



# The CLIA Research Agenda September 5, 2007

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# Establishing the CLIA Research Agenda

- Should the focus be on current or potential future issues?
- Who should be included in setting the research agenda?
- Should research be aimed at improving the evidence-base for laboratory medicine, such as comprehensive evaluations of new laboratory tests and practices?



Spring 2006

# Enhancing Connectivity Between Public Health and Clinical Laboratories

- CLIAC recommended formation of a workgroup to explore the impact of rapid and molecular tests for infectious disease agents on public health
  - ❖ Research based on this workgroup's report?



Fall 2006

# Future of Health Laboratory Practice

Challenges to laboratories performing “complex” testing in “traditional” locations

- Many possible topics for research including:
  - ❖ Studying the impact of new laboratory technology
  - ❖ Exploring ways to enhance the interface between the laboratory and clinician: information technology and electronic medical records
  - ❖ Exploring ways to address the workforce shortage
  - ❖ Impact of patient directed testing



# Spring 2007

## Future of Health Laboratory Practice

- Research on the challenges faced by laboratories performing “simple” testing in diverse locations
  - ❖ Best practices for point-of-care testing
  - ❖ Impact of the MMWR publication of Good Laboratory Practices for Waived Testing Sites
  - ❖ Impact of Rapid and Molecular Tests for Infectious Disease Agents



## Some important questions to ask

- Are the current laboratory practices adequate to meet the intended uses and provide the desired outcomes?
- Are the metrics and methods currently used adequate to determine whether laboratory practices meet the public health and clinical care needs?
- Which “good laboratory practices” seem to assure high quality services across all test locations?
- Are there policy gaps that should be addressed to assure that laboratory services are appropriate and effective?



# CLIA Research Agenda

## - What does the baseline look like?



Where is the field now and where is it headed?

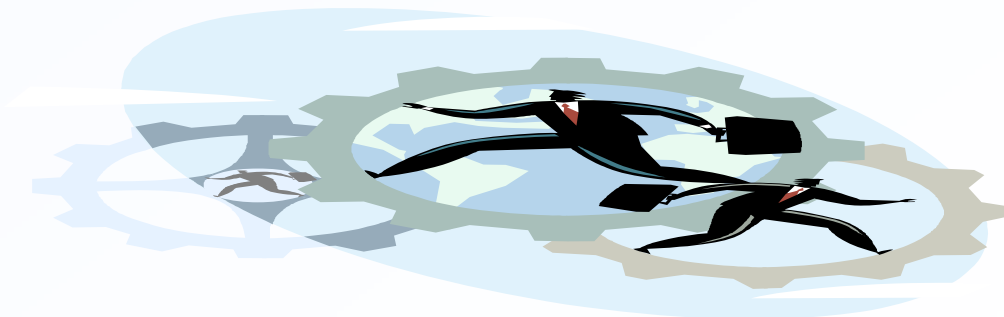
- Dr. Clifford Goodman – Lewin Group

Are current CLIA PT Programs meeting expectations?

- Dr. Robert Rej - PT Workgroup

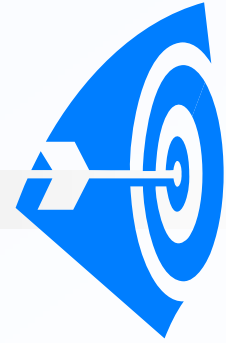
Can we rely on laboratory Quality Assurance activities?

- Dr. Dana Gryzbicki – Laboratory Medicine QA





# CLIA Research Agenda - Preparing for the future



Developing and implementing best laboratory practices

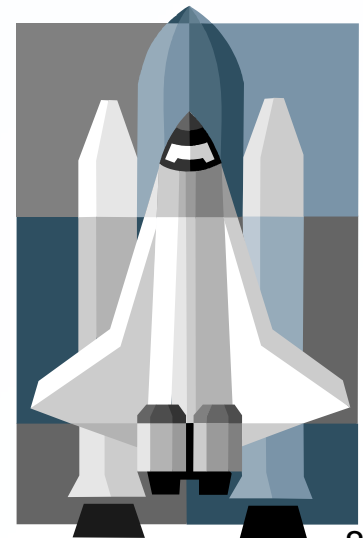
- Dr. Susan Snyder – CDC

2007 Institute: Managing for Better Health

- Dr. Linda McKibben - CDC Consultant

Developing a research agenda for the future

- Dr. Devery Howerton – CDC







# Questions for CLIAC Consideration

When setting a CLIA research agenda:

- Which stakeholders should be involved?
- What would it take to engage the non-laboratory stakeholders?
- Should the focus be on laboratory regulation, policy, standards and guidelines, or enhancing laboratory medicine practice or both?
- How should a national research agenda be established?
- What else should be considered?



**Thank you!**  
**Questions or Comments?**