Biodosimetry Stockpiling

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BARDA Industry Day

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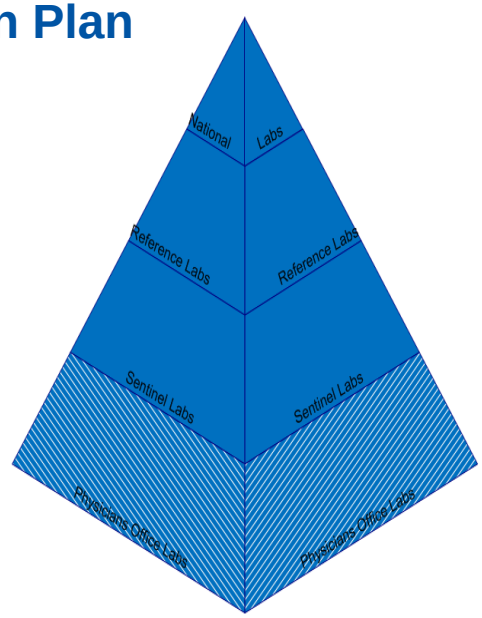
CBRN Diagnostics & Devices Program Strategy

Our objective is to develop tools to inform the efficient use of CBRN countermeasures, maximizing lives saved and minimizing casualties.

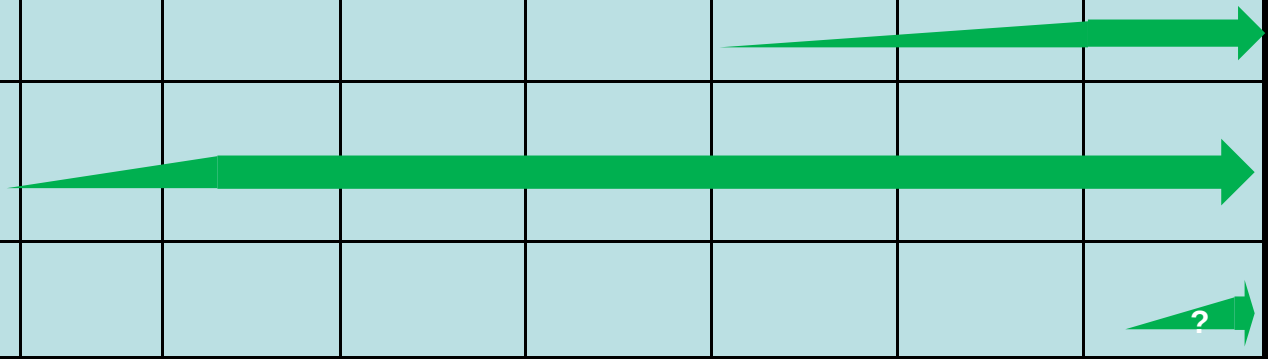
- Developing diagnostics and devices to inform CBRN countermeasure use
  - As identified in the PHEMCE Strategy Implementation Plan
  - Per PHEMCE needs assessments and requirements
- Key Strategies
  - Leverage existing clinical diagnostic laboratory infrastructure, instruments, practices, and IT
  - Stimulate development of Point of Care (POC) tools, moving testing closer to the casualty
  - Ensure appropriate capabilities at all levels
  - Correlate marker behavior with disease course



Informing Efficient Countermeasure Use,
Empowering Healthcare Laboratory Response

CBRN Diagnostics(Dx) Programs

Program	FY9	FY10	FY11	FY12	FY13	FY14	FY15
Biological Agent Dx							
Radiation Dx (Biodosimetry)							
Chemical Agent Dx							

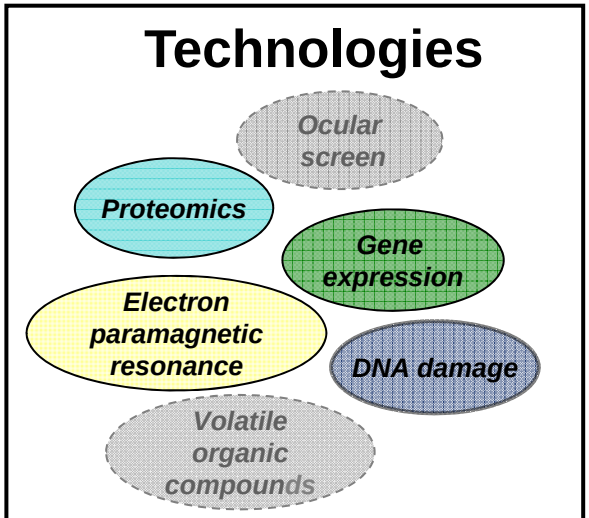


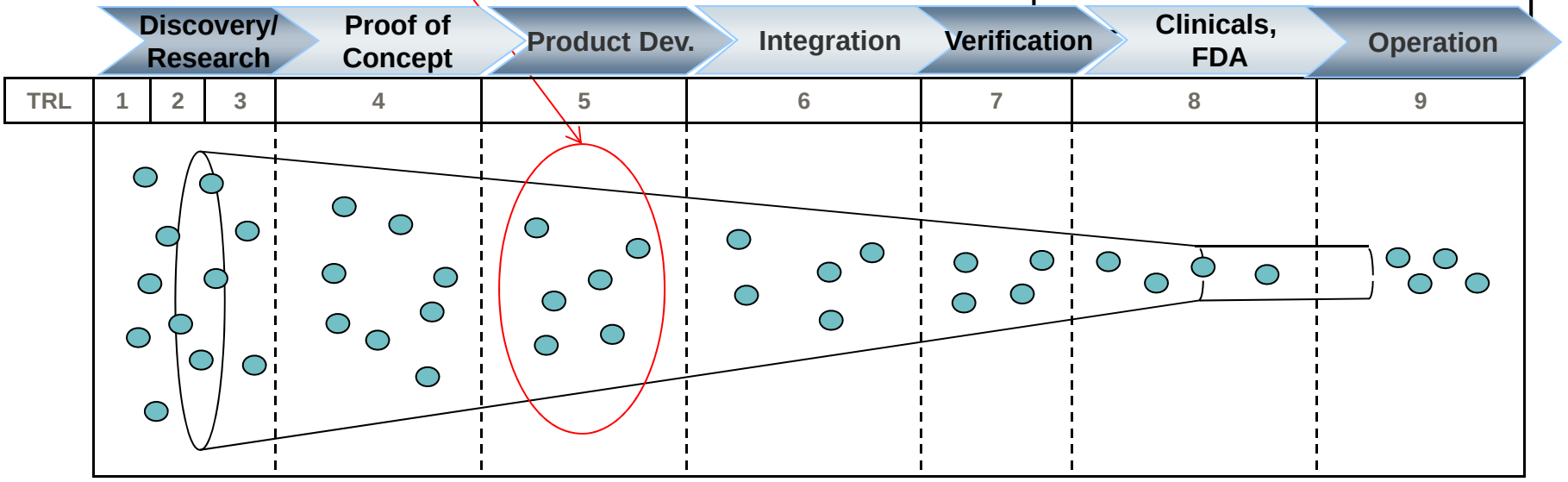
Diagnostics Instrument Strategy (All Threats)

- Laboratory
  - Leverage platforms widely placed in clinical labs (at the time of the incident) to inform routine healthcare.
  - Fund adaptation, if required, to allow utilization of existing products.
- Point of Care
  - Develop new platforms where existing platforms do not meet needs of ConOps.
  - Improve performance of existing platforms
  - Assays needed on multiple platforms for a given threat if a large Dx surge demand is expected.

BARDA Biodosimetry Program

- 11 projects awarded to date
- 6 projects currently funded
  - Biomarker feasibility shown
    - Mouse or human
    - Demonstrating feasibility in NHP
  - Phase - Product development
  - Envision product availability in 2016-17





Radiation Diagnostics

- Biodosimetry – the ability to estimate the dose of ionizing radiation a casualty has absorbed, post irradiation.

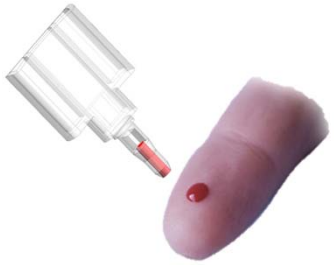
(10KT IND planning scenario)	Point of Care (POC)	Laboratory High Throughput (HT)
Type of Estimate	Qualitative; ≥ 2Gy	Quantitative
Dose Range	0-10Gy	0-10Gy
Ease of operation:	Easy to operate, Ideally CLIA waived	Laboratory Instrument – Highly skilled operator
Quantity	1,000,000 first 7 days	400, 000 first 7 days
Time to Result	~ 15 minutes	< 24 hours

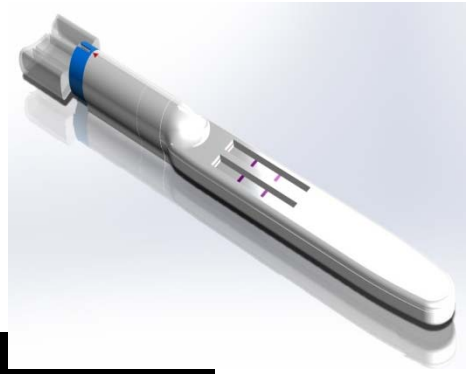
High Throughput Laboratory Biodosimetry Programs

Contractor	HT Technology	Automation	TTFR
Duke U	Gene expression	**Semi-automated including ABI 3500 Dx**	**<8hr**
Northrop Grumman	Cytology - *micronuclei*	**Semi-automated including Applied Spectral Imaging Cytology Microscopes**	**3.25 days**
Arizona State U	Gene expression	**Semi-automated including ABI 7500Dx or Life technologies Quantum studio 12K Flex**	**<8hr**

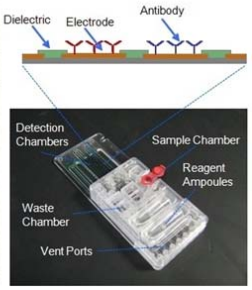
TTFR = Time to First Result

Radiation Dx
Point of Care Biodosimetry Programs





Contractor	POC Technology	Type	
SRI International	Protein Expression *immunoassay*	*Dual Lateral Flow w/ Reader & Cell Extractor*	*~15min*
MesoScale Diagnostics	Protein expression *immunoassay*	*Micro fluidic Cartridge & Instrument*	*~15min*
Dartmouth Medical School	*Election paramagnetic resonance*	*Kiosk*	*~15Min*



TTFR = Time to First Result

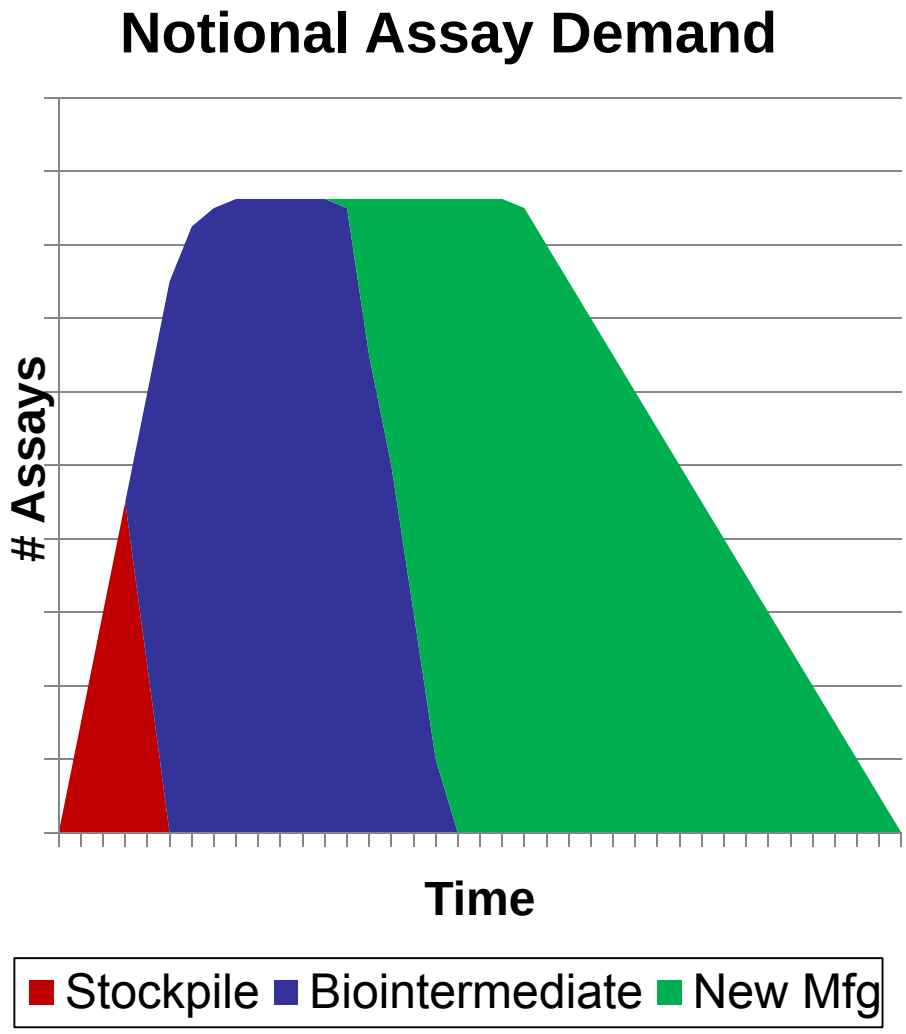
Draft Biodosimetry Stockpiling Concept

Clinical Laboratory	Component	Draft Stockpile Approach
	Biodosimetry Specific Reagents	Stockpile – Multiphase
	Ancillary Reagents	Vendor Managed Inventory
	Instruments	Utilize Healthcare Assets
	Consumables	Vendor Managed Inventory
	Facilities	Utilize Healthcare Assets

Point of Care	Component	Draft Stockpile Approach
	Biodosimetry Specific Reagents	Stockpile – Multiphase
	Ancillary Reagents	Vendor Managed Inventory
	Instruments	Encourage Health Care Placements / Stockpile/ Pre-place
	Consumables	Vendor Managed Inventory
	Facilities	Healthcare Assets, Temporary Facilities

Multiphase Assay Stockpiling Concept

- Currently no PHEMCE agreement on stockpile needs for biodosimetry assays
- Needs determination expected in FY14



Interfacing with BARDA

- www.hhs.gov/aspr/barda
  - Program description, information, news, announcements
- www.medicalcountermeasures.gov
  - Portal to BARDA
  - Register, request a meeting
  - Tech Watch
- www.fedbizopps.gov
  - Official announcements and detailed information about all government solicitations
- Rodney.Wallace@hhs.gov

Backup Slides

Current Post Radiation Event Diagnostics Capabilities

- Capacity sufficient to respond to an industrial accident

Prompt Radiation Injury (shine)			
Technology	Capacity	Locations	Time to Results
Chromosomal Aberration	10's to 100's Per Day	•Oak Ridge •AFRRI •Health Canada •Europe Biodosnet	3+Days
Lymphocyte Depletion Kinetics	1000's per day	•Hospitals Labs •Referral Labs	1 +Days

Ingested or Inhaled Radio Nucleotide (fallout)			
Technology	Capacity	Location	Time to Results
Radioisotope in Urine	Screen •Gama emitters – 3000 /day •Alpha or Beta emitters - 300 /day	•CDC	1 + Days

Target Product Profiles

	Point of Care Device (POC)	High Throughput Device (HT)
Type of result:	Qualitative	Quantitative (accuracy ± 0.5Gy)
CONOPs:	Initial Triage / Sorting	Injury Assessment / Treatment
Exposure level:	2 Gy (200 rad) (threshold)	Range: 0.5 – 10 Gy
Ease of operation:	Easy to operate, minimal complexity, requires minimal training, CLIA waived	Laboratory instrument—more labor intensive, requires training
Device characteristics:	Integrated components—no separate sample preparation	May include separate components as needed. High automation desired.
Intended use:	Tents, shelters, open settings	Labs, hospitals, fixed facilities
# Patients / Event	Up to 1,000,000 in 6 days	Up to 400,000 (may need multiple assessments)
Time to result:	Rapid but individual sample result (15 to 30 minutes)	Up to 24 hours