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FOR MEDICAL SCIENCES

# Research Support Information Network (RESIN)

**Presented by: Office of the Vice Chancellor for Research**

**Date: January 6, 2015**

# Agenda

- **Updates & Timely Information from Research Support:**

Office of the VCR
- TRSC
- IRB
- IACUC
- HIPAA
- UAMS Library
- BioVentures
- Cost Accounting

COI
- ORSP
- ORC

DLAM
- OGSP
- Core Facilities
- Medical Informatics

# Conflict of Interest

**Robert W. Bishop, JD**
**Vice Chancellor for Institutional Compliance**

- **Lucie Ingram**
  - Director of Conflict of Interest
    - 501-686-6556
    - LIngram@uams.edu

# CT.gov Proposed Final Rule Making

Tracy Gatlin, UAMS CT.gov Administrator

- ClinicalTrials.gov Notice of Proposed Rule Making (NPRM) came out in late November 2014
  - This is proposed and is subject to change.
  - Purpose is to enhance transparency of clinical trial results.
  - Once final, this will become enforceable regulation.

# CT.gov Proposed Final Rule Making

Tracy Gatlin, UAMS CT.gov Administrator

- ***Notable changes include:***
  - A streamlined approach for determining which trials are subject to the proposed regulations and who is responsible for submitting required information.
    - Clarification of definitions (clinical trial, RP, Sponsor, ACT)-Broader definitions than current FDAAA Act
  - Expansion of trials subject to results reporting to include trials of unapproved, unlicensed and uncleared products and pediatric postmarket surveillance device studies.

# CT.gov Proposed Final Rule Making

Tracy Gatlin, UAMS CT.gov Administrator

- ***Notable Changes continued:***
  - Additional data elements that must be provided at the time of registration and results submission.
    - Ex. Outcome measures at time of registration
- Clarified procedures for:
  - Delaying results submission when studying an unapproved, unlicensed or uncleared product or a new use of a previously approved, licensed or cleared product
  - Requesting extensions to the results reporting deadline for good cause.

# CT.gov Proposed Final Rule Making

Tracy Gatlin, UAMS CT.gov Administrator

- More rapid updating of several data elements to help ensure that users of ClinicalTrials.gov have access to accurate, up-to-date information.
  - Ex. Intervention names and Expanded Access information
- Procedures for timely corrections to any errors.
  - Within 15 calendar days after the date that the Responsible Party becomes aware or has been notified of the error

# CT.gov Proposed Final Rule Making

Tracy Gatlin, UAMS CT.gov Administrator

- **CT.gov-Proposed Final Rule Making**
  - The full rule can be found at http://www.regulations.gov/#!documentDetail;D=NIH-2011-0003-0003
    - Submit comments by **Feb. 19, 2015**
  - Contact **Tracy Gatlin**, UAMS ClinicalTrials.gov Administrator

    Phone: **501-686-6803**

    Email: tlgatlin@uams.edu

# New NIH Biosketch

## Suzanne Alstadt, Director, ORSP

- **Why?**
  - Primary focus of the new NIH biosketch magnitude and significance of the scientific advances associated with a researcher's discoveries and the specific role the researcher played in those findings
  - NIH believes new format will help reviewers evaluate PI not by where published or how many times, but instead by what PI has accomplished
  - NIH hopes change will redirect focus of reviewers and scientific community from widely questioned metrics such as number of published papers, number of citations received by those papers, or other statistical approaches used to normalize citations

# New NIH Biosketch

Suzanne Alstadt, Director, ORSP

## What About Young Investigators?

"We strongly believe that allowing a researcher to generate an account of his or her own work will provide a clearer picture of each individual's contributions and capabilities. But one might question whether this new biosketch will have a negative impact on younger investigators whose body of work may not be as robust as more established investigators. I believe the contrary is true; this new format will give early career investigators a platform for describing and framing the significance of their contributions, which should help reviewers better understand their accomplishments without having to rely simply on a list of publications."

**-Sally Rockey, NIH Deputy Director for Extramural Research**

# New NIH Biosketch

Suzanne Alstadt, Director, ORSP

- **What?**
  - Individual fellowship, R36 dissertation, and diversity supplement applications use the Fellowship Application Biographical Sketch Format Page
  - Research grant, career development, training and all other application types use the general Biographical Sketch Format Page

# New NIH Biosketch

## Suzanne Alstadt, Director, ORSP

- **What?**
  - 5 page limit (includes the table on top of first page)
  - **A. Personal Statement** Briefly describe why you are well-suited for your role in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

# New NIH Biosketch

## Suzanne Alstadt, Director, ORSP

- **What?**
  - **C. Contribution to Science** Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.
  - NIH recommends use of SciENcv to build the new biosketch. SciENcv was designed to create biosketches for multiple federal agencies.

# New NIH Biosketch

Suzanne Alstadt, Director, ORSP

- **When?**
  - Due dates on/after May 25, 2015 – required for all NIH and AHRQ applications
    - Even if submitting early for these due dates
  - Due dates on/after January 25, 2015 – encouraged for all NIH and AHRQ applications
  - Due dates before January 25, 2015 – go for it

# New NIH Biosketch

Suzanne Alstadt, Director, ORSP

- **Helpful Links**

NOT-OD-15-032 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html

NIH SF424 R&R Application Guide http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf

Biosketch FAQs http://grants.nih.gov/grants/policy/faq_biosketches.htm#

**Includes links to sample biosketches

SciENcv: Science Experts Network Curriculum Vitae http://www.ncbi.nlm.nih.gov/sciencv/

# New NIH Biosketch

## Suzanne Alstadt, Director, ORSP

- **Questions?**

# Office of Grants & Scientific Publications (OGSP)

DeAnn E. Hubberd, Associate Director

- **Who We Are**
  - Scientific editorial resource for researchers
  - Editors with >40 years of combined experience
    - Grounded in the biological sciences and technical writing fields
    - Experienced in research project and consortium development
    - Skilled in grantsmanship and document organization and design

# Office of Grants & Scientific Publications (OGSP)

DeAnn E. Hubberd, Associate Director

- **What We Do**
  - Work collaboratively with investigators to produce effective and persuasive scientific documents
    - Grant applications
    - Manuscripts
  - Provide a substantive edit before the peer review—when you have the opportunity to make revisions

# Office of Grants & Scientific Publications (OGSP)

DeAnn E. Hubberd, Associate Director

- **What We Do**
  - Help you
    - Build a strong argument for funding
    - Use common language that avoids jargon and communicates well with reviewers who are not in your field
    - Address all the review criteria

# Office of Grants & Scientific Publications (OGSP)

DeAnn E. Hubberd, Associate Director

- **We Also**
  - Provide a grant writing seminar series
    - Next series scheduled for **February 2016**
  - Sponsor campus-wide panel discussions
    - The next discussion, “Fund My Grant: Learn How to Make It Happen from a Panel of Expert Reviewers,” will be an expert panel of study section members from UAMS
    - Monday, **April 6, 2015** from **1 – 2 p.m.**

# Office of Grants & Scientific Publications (OGSP)

DeAnn E. Hubberd, Associate Director

- **Ask Questions and Obtain Services**
  - Contact **DeAnn Hubberd**
    - dehubberd@uams.edu
    - 501-686-6004

# Metabolomics Core(s)

## Gunnar Boysen, Ph.D., Director, Dept. of Environmental & Occupational Health, COPH

- **Fancy Analytical Cores**

### UAMS Metabolomics Core

**(developing)**
Cancer Institute 11 floor, Room 144
4301 West Markham Street
Mail Slot 622
Little Rock, AR 72205

**Gunnar Boysen, Ph.D.,** Director
Department of Environmental & Occupational Health
UAMS College of Public Health
gboysen@uams.edu
501-526-4956

### Biodosimetry Core

Biomedical Research Building II, Room 131-2
4301 West Markham Street
Mail Slot 622
Little Rock, AR 72205

**Howard Hendrickson, Ph.D**., Director
Department of Pharmaceutical Sciences
UAMS College of Pharmacy
hendricksonhowardp@uams.edu
501-603-1547

- With ultrahigh-performance liquid chromatography-tandem mass spectrometry (UHPLC-MS/MS), both cores offer high-throughput analytical services for quantitation of endogenous/exogenous compounds & metabolites.

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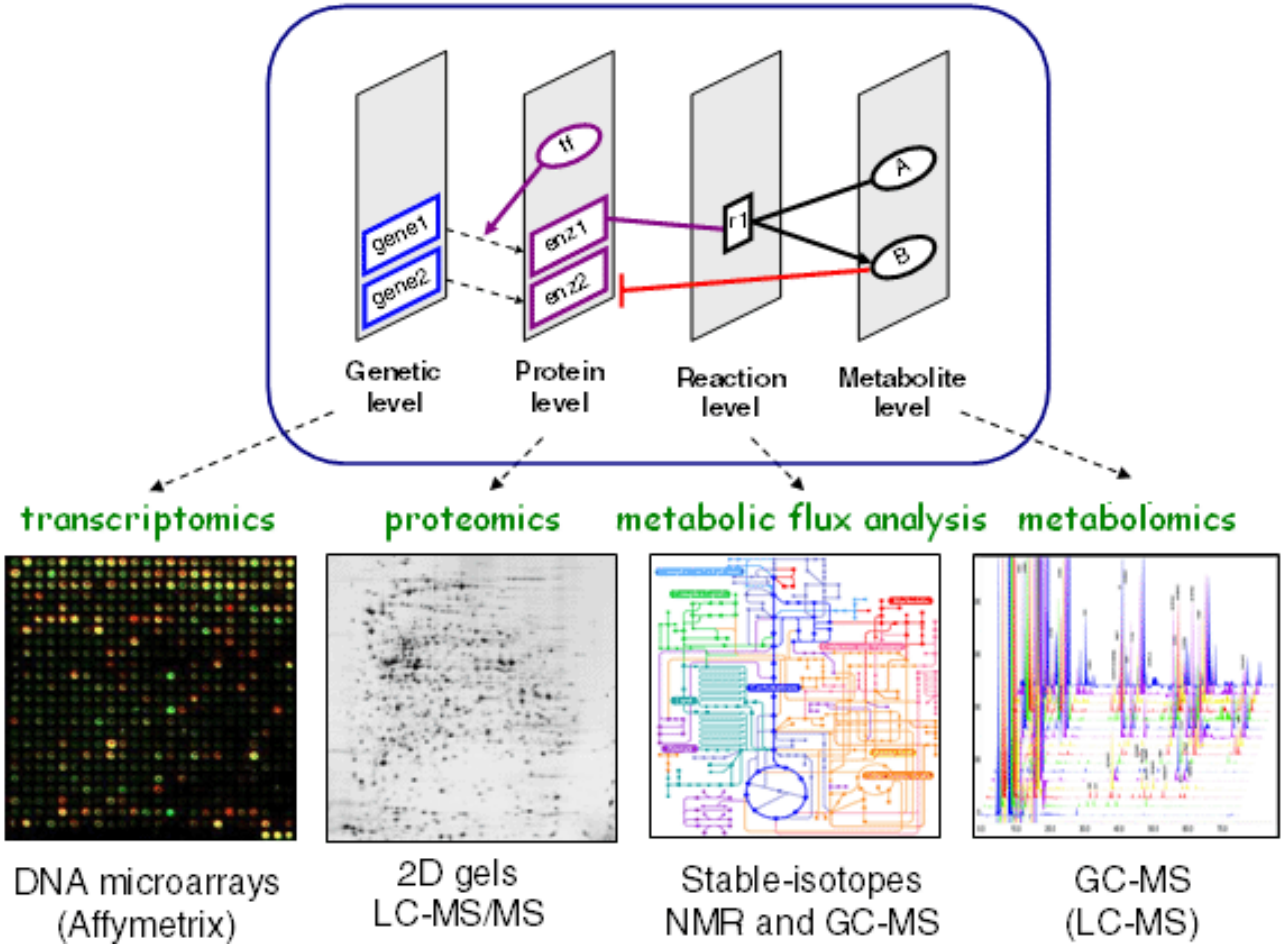
# Metabolomics Core(s)

Gunnar Boysen, Ph.D., Director, Dept. of Environmental & Occupational Health, COPH

- **Why Metabolomics???**



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# Metabolomics Core(s)

Gunnar Boysen, Ph.D., Director, Dept. of Environmental & Occupational Health, COPH

## Instrumentation

| **Chromatography** | + | **Ionization** | + | **MS-Analyzer** | = | **LC-ESI-MS/MS** |
|---|---|---|---|---|---|---|
| LC | | ESI | | Quadrupole | | |
| GC | | APCI | | Time of Flight | | |
| UPLC | | others | | others | | |
| others | | | | | | |



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# Metabolomics Core(s)

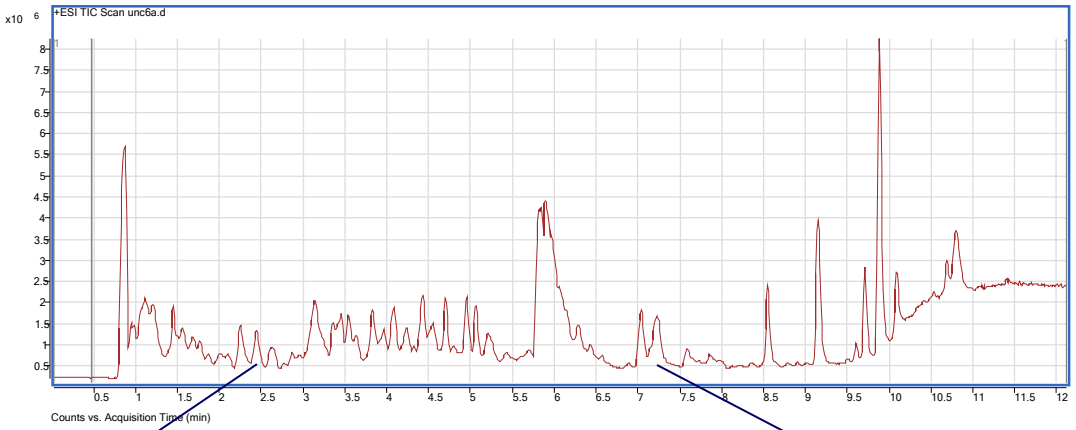
**Gunnar Boysen, Ph.D., Director, Dept. of Environmental & Occupational Health, COPH**

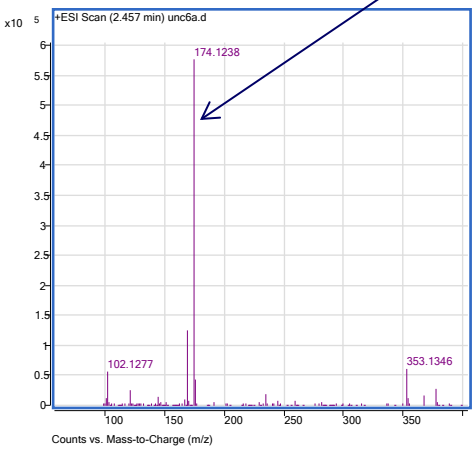
- **Un-Targeted Analyses**
  - Measures as many ions or m/z features as possible
  - Hypothesis generated after data analysis

# Metabolomics Core(s)

Gunnar Boysen, Ph.D., Director, Dept. of Environmental & Occupational Health, COPH

- **Compounds Resolved by Time**

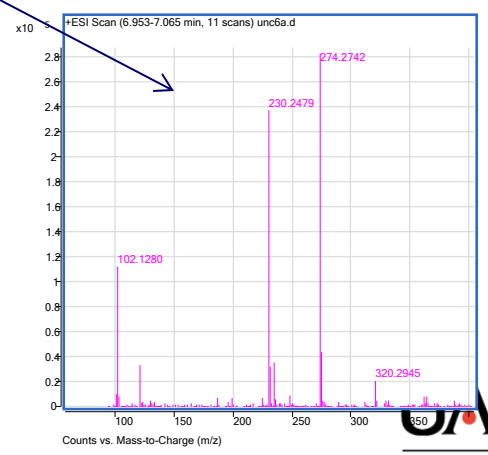



Compounds resolved by m/z

=

Molecular feature m/z (RT)



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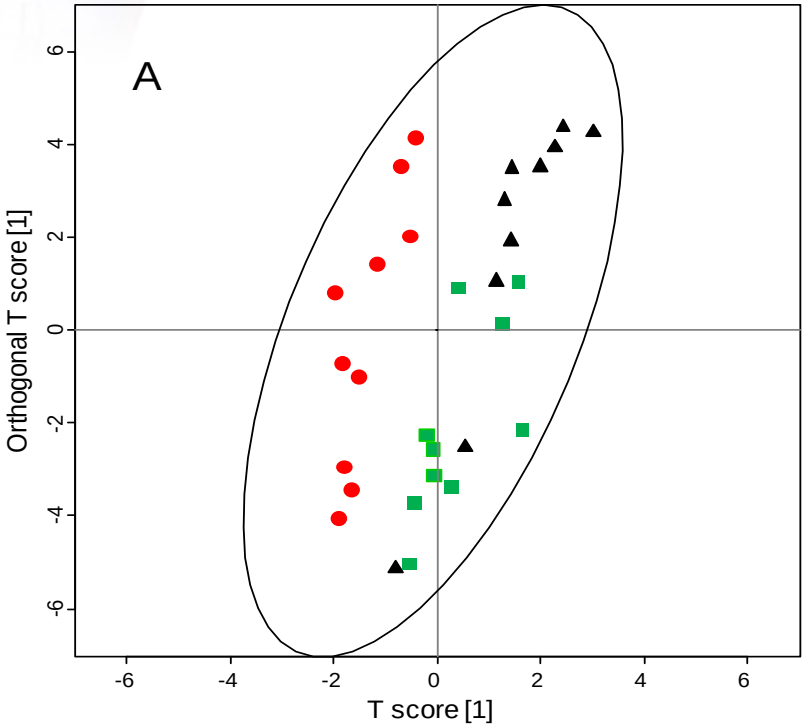
## Features Selection

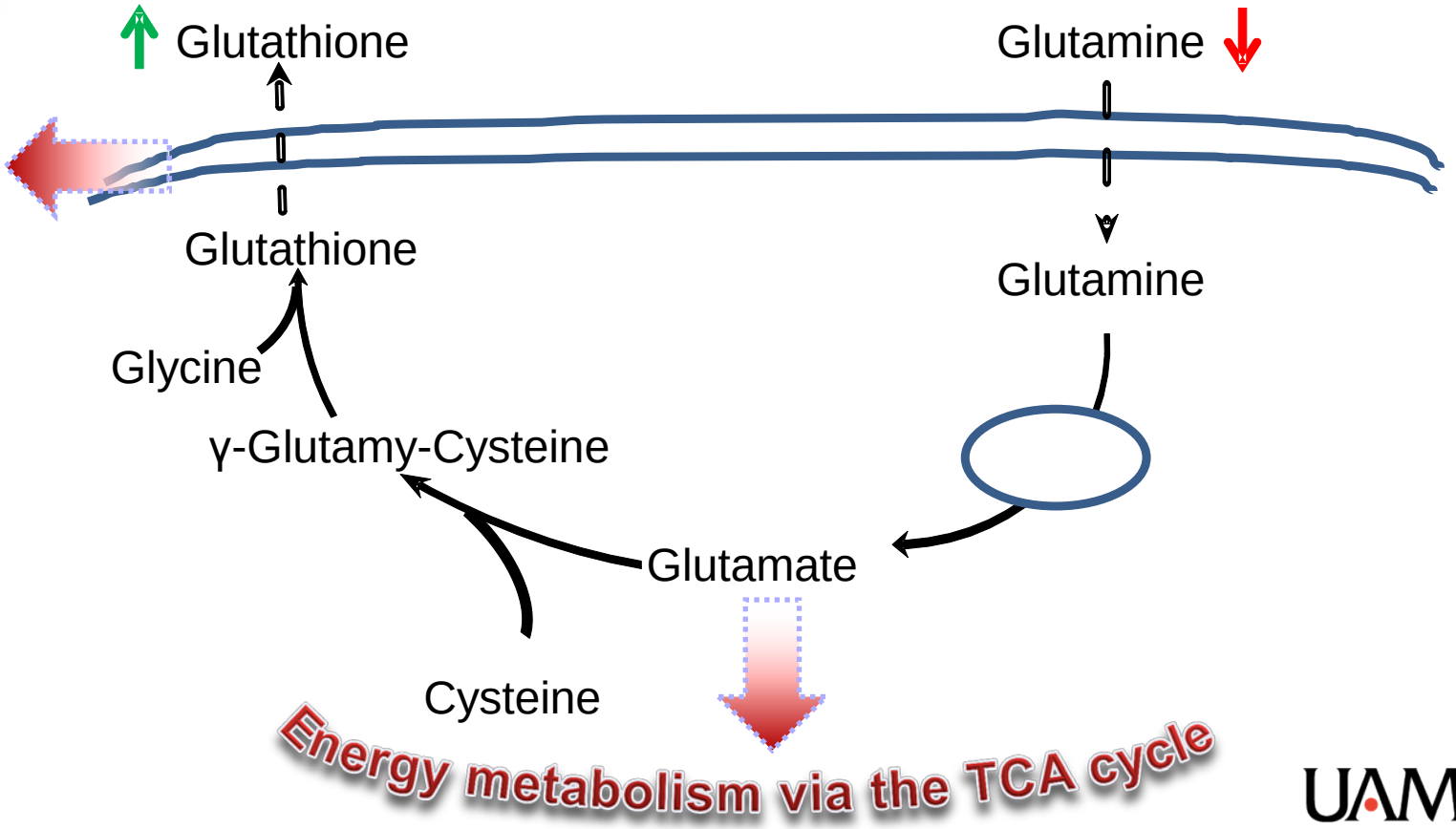



| MAL vs. NM | | SqCCa vs. AdenoCa | |
|---|---|---|---|
| Feature (Mass@Minute) | Fold Change | Feature (Mass@Minute) | Fold Change |
| 434.2@11.9 | 2.3 | 649.1@9.02 | 3.7 |
| 487.9@1.16 | 2.0 | 132.0@5.59 | 2.6 |
| 419.9@1.17 | 2.0 | 631.2@8.10 | 2.5 |
| 351.9@1.17 | 1.9 | 649.1@9.39 | 2.5 |
| 136.0@5.59 | 1.8 | 649.2@7.30 | 2.3 |
| 338.1@10.8 | 1.6 | 136.0@5.59 | 2.2 |
| 611.9@1.13 | 1.6 | 617.1@8.11 | 2.0 |
| 239.2@8.20 | 1.5 | 616.2@9.05 | 1.9 |
| 134.0@5.59 | 1.5 | 613.2@9.04 | 1.9 |
| 817.8@1.16 | 1.5 | 629.2@9.71 | 1.8 |
| 554.2@9.05 | -1.5 | 475.9@1.13 | -1.7 |
| 616.2@9.05 | -1.6 | 295.3@11.5 | -1.7 |
| 637.2@9.05 | -1.6 | 436.3@5.94 | -1.7 |
| 613.2@9.04 | -1.6 | 817.8@1.16 | -1.8 |
| 649.1@9.02 | -2.6 | 239.2@8.20 | -1.9 |

# Metabolomics Core(s)

Gunnar Boysen, Ph.D., Director, Dept. of Environmental & Occupational Health, COPH

## From Discovery to Pathway



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# Metabolomics Core(s)

**Gunnar Boysen, Ph.D., Director, Dept. of Environmental & Occupational Health, COPH**

- **Targeted MS Analyses**
  - Most targeted analysis uses MS/MS to improve specificity and reduce noise.
  - Single compounds or groups of compound are selected based on *previous hypothesis*.

# Metabolomics Core(s)

Gunnar Boysen, Ph.D., Director, Dept. of Environmental & Occupational Health, COPH

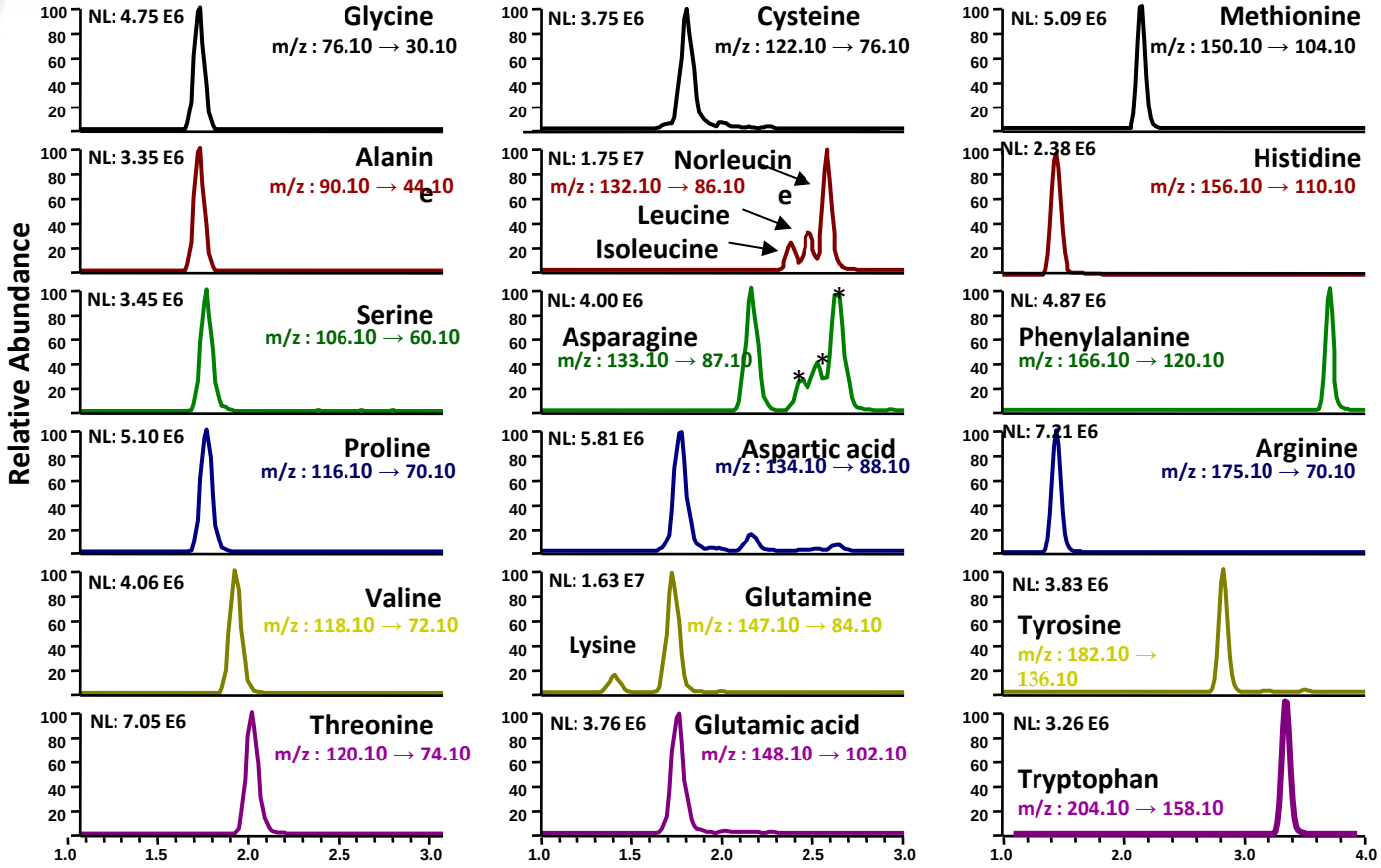
## Current Metabolites of Interest

| | | |
|---|---|---|
| Glycine | Lysine | Methyl-Glutaryl-Carnitine |
| Pyruvate | 2-OH-Glutamate | GSH(-) |
| Alanine | Glutamate | GSH(+) |
| alpha-Ketobutyrate | Methionine | AMP |
| Serine | Histidine | SAH |
| Fumarate | L-Carnitine | SAM |
| Proline | PEITC | ADP |
| 3-HIA | Phenylalanine | EGCG |
| Succinate | cis-Aconitate | ATP |
| Valine | Arginine | BPTES |
| Threonine | Citrulline | GSSG(-) |
| Homoserine | CYS-GLY | GSSG(+) |
| Cysteine | Tyrosine | GSSSG |
| Taurine | Citrate_Isocitrate | NAD+ |
| Pyroglutamate | Acetyl-Carnitine | NADH |
| Oxaloacetate | Tryptophan | Succinyl-CoA |
| Leucine | Kynurenine | NADP+ |
| Aspartate | Propionyl-Carnitine | NADPH |
| Asparagine | Cystathionine | Malonyl-CoA |
| Malate | Cystine | Acetyl-CoA |
| Ornithine | Malonyl-Carnitine | Propionyl-CoA |
| Homocysteine | GLU-CYS | Acetoacytl-CoA |
| alpha-Ketoglutarate | Glucose-6-phosphate | CoA |
| Glutamine | 3-HIA-Carnitine | |

# Metabolomics Core(s)

Gunnar Boysen, Ph.D., Director, Dept. of Environmental & Occupational Health, COPH

- **Amino Acid analysis by targeted LC-MS/MS**



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# Metabolomics Core(s)

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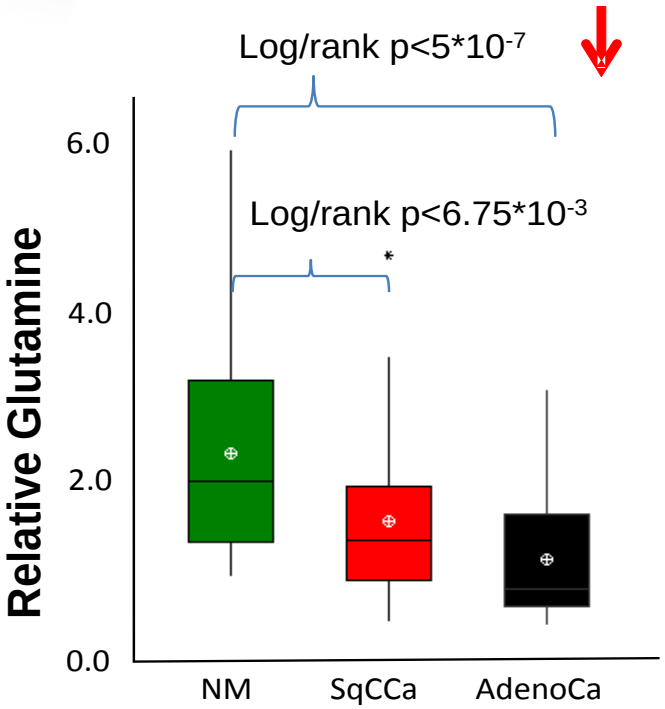
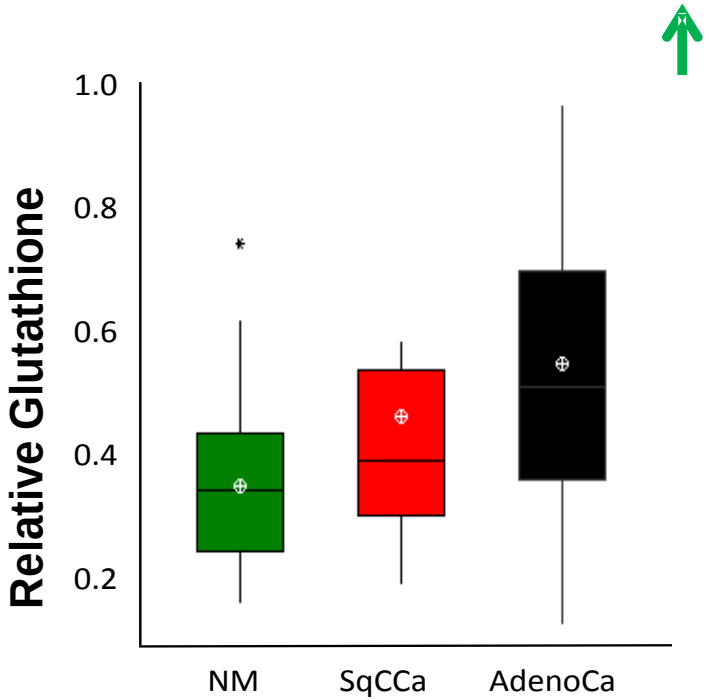
## Selected Metabolites

### Glutamine (Gln)




### Glutathione (GSH)

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# Metabolomics Core(s)

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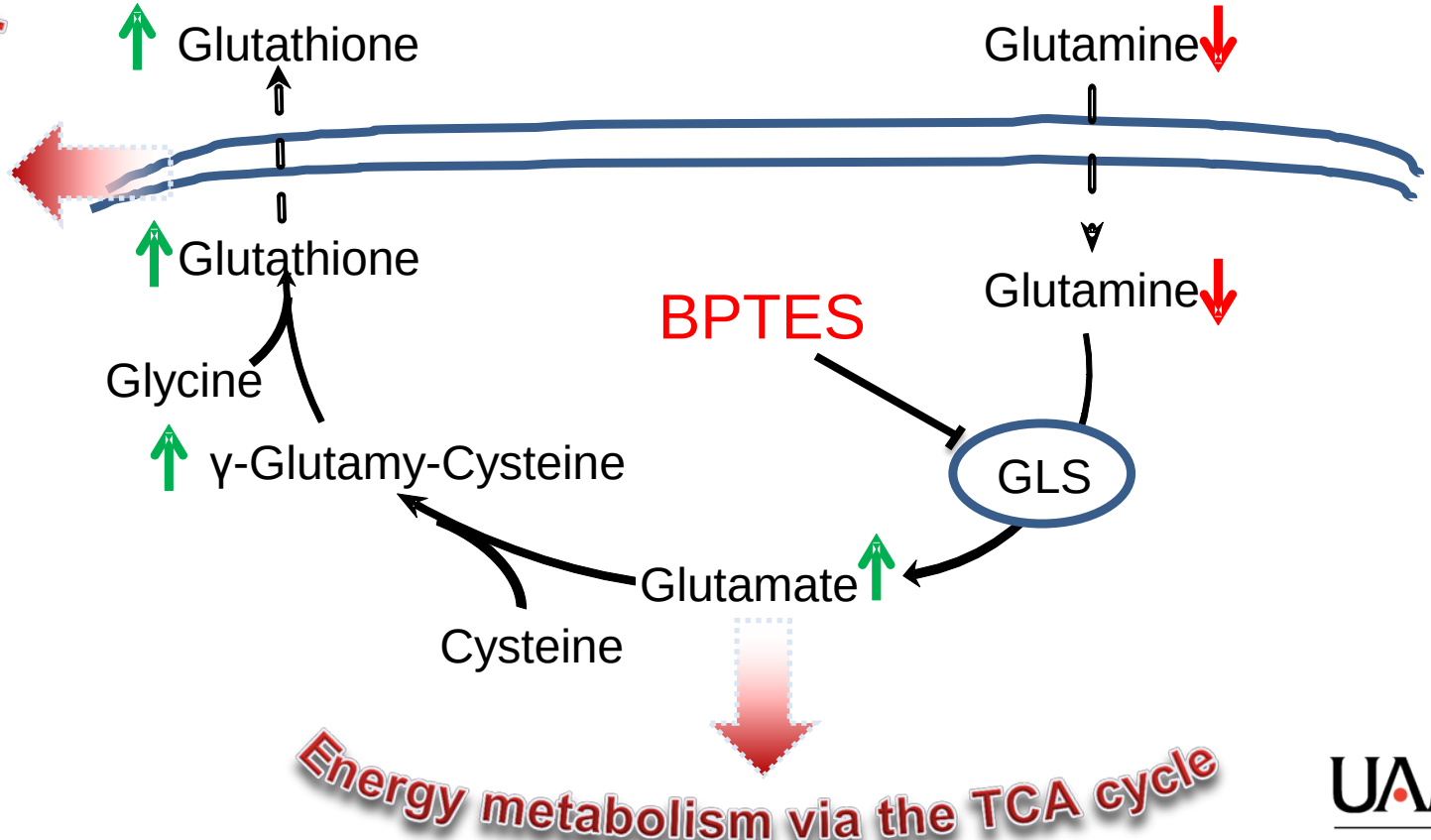
- **From Discovery to Pathway**



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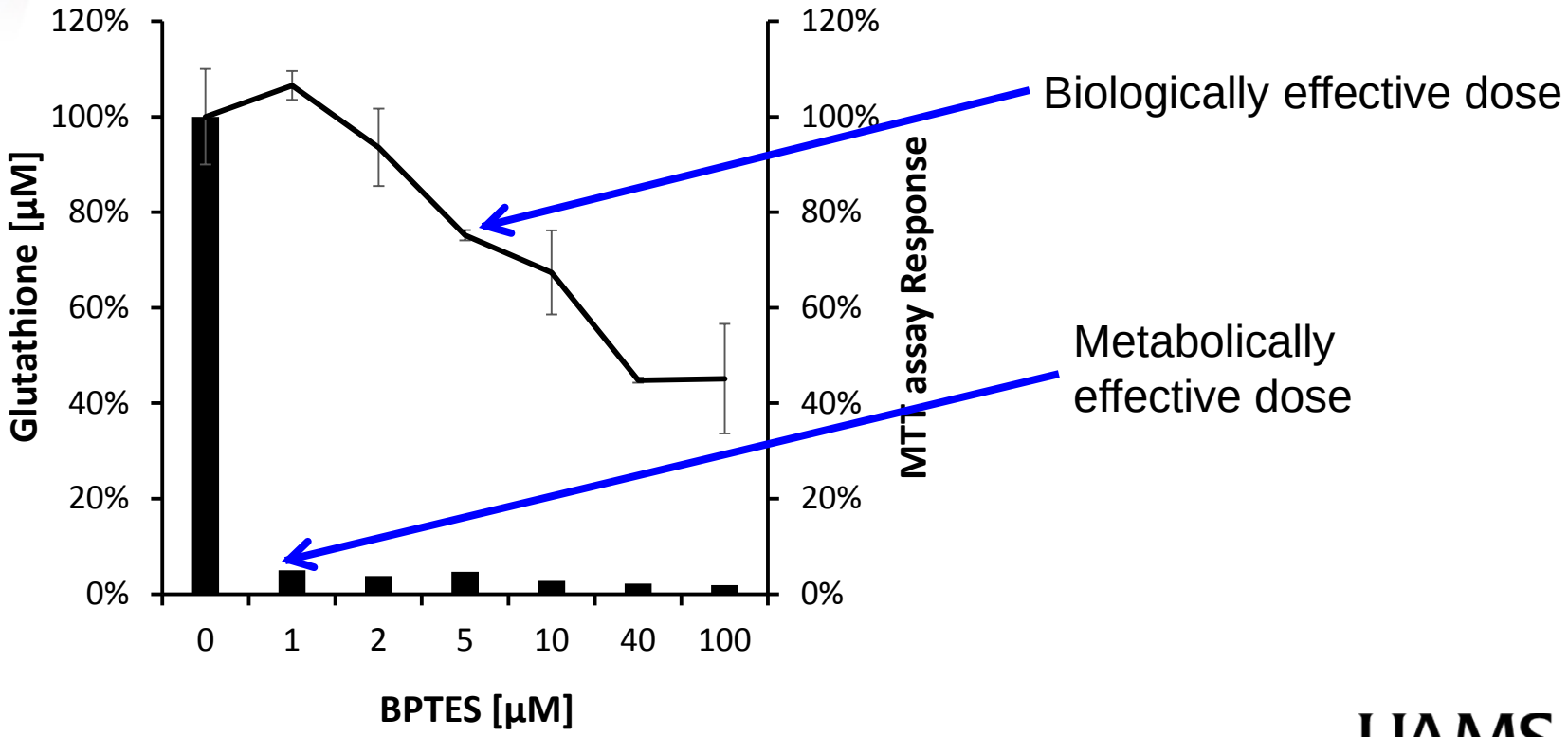
# Metabolomics Core(s)

Gunnar Boysen, Ph.D., Director, Dept. of Environmental & Occupational Health, COPH

## Validation – Effect of BPTES on GSH



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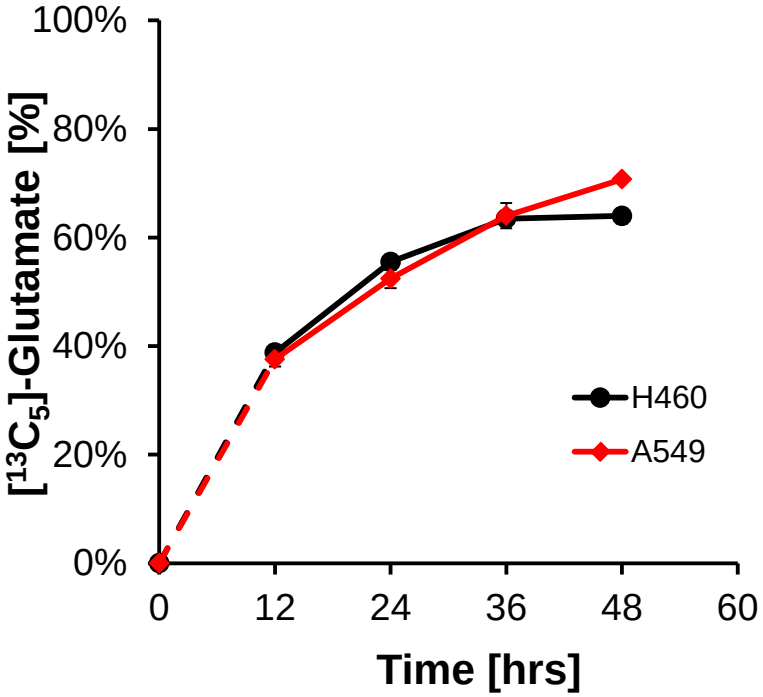
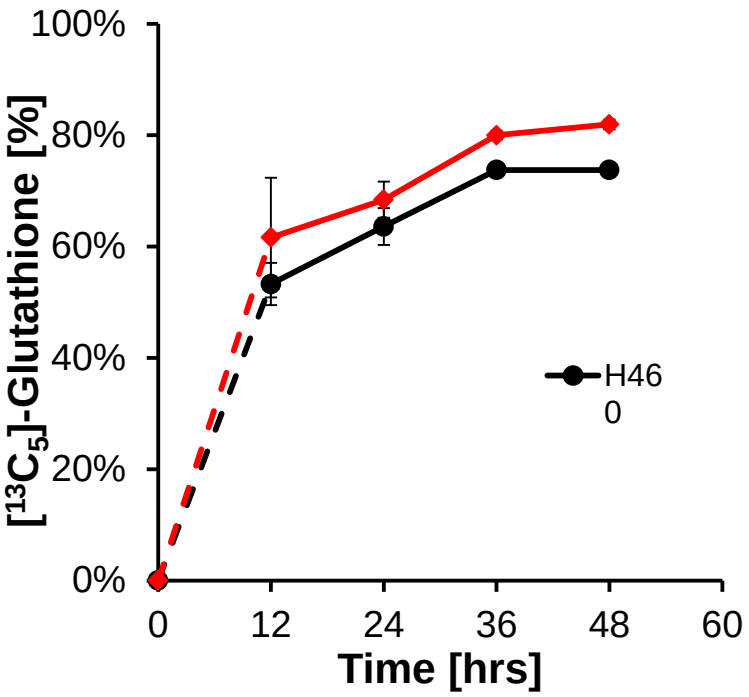
# Metabolomics Core(s)

Gunnar Boysen, Ph.D., Director, Dept. of Environmental & Occupational Health, COPH

## Validation – Stable Isotopes



# Metabolomics Core(s)

**Gunnar Boysen, Ph.D., Director, Dept. of Environmental & Occupational Health, COPH**

- **How is it Done???**
  1. Compound(s) of interest identified
  2. Literature searched for analytical methods
  3. Determine Limit of Detection – authentic standards
  4. Proof-of-Concept – biological test samples
- **On average, it takes ~2 weeks to 2 yrs. to develop a suitable method!!!**

# Next RESIN

- **Next RESIN**
  - **February 3, 2015 @ 12:00 p.m.**
  - Location - **Walton Auditorium**, Winthrop P. Rockefeller Cancer Institute, 10th floor
  - All RESIN presentations archived on the UAMS Research website
    - http://www.uams.edu/research/RESIN_Achive.asp