

Healthcare Infrastructure

Monday November 4th 2019

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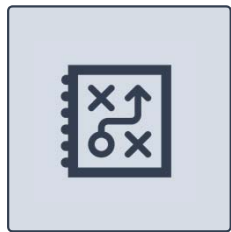
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Associate Professor, Harvard Medical School



I have no conflicts of interest

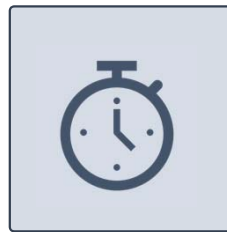
Outline



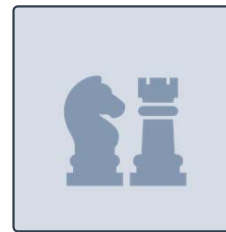
Healthcare
Infrastructure



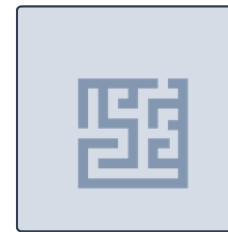
Assay
Validation



The Innovation
Approach



CPT Codes
AMA, Tiers

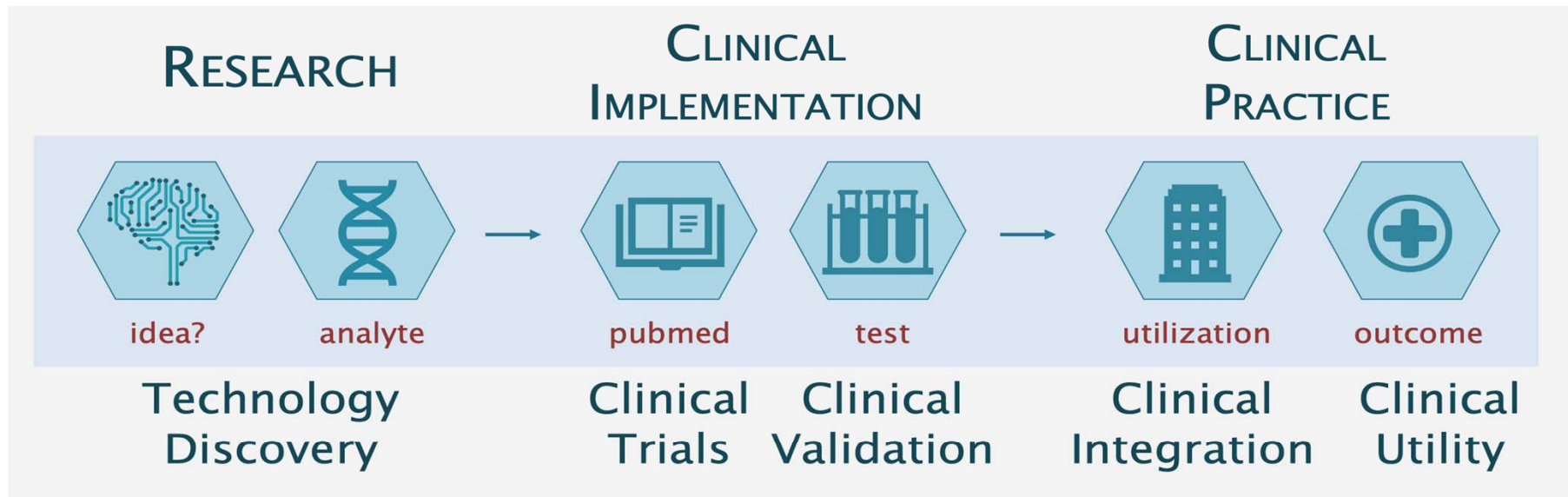


Revenue
Cycle Management



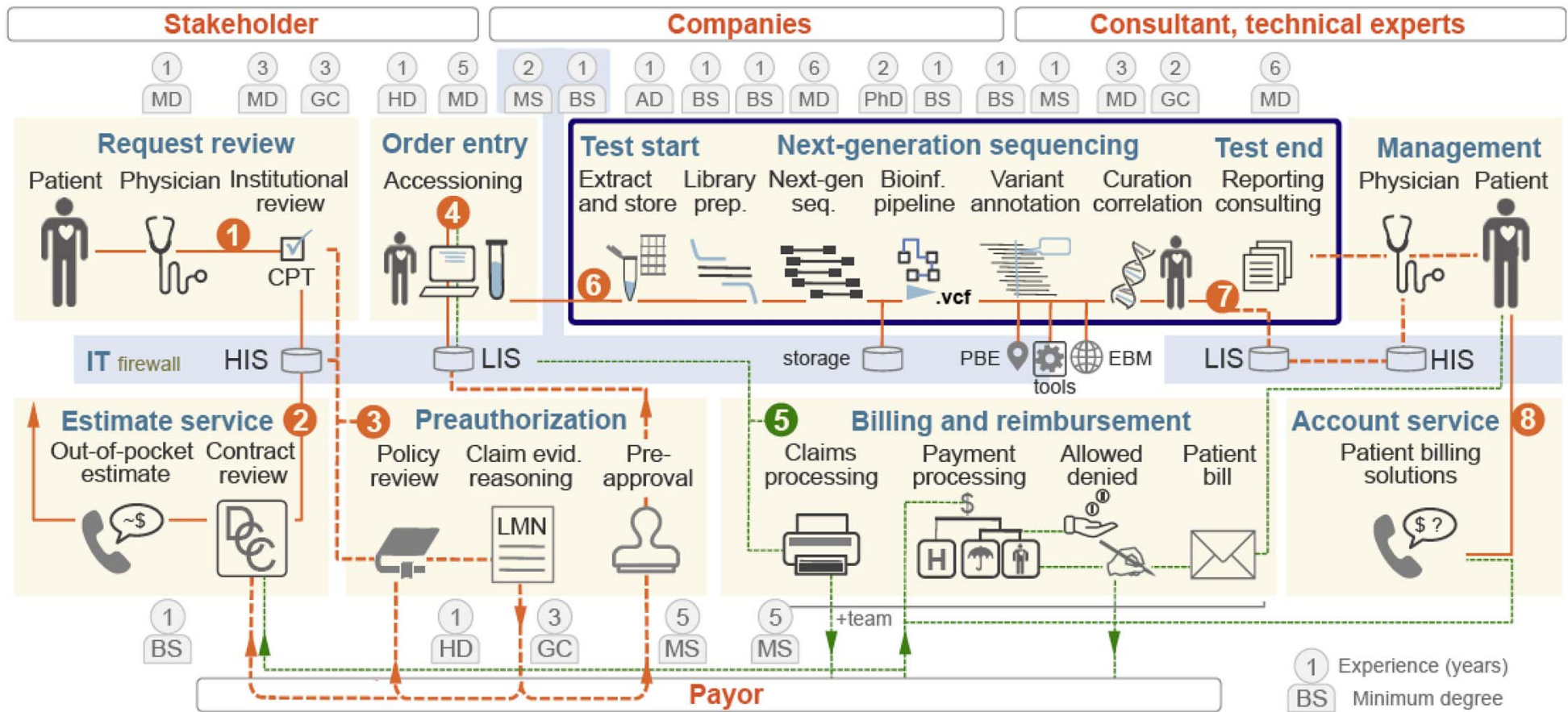
Financial
Sustainability

Center for Integrated Diagnostics - Concept

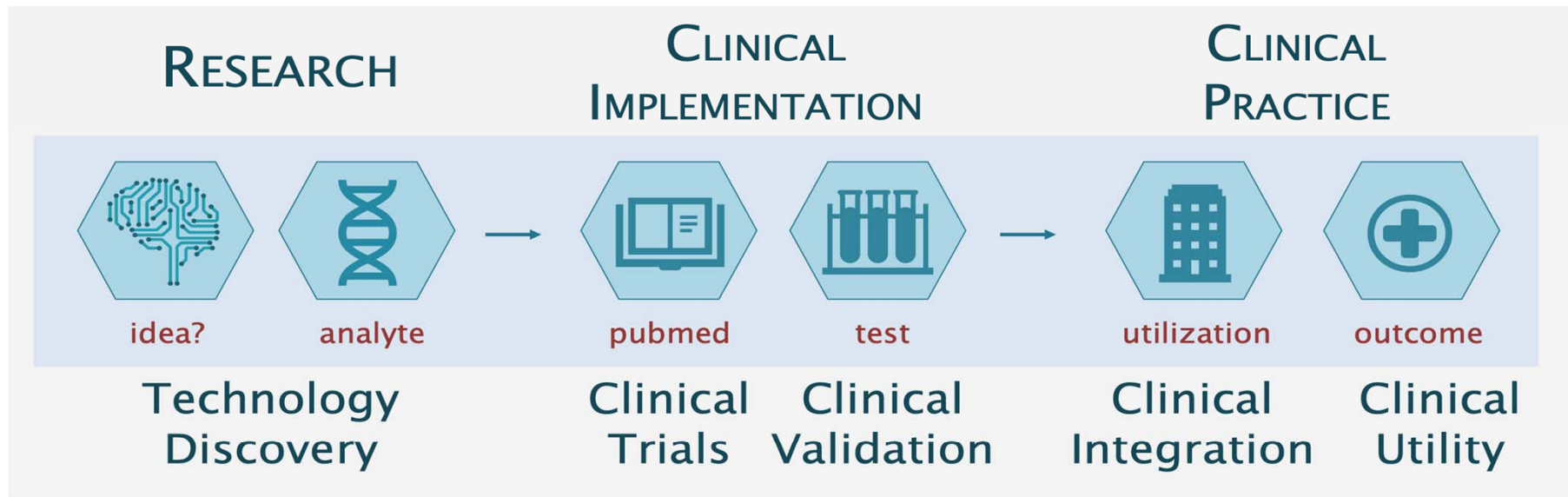


CENTER FOR INTEGRATED DIAGNOSTICS

Synthesize the healthcare infrastructure for financially-sustainable genomics



Center for Integrated Diagnostics - Concept



CENTER FOR INTEGRATED DIAGNOSTICS

“A New Assay to Launch” ...

- Purpose
- Laboratory Test Validation = Specifications for Analytical (Test) Validation
 - Analytical accuracy
 - Precision
 - Analytical Sensitivity (limit of detection, LOD)
 - Analytical Specificity (interferences)
 - Reportable range
 - Reference range
- Conclusion

What does that actually mean

- The term **validation**, although used widely by laboratories to mean ‘**establishing the performance characteristics**’ for the test, may not appear in regulatory standards.
- The term **verification** is termed as ‘**test evaluation**’

Requirement ISO 15189:2007	5.5.1 ‘If in-house procedures are used, they shall be appropriately validated for their intended use and fully documented’ 5.5.2 ‘The methods and procedures selected for use shall be evaluated* and found to give satisfactory results before being used for medical examinations. A review of procedures by the laboratory director or designated person shall be undertaken initially and at defined intervals’.
Requirement CLIA 1988, Sec.493.1253	‘(...) introduces a test system not subject to FDA clearance or approval (...) must, (...) establish (...) the performance specifications** (...)’
EuroGentest ¹	‘STATEMENT 01: NGS should not be transferred to clinical practice without an acceptable validation of the tests according to the emerging guidelines’
College of American Pathologist (CAP) ²	MOL.34936: NGS Wet Bench Process Validation MOL.34960: NGS Bioinformatics Pipeline Validation

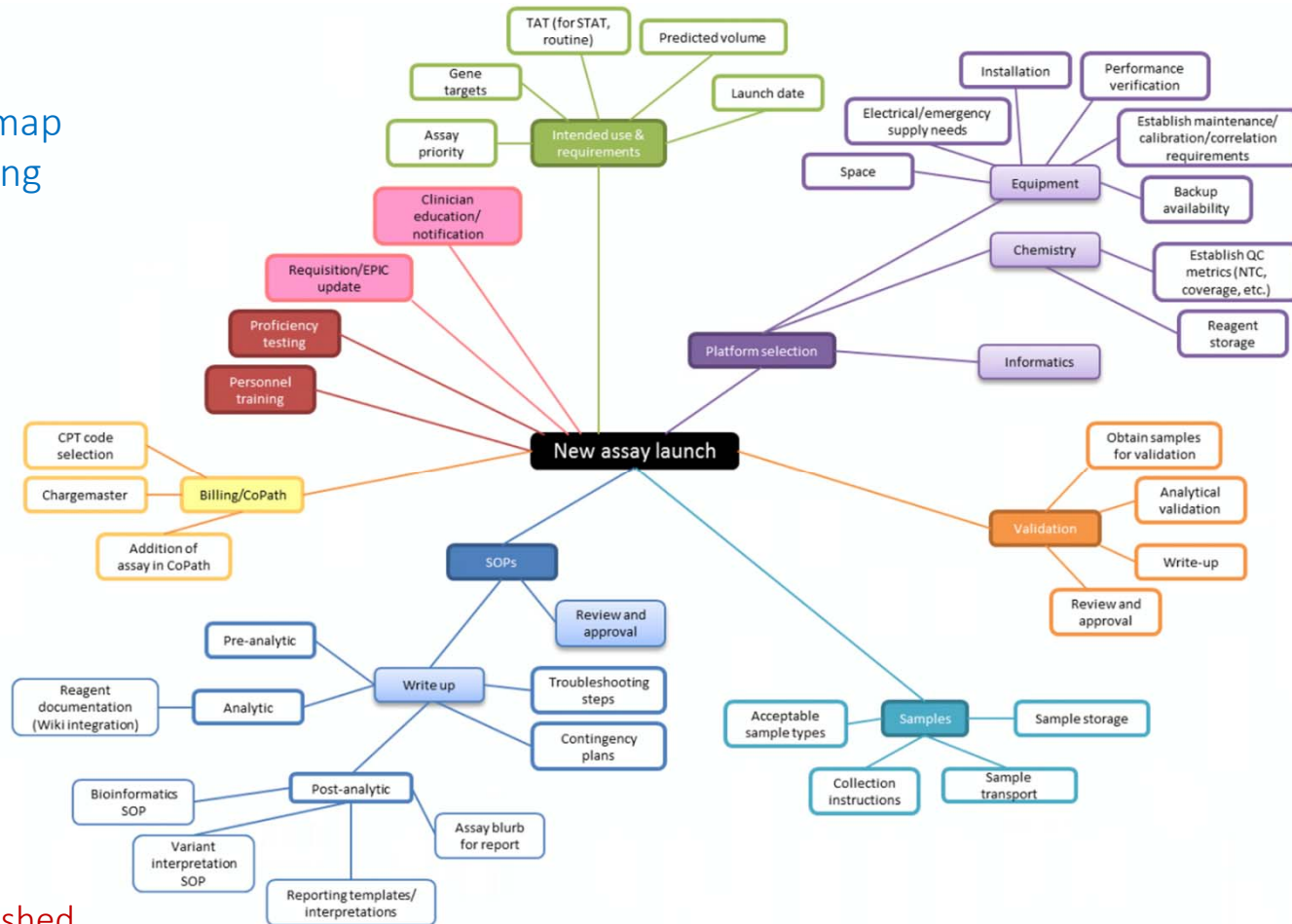
<https://euformatics.com/validation-for-ngs-based-clinical-tests/>

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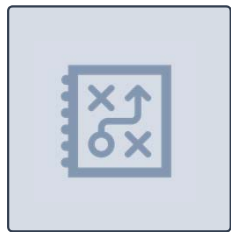
Identify key elements for integration of new diagnostic tools into routine clinical practice

Spidermap/Mindmap
Designated meeting
Scrum/Agile



CID-internal, unpublished

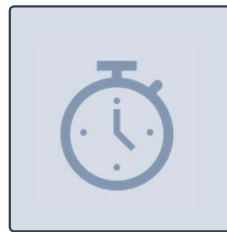
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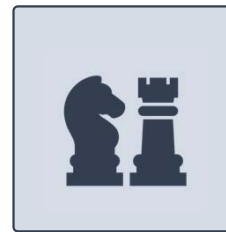
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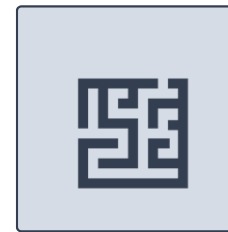
Assay
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The Innovation
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CPT Codes
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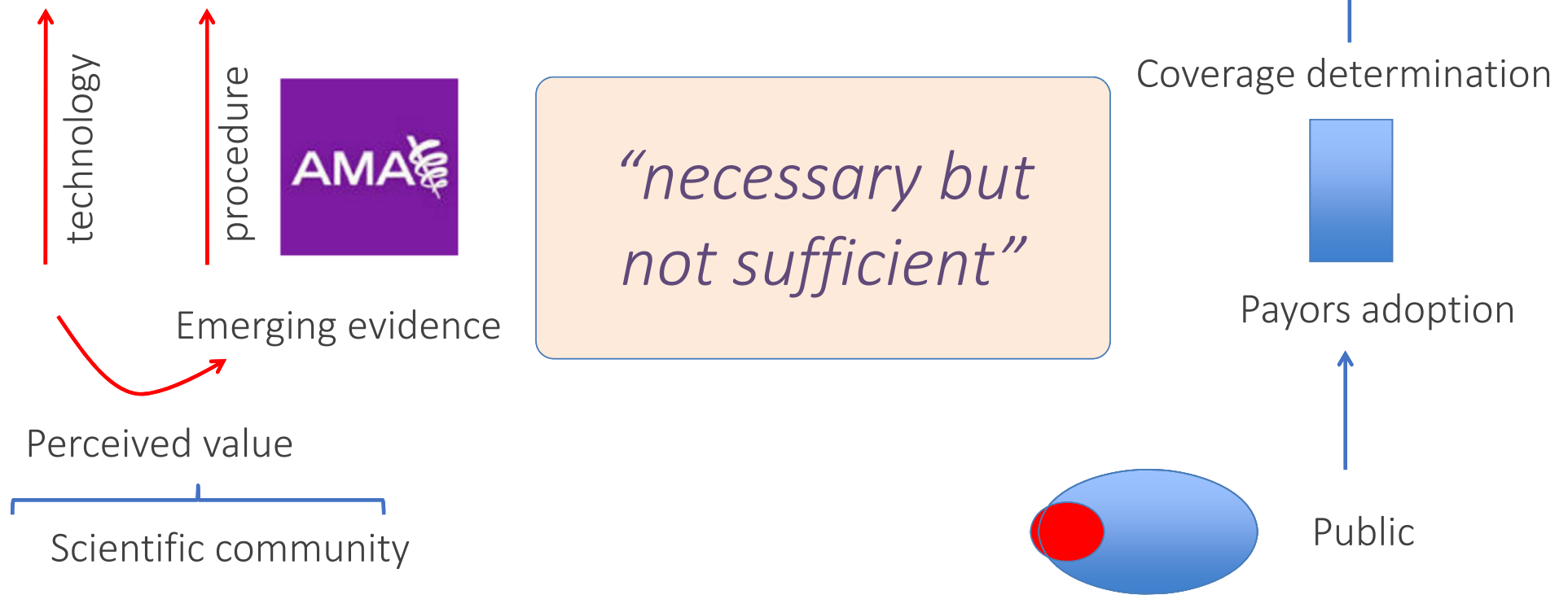


Revenue
Cycle Management

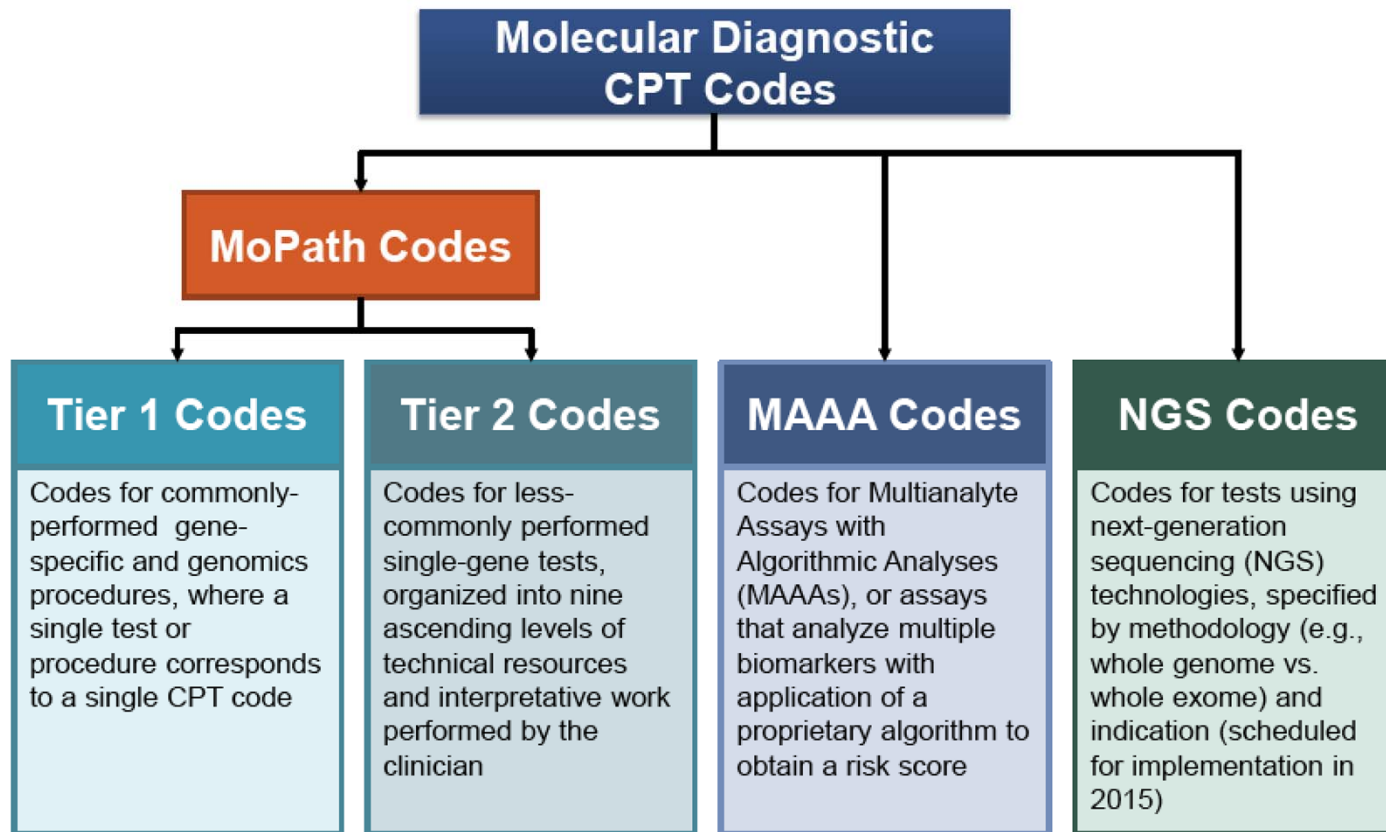


Financial
Sustainability

NGS + CPT \neq Reimbursement (“challenging”)

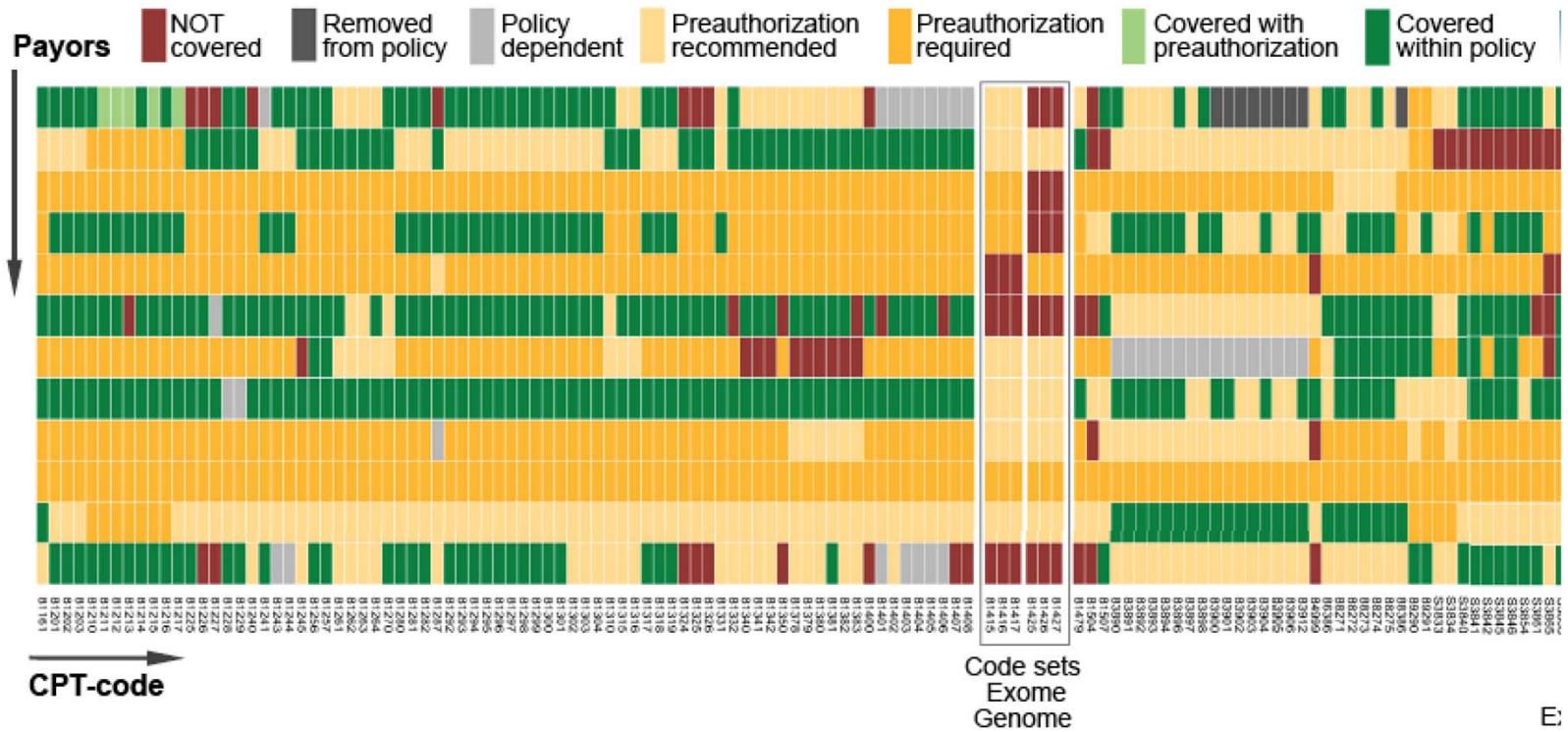


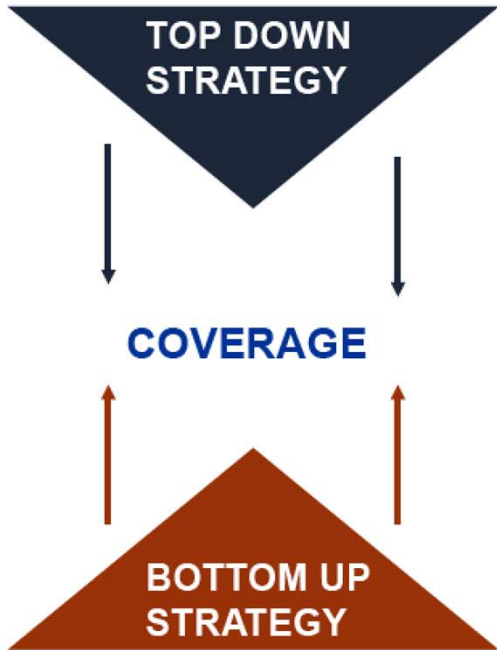
The AMA Has Established Several CPT Code Sets for Molecular Diagnostic Tests



Payor Rules by CPT-codes of Selected Molecular-Genetic Tests

“Policy-tailored claim evidence reasoning”

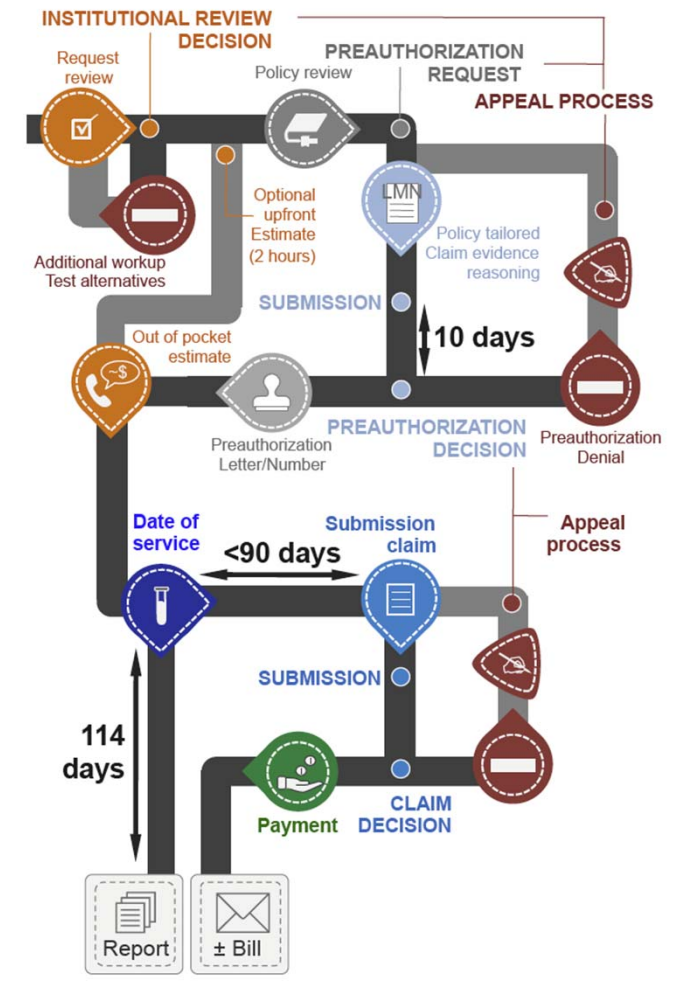




- ✓ Developing and publishing strong clinical utility evidence
- ✓ Engaging payer medical directors to advocate for publication of favorable coverage policies

- ✓ Developing a robust appeals program to overturn medical necessity claim denials
- ✓ Leveraging successful appeals to make a case for formal coverage

In the absence of strong clinical utility evidence, a robust appeals program can be an effective tool to secure coverage



Lennerz et al., 2016 JMD

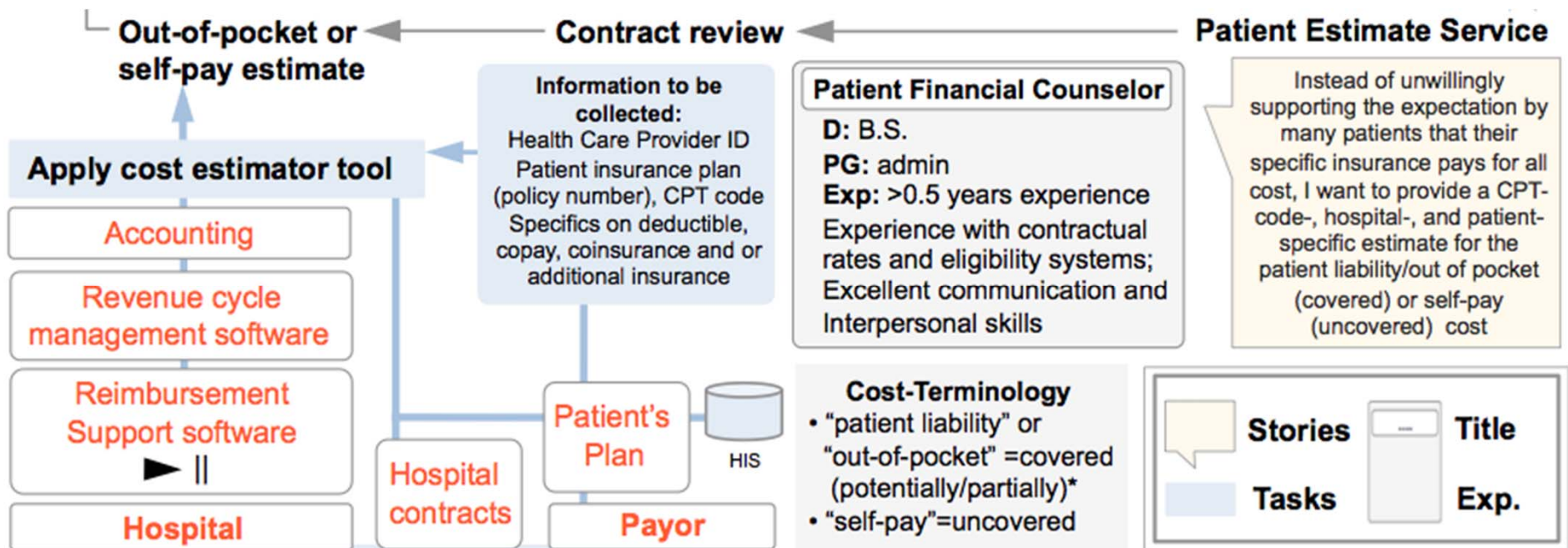
Update on expanded molecular testing (payor initiatives)

- BCBS Initiative (MGH/BWH/DFCI) started in late 2015
- First co-developed policy 7/2016
- August 2016 => added B/T-cell NHL
- January 2017 => update GBM/Medulloblastoma
- October 2017 => Diagnostic code update
- March 2018 => DEX registration requirement removed
- April 2018 => Diagnostic code update
- August 2018 => LCD hematolymphoid
- September 2018 => Diagnostic code update
- October 2018 => Diagnostic code update
- December 2018 => pediatric tumors
- ~April 2019 => see right

Table 2a. Conditions for which Solid Tumor NGS Panel Testing is [MEDICALLY NECESSARY](#)

Disease For Which Test is Covered	Additional Requirements
B-Cell NHL	Diagnostic, Prognostic, Monitoring
Bladder Urothelial Carcinoma	Stage IV or recurrent or unresectable
Breast	Stage IV or refractory or recurrent
Cholangiocarcinoma	Stage IV or recurrent or unresectable
Colorectal Cancer	Stage IV or recurrent or unresectable
Endometrial Carcinoma	Stage IV or recurrent or unresectable
GI Stromal Tumor	Any stage
Glioma	Diagnostic, Prognostic, Monitoring
Medulloblastoma	Diagnostic, Prognostic, Monitoring
Melanoma	Stage IIIB, IIIC, IV or recurrent or unresectable
Meningioma	Grade 2 to 4 (only recurrent or unresectable)
Neuroblastoma	Any stage
Non-Small Cell Lung Cancer	Stage IIIB, IV or recurrent
Ovarian	Relapsed or refractory advanced (stage II or higher), non-mucinous ovarian cancer being considered for PARP inhibitor therapy
Pancreatic Tumors	Diagnostic, Prognostic
Pediatric Tumors	Patient age under 18 years
Prostate	Metastatic castration-resistant
Rare Tumors	Less than 5,000/year in US; Metastatic or recurrent or unresectable
Stomach/Esophageal Cancer	Stage IV or recurrent or unresectable
T-Cell NHL	Diagnostic, Prognostic
Thyroid Cancer	Stage IV or recurrent or unresectable
Unknown Primary	May be used for Diagnosis or Therapeutic Decision Making

Out of Pocket Estimates





What's next?
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