PATIENT SAFETY AND SYSTEMIC HARMONIZATION AND INTEROPERABILITY ENHANCEMENT FOR LAB DATA (SHIELD)

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This presentation does not reflect official FDA policy. The views are those of the author.

In Memoriam Mike Waters (1973-2020)

This body of work remembers Michael Steven Waters (1973-2020) who died working fighting the COVID-19 pandemic. Public health workers are at the front line fighting the pandemic both risking infection with SARS-CoV-2 and in a national wave of suicides.[1] Mike worked at the Food and Drug Administration (FDA), was a national thought-leader in microbiology and in vitro diagnostics and understood how hampered we are with our obsolete data systems

Overview

- Real-world evidence (RWE) and Interoperability
- Lab as the long hanging fruit
- SHIELD
- SHIELD Strategic Planning

Lack of interoperability explains the unrealized promise of RWE in health care

- The narrative that has been used…
  - Wealth of data -- electronic medical records, medical imaging, mobile apps, and more recently low-cost gene sequencing and wearable devices, unlocked using artificial intelligence, cloud computing and blockchain – for better diagnostics, personalized treatments, and early disease prevention for millions .https://www.ehidc.org/sites/default/files/resources/files/why%20digital%20medicine%20depends%20on%20interoperability.pdf
  - A comprehensive interoperability -- a “plug and play” environment -- may help medicine in the way it has made possible international banking on a cell phone, the “internet of things,” and shopping over the internet.
- The vision of a national interoperable health information system has been *elusive*, however, because of clinical care in isolated databases, silos of incompatible systems, proprietary software, and data bases that are difficult to exchange, analyze, and interpret.
  - https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia
- These observations have been underscored the US response to the pandemic has reveals the weakness of our data systems
  - Schneider, Eric C. "Failing the test—the tragic data gap undermining the US pandemic response." New England Journal of Medicine 383.4 (2020): 299-302.

A lot of innovation is being held back by problem with the data

- Patient safety
  - Colleges at College of American Pathologists emphasize that coding errors can lead to loss of life.
- Clinical Decision Support (CDS)
- Epidemiology/outbreak monitoring
- Healthcare research and innovation
- Public health reporting
- Regulatory decisions
- Signal detection

Interoperablity

Semantic

Syntactic

Institutional

Interoperability challenges in health care data; a ranges of current uses and barriers.

- Currently used routinely → Medical claims (but still require curation)
- "Low hanging fruit" → Labs
- Near Future → Remote monitoring measurements
- Major barriers → Psychiatric care – DSM3 does not render current practice, institutional and semantic issues

Why focus on lab data?

Can’t boil the ocean; interoperability of lab data will provide very useful data so is an appealing place to start

Labs have been digitalized for decades

CLIA reference labs began in 1988 regulates laboratories that test human specimens and ensures laboratories produce safe and effective patient test results

Standards exist (LOINC, SNOMED, and others)

Remaining problem is harmonization of *application* of laboratory data; ***labs apply codes in an idiosyncratic way.*** There has been no authoritative source to guide coding..

College of American Pathologists (2013) in a White Paper titled “Laboratory Interoperability Best Practices.”

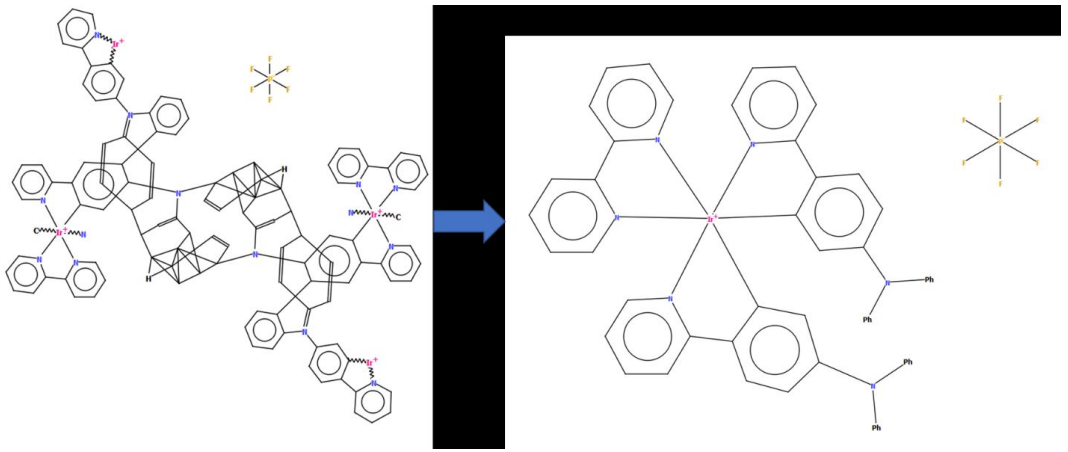
- Mistake #1: Not having standardized test definitions
- Mistake #2: Having unsynchronized test catalogs
- Mistake #3: Not uniquely identifying test names using LOINC
- Mistake #4: Assuming that it will be easy to establish a secure electronic connection
- Mistake #5: Not having a thorough testing plan
- Mistake #6: Failing to recognize that validation of the EHR result display is an important responsibility
- Mistake #7: Not recognizing challenges and pitfalls associated with patient identifiers
- Mistake #8: Not considering all results delivery situations
- Mistake #9: Not anticipating that results may be passed through multiple EHRs
- Mistake #10: Assuming that EHRs can properly display complex reports

Pathologists have embraced interoperability first to improve patient safety.

More than a clinical necessity: potential efficiencies are real!

Current practice is manual curation --expensive time consuming.

- Usual a team of nurses
- Some of the information need to render data interoperable requires access to other data sets or speaking with people; it's a lot like *archeology.*
  - E.g., what machine or processes are used in the lab
- Duke cath lab saved the work of *two full time nurses* when they automated.
- Find Dr. Jimmy Tcheng at Duke to learn about that effort in engineering data collection as part of the workflow.



Learn more about SHIELD

5 years in the making

on websites of MDIC and MDEpiNet

SHIELD

Overview

Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) is a multi -stakeholder, public-private partnership to improve the quality, utility and portability of electronic laboratory data (i.e., in vitro diagnostic [IVD] data) through the harmonized implementation of semantic data standards that have been appropriately qualified by a sole authoritative source. Codes for laboratory data should be interoperable: "Describe the same test the same way, every time."

By improving the semantic interoperability of laboratory data within and between institutions, diagnostic information can be used to better support clinical decisions and enable Real-World Evidence (RWE) relevance and reliability. SHIELD supports the provision of vetted and harmonized codes from manufactures/industry to laboratories; this enables consistent representation in LIS and downstream to EHR, achieving cross-institutional semantic interoperability.

SHIELD$_x$

SHIELD provides MDEpiNet with harmonized laboratory data coding support for the Collaborative Learning Communities (CLC). CLC brings together Coordinated Registry Networks (CRNs) from a variety of clinical spaces. This partnership enables efficient incorporation of laboratory data into CRNs without the need for extensive manual curation. This partnership is funded by the Patient-Centered Outcome Research Trust Fund (PCORTF), Office of the Assistant Secretary for Planning and Evaluation (ASPE)/Health and Human Services (HHS).

"describing the same test, the same way, every time."

Institutional Foundations of SHIELD

SHIELD emerged out of multi-agency workshops held in 2015 and 2016.

- The 2016 workshop included the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Library of Medicine (NLM) of the National Institutes of Health (NIH), the Office of the National Coordinator for Health Information Technology (ONC), and the Centers for Medicare and Medicaid Services (CMS). Titled the "CDC/FDA/NLM/ONC/CMS Workshop on Promoting Semantic Interoperability of Laboratory Data" the meeting received and discussed input from stakeholders regarding proposed approaches to facilitate the adoption and implementation of interoperability standards in a manner that enables consistent, accurate, and harmonized descriptions of *in vitro* diagnostic tests (IVD) and results.
- https://wayback.archive-it.org/7993/20170111193824/http:/www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm453897.htm Accessed October 17, 2020

FDA Data Standards Advisory Board (DSAB)

- Clinical Laboratory Interoperability Consortium (CLIC) Working Group (WG)
- Under its charter the CLIC WG coordinates the FDA activities with SHIELD

Funding received

- Medical Counter Measures
- Office of the Assistant for Planning and Evaluation (ASPE)
  - Part of the PCORTF portfolio
  - The Office of the Secretary (OS) of HHS receives 4% annually (2011-2019) of the Patient-Centered Outcomes Research Trust Fund (PCORTF) to build data capacity
  - With a major emphasis on RWE

The ecosystem: SHIELD provides an authoritative source for coding by working with over 70 stakeholders including:

Government

- FDA (CDRH, CDER, CBER), CDC, NIH, ONC, CMS, VA

Private Sector

- IVD Manufacturers, commercial and laboratory laboratories, Association of Public Health Labs, (APHL), EHR vendors, PEW Charitable Trusts, NEST/MDIC, MDEpiNet, Academia, College of American Pathologists, IICC (IVD Industry Connectivity Consortium), AACC (American Association for Clinical Chemistry), LOGICA

Coding organizations

- LOINC, SNOMED, UCUM, UDI, LAW and LIVD and FHIR.

Workflow and data collection

Each IVD asks a 'question' of a specimen to get an 'answer'.

1) Collect and prepare a specimen (nasopharyngeal swab).

2) **Ask Question:**
Does the nasopharyngeal swab contain:

3) **Provide Answer:**

Report

Device Identifier:
00382902560715

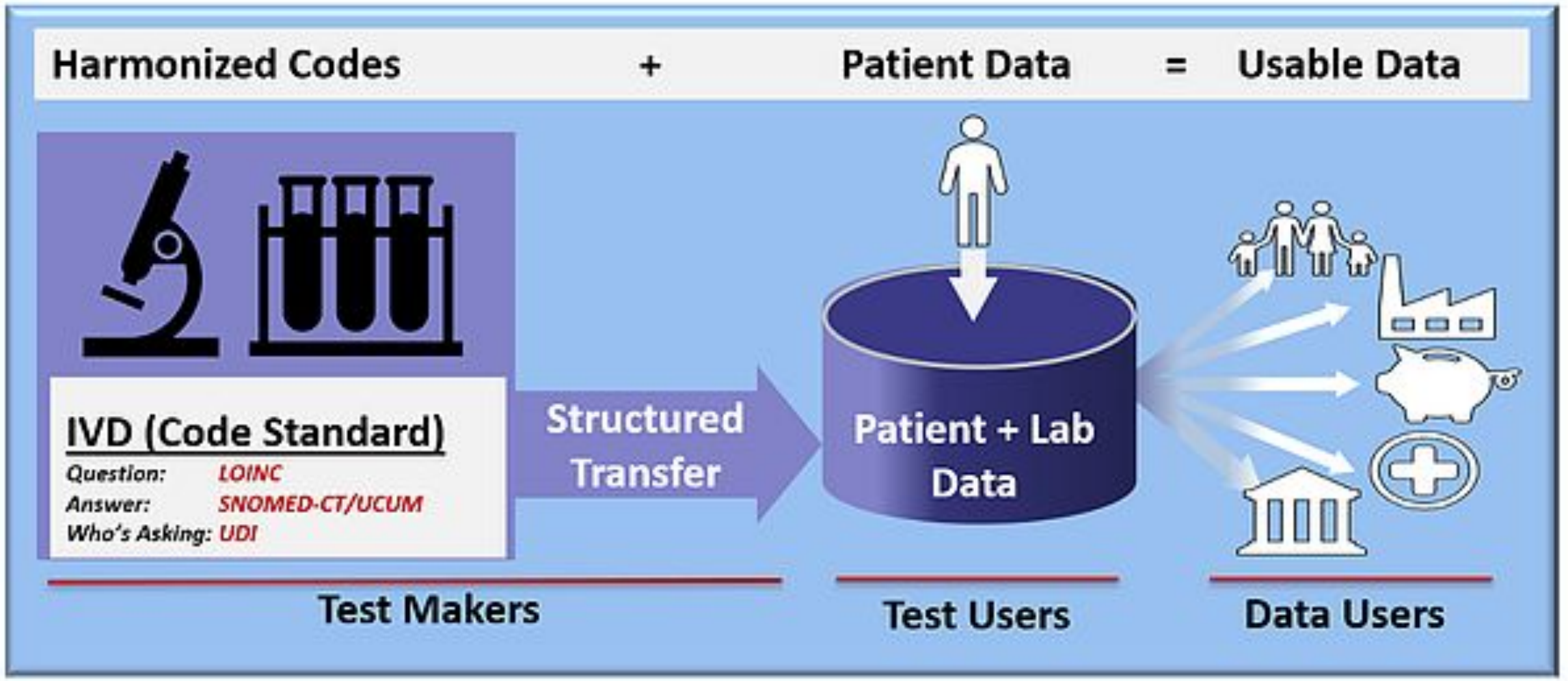
Influenza A antigens?
- *LOINC Code: 43874-7*

Influenza B antigens?
- *LOINC Code: 43895-2*

Influenza A antigens: Detected;
- *SNOMED-CT: 260373001*

Influenza B antigens: Not detected
- *SNOMED-CT: 260415000*

Value chain: where action is needed



SHIELD took a big step during the pandemic

- Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires “every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19” to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS).
- In addition, the statute authorizes the Secretary to prescribe the form and manner, and timing and frequency, of such reporting. A policy was issued in June 2020 that outlines the requirements for data submission to HHS as authorized under this law.
- A new requirement, which went into effect Aug. 1, 2020 will help provide crucial information needed to monitor and fight the pandemic nationally. https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf

- Related news reports

https://www.nejm.org/doi/full/10.1056/NEJMp2008512

https://www.cnbc.com/2020/06/04/us-needs-to-ensure-underserved-minorities-have-equitable-access-to-coronavirus-testing-testing-chief-says.html

https://www.npr.org/sections/coronavirus-live-updates/2020/06/04/869815033/race-ethnicity-data-to-be-required-with-coronavirus-tests-in-u-s

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An example of bottom-up development followed by a top-down authorization.

Historic moment for interoperability

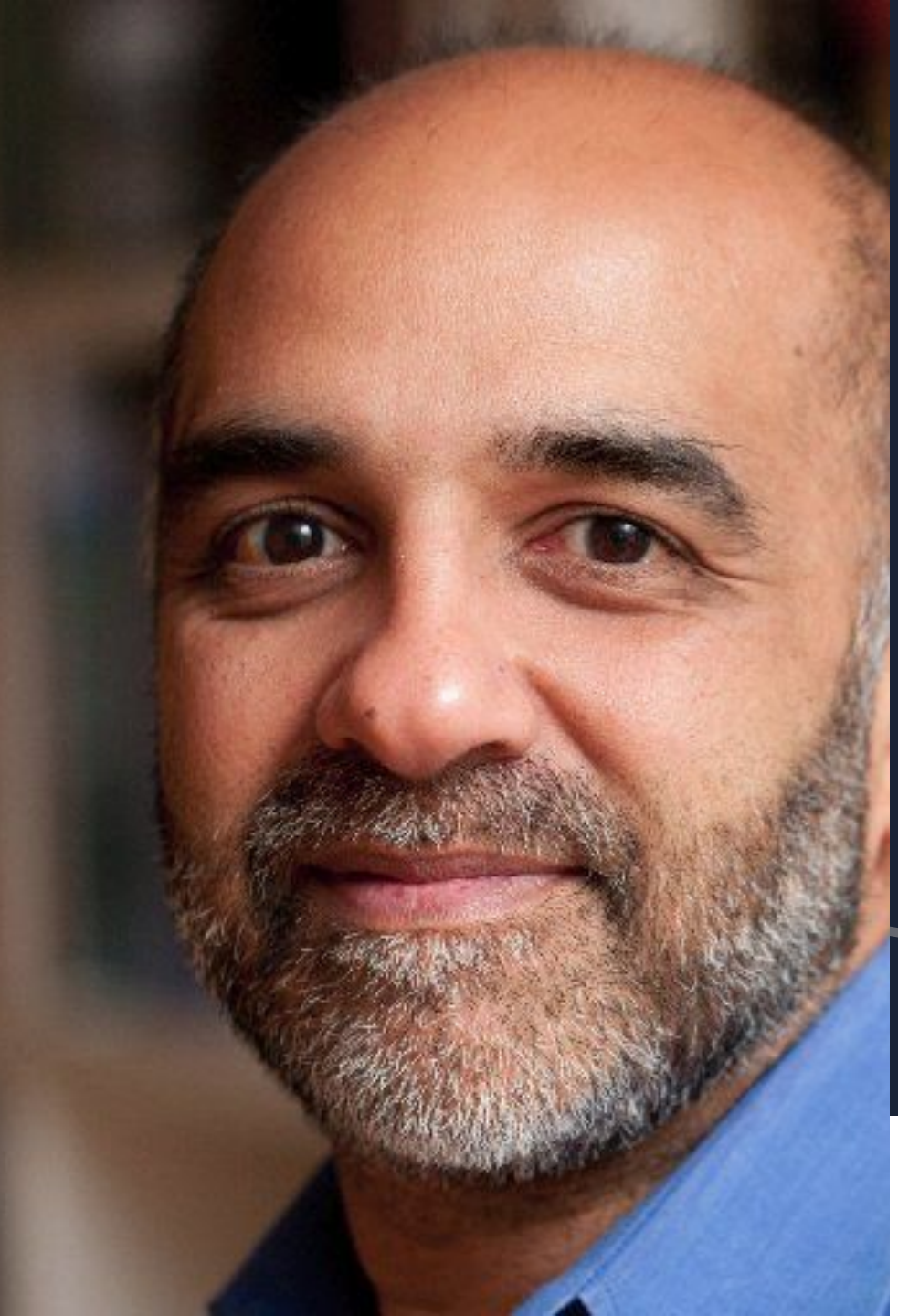
- Can we build on the response to the pandemic to promote interoperability beyond COVID-19 testing?

“Plans are worthless, but planning is essential.” Dwight D. Eisenhower https://quoteinvestigator.com/2017/11/18/planning/

- SHIELD has taken an important step
  - White Paper calling for a Strategic Plan
  - Initiation of full-scale strategic plan for the Stakeholder.

SHIELD Strategy Planning Process

Launched May 4th, 2021



CHAIR OF SHIELD STRATEGIC PLANNING

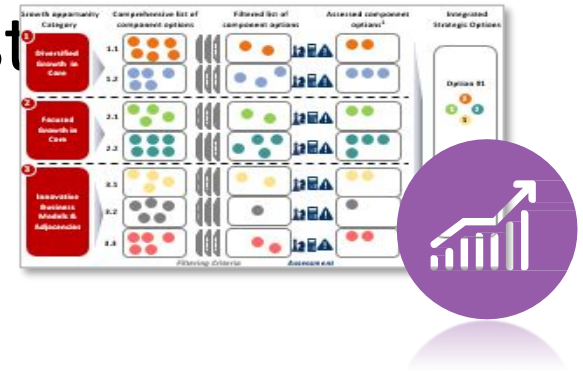
- Micky Tripathi, PhD
- Coordinator
- ONC/HHS

What the Planning Process Will Deliver

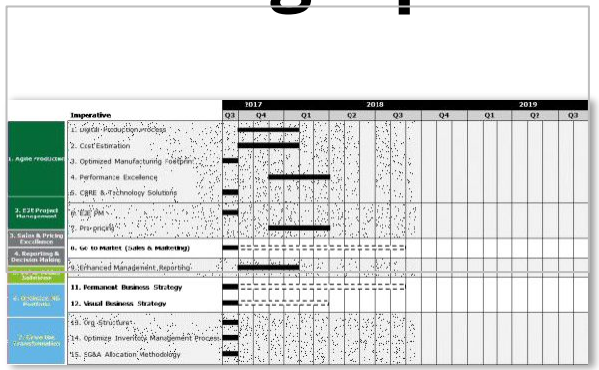
A clearly articulated STRATEGY

…

with a BUSINESS CASE that outlines the IMPACT of the st



and a ROADMAP of supporting activities Five-year strategic plan



Introduction of Committee Chairpersons

Committee	Chair(s)
Coordination Committee	Wendy Rubinstein (FDA) Micky Tripathi (ONC)
Communications/Training/Education Committee	Stan Huff (Logica) Molly Polen (AACC)
Strategic Alignment Committee	Micky Tripathi (ONC) Colin Shepard (CDC) Sara Brenner (HHS/FDA)
LIVD File Expansion Committee	Wendy Rubinstein (FDA) Riki Merrick (APHL) John Snyder (NLM)
Implementation Committee	Scott Campbell (UNMC) Hung Luu (Utah)
Tooling, Technology and Knowledge management	Keith Campbell (VA) Andrew Sills (Deloitte)
Industry Committee	Serge Jonnaert (IICC) Ed Heierman (Abbott)
Effectiveness Committee (Monitoring and Evaluation)	David Baorto (Regenstrief) Vaishali Patel (ONC)

THANK YOU!