipment supports the following claims:

Claim 1: Nodule Volume - For a measured nodule volume of Y, and a Coefficient of Variation (CV) as specified in table 1, the 95% confidence interval for the true nodule volume is Y ± (1.96 x Y x CV).

Claim 2: Nodule Volume Change - A measured nodule volume percentage change of X indicates that a true change in nodule volume has occurred if X > (2.77 x CV1 x 100), with 95% confidence."

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For Volume Change (SLN)…

Table 1. Coefficients of Variation (CV)

Nodule Diameter (mm)	Nodule Volume (mm3)	Coefficient of Variation (CV)	True Volume 95% CI Limits (mm3)	Minimum Detectable Difference (from Claim 2a)
6 mm	113	0.29	+/- 64	80.3%
7 mm	154	0.23	+/- 69	63.7%
8 mm	268	0.19	+/- 100	52.6%
9 mm	382	0.16	+/- 120	44.3%
10 mm	524	0.14	+/- 144	38.8%

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Minimum Detectable Change in Tumor Volume, as a Function of Other Variables

Tumor Diameter	Different Scanner				Same Scanner			
	Different Radiologist		Same Radiologist		Different Radiologist		Same Radiologist	
	Different Analysis Tool	Same Analysis Tool	Different Analysis Tool	Same Analysis Tool	Different Analysis Tool	Same Analysis Tool	Different Analysis Tool	Same Analysis Tool
>50mm	43%	24%	43%	24%	37%	10%	37%	8%
35-49mm	67%	33%	65%	29%	62%	22%	60%	14%
10-34mm	139%	120%	80%	39%	136%	117%	75%	28%

2017 Fleischner Society Guidelines for Management of CT Pulmonary Nodules

A: Solid Nodules*

Nodule Type	Size <6 mm (<100 mm³)	Size 6–8 mm (100–250 mm³)	Size >8 mm (>250 mm³)	Comments
Single				
Low risk†	No routine follow-up	CT at 6–12 months, then consider CT at 18–24 months	Consider CT at 3 months, PET/CT, or tissue sampling	Nodules <6 mm do not require routine follow-up, but certain patients at high risk with suspicious nodule morphology, upper lobe location, or both may warrant 12-month follow-up (recommendation 1A).

Radiology. 2017 Feb 23

7 mm is a useful threshold for "wait" versus "intervene"

Overall Goal of QMIC Guidelines

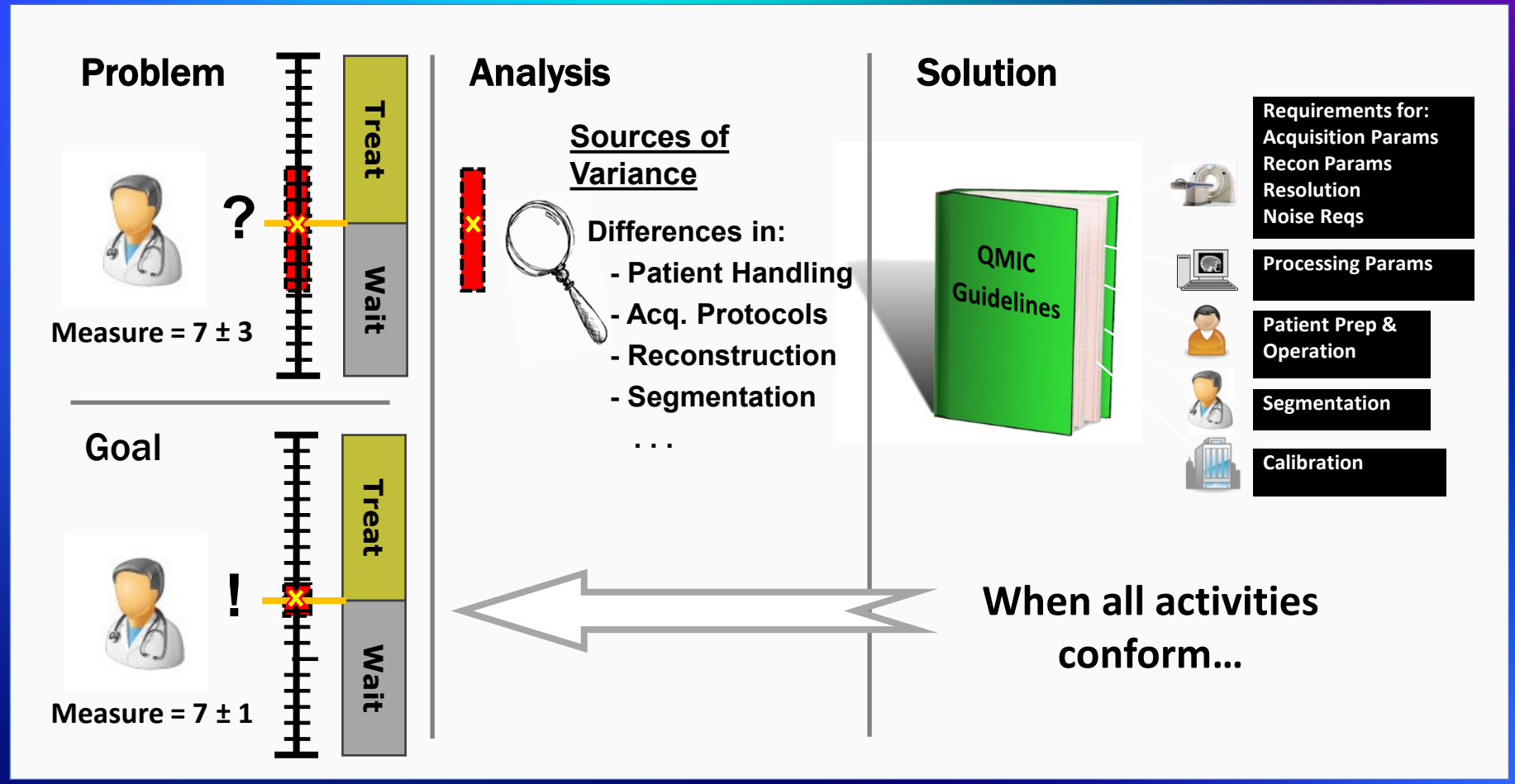


Image compliments of Kevin O'Donnell

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Challenges: 1. Inertia

Need Robust Educational and Advocacy efforts, especially from professional organizations.

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Challenges: 2. Implementation hurdles

1. Need outcome data to demonstrate clinical benefit.
   a. Ideally from clinical trials – but resources are scarce
   b. Alternatively, from large registries of real-world data.

2. Need industry agreement on cross-vendor harmonization and interoperability.

3. Need “triggers" for adoption — e.g., political, reimbursement, or regulatory.

4. Need a QA evaluation and accreditation process.

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Implementation example 1: EU CT lung cancer screening



1. Lung nodule management decisions are driven directly by measurements — initially linear; increasingly volumetric.

2. SLN CT QI Standards began as QIBA Profile; now a QMIC Guideline.

3. European status: SOLACE, funded from 2023 to 2026 (EU4Health)

4. Transitioning to European Lung Cancer Screening Alliance (ELCSA) by the European Society of Radiology (ESR) and the European Respiratory Society (ERS); a new initiative to ensure the achievements of SOLACE.

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European Lung Cancer Screening Alliance (ELCSA)

- Promote prevention, screening and early diagnosis of lung cancer
- Harmonize standards, training and quality assurance across Europe
- Develop and maintain guidance, tools and resources for lung cancer screening
- QMIC Guidelines Document is basis for national QA programs.

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Legislative QA in Germany

Two legal instruments covering CT lung screening:

- the Lungenkrebs-Früherkennungs-Verordnung (a federal ordinance from the environment/radiation-protection ministry, BMUV, July 2024)
- the G-BA's Krebsfrüherkennungs-Richtlinie (the Federal Joint Committee's directive, amended to cover lung screening, March 12, 2026).
- Together these mandate specific QA requirements
  - radiologist qualifications
  - QA requirements for the CT equipment
  - QA requirements for the reading workstation, and the software used for computer-assisted detection
  - mandatory double reading, and mandatory AI-assisted nodule-detection software.

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German Legislation re: Lung Cancer Screening QA

Bundesministerium der Justiz und für Verbraucherschutz | Bundesamt für Justiz

Example Germany

Verordnung über die Zulässigkeit der Anwendung der Niedrigdosis-Computertomographie zur Früherkennung von Lungenkrebs bei rauchenden Personen[1] (Lungenkrebs-Früherkennungs-Verordnung - LuKrFrühErkV)

Nichtamtliches Inhaltsverzeichnis

LuKrFrühErkV

Ausfertigungsdatum: 15.05.2024

Vollzitat:

"Lungenkrebs-Früherkennungs-Verordnung vom 15. Mai 2024 (BGBl. 2024 I Nr. 162)"

1 Diese Verordnung dient der Umsetzung von Artikel 55 Absatz 2 Buchstabe f und h der Richtlinie 2013/59/Euratom des Rates vom 5. Dezember 2013 zur Festlegung grundlegender Sicherheitsnormen für den Schutz vor den Gefahren einer Exposition gegenüber ionisierender Strahlung und zur Aufhebung der Richtlinien 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom und 2003/122/Euratom (ABl. L 13 vom 17.1.2014, S. 1).

LDCT with volumetric assessment as in QMIC TG

(1) Niedrigdosis-Computertomographie ist eine Computertomographie des Thorax, bei deren Anwendung zur Erreichung der erforderlichen Bildqualität zur Lungenkrebsfrüherkennung

1. ein Volumen-Computertomographie-Dosisindex von 1,3 Milligray nicht überschritten wird oder
2. ein höherer Volumen-Computertomographie-Dosisindex als 1,3 Milligray im Einzelfall aufgrund der Körperstatur der zu untersuchenden Person notwendig ist.

§ 7 Qualitätssicherung

(1) Der Strahlenschutzverantwortliche hat ein umfassendes Qualitätssicherungssystem einzurichten und zu betreiben. Dieses muss organisatorische, medizinische und technische Aspekte berücksichtigen, insbesondere

1. die Art und Durchführung der Untersuchungen zur Lungenkrebsfrüherkennung,
2. die diagnostische Bildqualität der Computertomographieaufnahme,
3. die physikalisch-technischen Parameter bei der Erstellung der Computertomographieaufnahme und
4. die Befundung der Computertomographieaufnahme.

(2) Der Strahlenschutzverantwortliche hat dafür zu sorgen, dass für eine Prozess- und Ergebnisevaluation der Untersuchung Lungenkrebsfrüherkennung bei rauchenden Personen anonymisierte Daten über folgende Punkte erhoben und aufgezeichnet

1. die Anzahl der untersuchten Personen und
2. die Anzahl der kontrollbedürftigen und der abklärungsbedürftigen Befunde.

Der Strahlenschutzverantwortliche hat die Aufzeichnungen für die Dauer von zehn Jahren aufzubewahren.

(3) Der Strahlenschutzverantwortliche hat auf Verlangen der ärztlichen Stelle oder der zuständigen Behörde die Informationen nach Absatz 2 zur Verfügung zu stellen.

Nichtamtliches Inhaltsverzeichnis

Parameter	Anforderungen
Volumen-Computertomographie-Dosisindex der Übersichtsaufnahme	≤ 0,2 × angestrebter Spiral-Computertomogramm-Volumen-Computertomographie-Dosisindex
Übersichtsaufnahme	In posterior-anteriorer Projektion und in gleicher Atemlage wie im darauffolgenden diagnostischen Computertomographie-Scan Falls für Dosisautomatik technisch erforderlich, mit zusätzlicher lateraler Übersichtsaufnahme
Scanmodus	Spirale zur lückenlosen Erfassung in einer Atempause
[illegible]	≤ 15 Sekunden
Rotationszeit	≤ 0,5 Sekunden
Dosisautomatik/Röhrenstromautomatik	Verwendung von Protokollen mit an die Körperstatur [illegible] angepasster Röhrenspannung (z. B. mittels Spannungsautomatik) und angepasstem Röhrenstrom (z. B. mittels [illegible] Konstantmabsenkung)
Dynamische Kollimation	Hardwarebasierte Methode zur Vermeidung von Overranging bei Detektorabdeckung größer als 4 Zentimeter
Faltungskern	Lunge: kantenbetonter Rekonstruktionsfilter Mediastinum: glättender Rekonstruktionsfilter
Rekonstruktionsverfahren	Modellbasierte iterative Rekonstruktion oder andere Methoden mit mindestens vergleichbarer Dosiseinsparung
Auflösung lateral (xy)	Eine isotrope räumliche Auflösung von 0,8 bis 1 Millimeter für Kontraste ab 150 Hounsfield-Einheiten Die Voxelgröße liegt bei 70 bis 80 % der Auflösung.
Lagerung der zu untersuchenden Person	Rückenlage mit Armen über dem Kopf; zentriert im Isozentrum
Gantrykippung	0°
Scanrichtung	Caudal-cranial
Spiral-Scan	Durchführung in einer Atempause in tiefer Inspiration
Kontrastmittel	Nein
Scanbereich	Lungenspitze bis dorsaler Recessus
Gesichtsfeld	Gesamte Lunge, ansonsten so gering wie möglich
Darstellung am Befundarbeitsplatz	Verwendung einer Software zur interaktiven Darstellung dickerer Schichten und von Dünnschicht-Maximalintensitätsprojektion
Software zur computerassistierten Detektion	Detektion und Volumetrie von Lungenrundherden sowie Berechnung der Volumenverdopplungszeit und Speicherung der Auswertung als erweiterte Bilddokumentation zur strukturierten Befundung

Scan parameter comparable to QMIC TG

QA/QC without detailed technical parameters
Task for QMIC to educate and support implementation based on TG

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Implementation example 2: MASLD – Resmetirom Rx.

Reimbursement trigger

- MASLD (metabolic dysfunction-associated steatotic liver disease) is a chronic liver disease
- FDA approved resmetirom in March 2024.
- MR experts contend the BCBS established coverage eligibility criteria (thresholds/cutpoints of MRE and PDFF measurements) are not optimum.
- Modeling could very likely propose better cutpoints to improve patient benefit, cost-effectiveness, and appropriate QA requirements.

For a Claim, what level of precision is needed?

- It depends …
- What is the current performance of QIB? What is the range of plausible performance values (RC, wCV, wSD)
- How good does the measurement need to be to inform a clinical decision? Minimum acceptable performance threshold?
- What will be the sensitivity/specificity implications of a selected threshold?
- What are the clinical consequences of the false negatives and false positives?

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Recommendation 1

A QI Metrology Center of Excellence for Clinical Imaging

- **Detailed Proposal:**
  - **Federation of American Scientists (FAS) Publication (2024)**
  - ***"A Quantitative Imaging Infrastructure to Revolutionize AI-Enabled Precision Medicine"***
  - **fas.org/publication/ai-enabled-precision-medicine/**
- **Potential models:**
  - **Centers for Disease Control (CDC) Lipid Standardization Program; or**
  - **Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments Program (CLIA)**

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Recommendation 2

NIST Programs & Infrastructure

NIST is the most authoritative source for:

- **Reference standards for measurements**
  - **Guidance documents**
  - **Physical reference materials/phantoms**
    - » **“Metrological Traceability”**
- **Scanner Calibration Reference Facilities**

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Summary – Takeaways:

- Quantitative clinical imaging is an assay.
- QI must be grounded in fundamental metrology principles
  - Basic QMIC premise
- Professional organizations must educate users to implement QI as an assay – QMIC will assist
- Federal agencies can provide standards and QA infrastructure.

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Thank you.

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