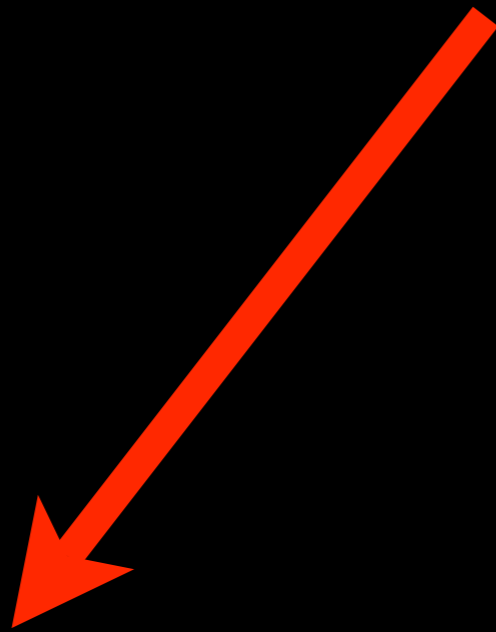


ELNs and Compliance

Simon Coles



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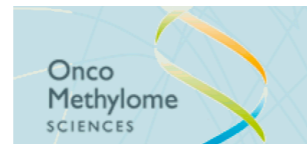
ELNs and Compliance

- Compliant with what?
- Typical approaches
- Common problems

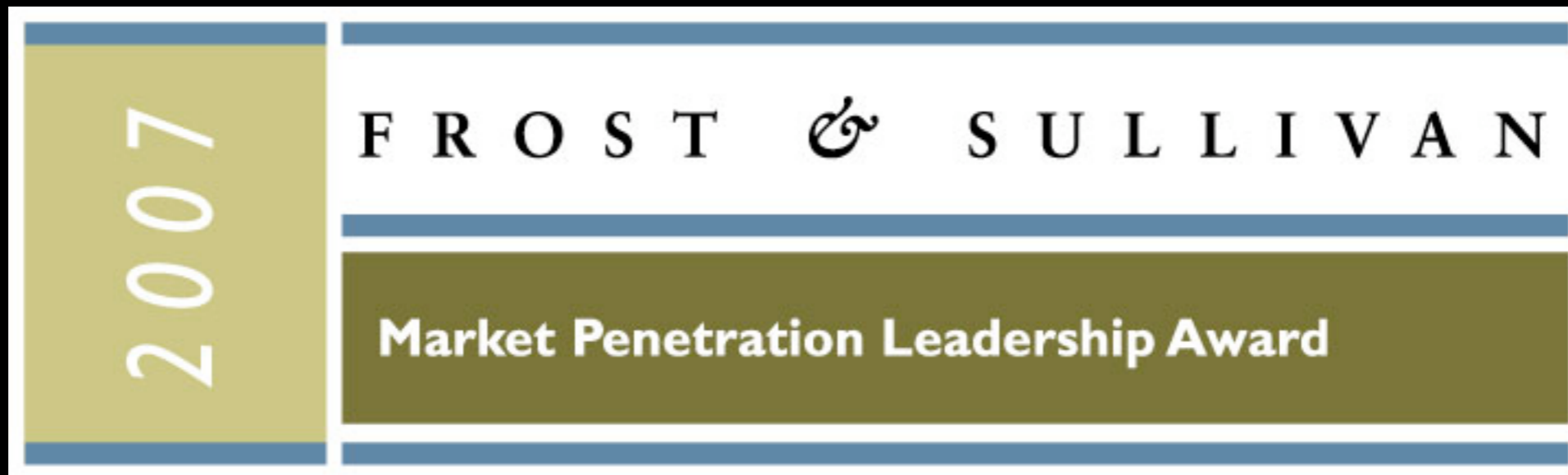
About Amphora

- Started in ELNs in 1996
 - Globally deployed, fully electronic ELN for Kodak
 - Grew from there...
- Now work with large & small companies
 - Biotechs, Pharma, Chemicals

Who we work with



Industry



What we do

- Patent Evidence Creation & Preservation
 - Make lawyers happy
 - Which means you can make scientists happy

What we do

- Sometimes our stuff is used...
 - Standalone (e.g. CRT presentation)
 - In conjunction with other “ELN” products (e.g. Solvay, Array etc.)
 - With in house systems (e.g. J&J)

“ELNs and Compliance”

Compliant with what?

- The world cares about what your company does and how you do it (Regulation)
- You want to be able to prove what you did so you can get the credit for it (Patents)
- You have some internal requirements for retention & use of scientific data

What is an ELN?

- Helpful to distinguish
 - The different functionality that is provided by ELN systems
 - The different data which is created in the Research Lab

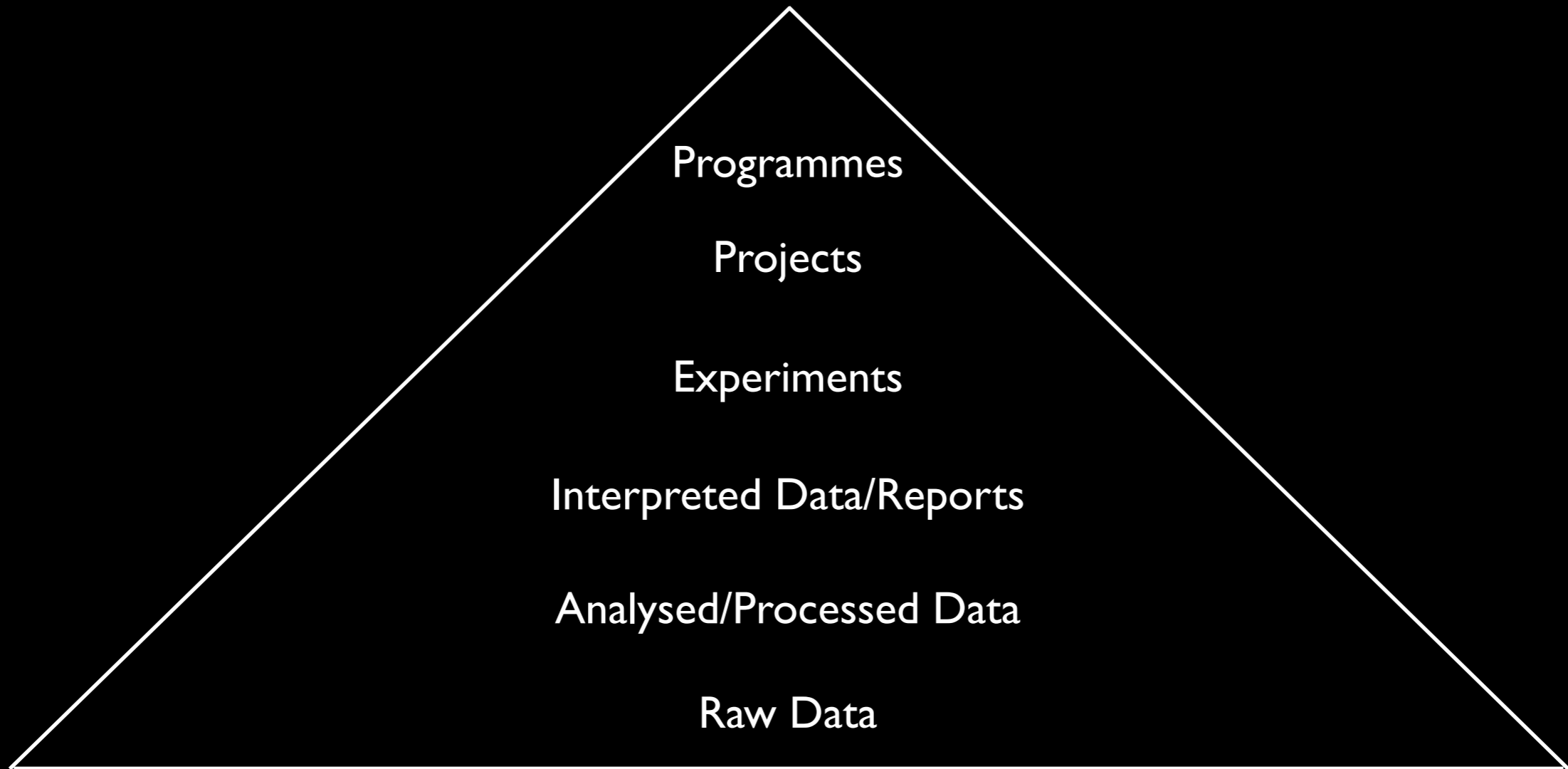
What's in an ELN?

“Broad” aspects Security, Collaboration, Patent Protection etc.			
Chemistry	Biology	etc.	etc.

What's sloshing around?

- Not all the “Stuff” on our hard disks is the same
 - Various levels of abstraction
 - Need to keep it for different periods
 - Different levels of importance

Different types of stuff



Records Requirements

	Quality criteria	Material to be preserved	Scrutiny	Timescale	Format
Internal use	Internal requirements	Scientific data Experiment write up	Little, if any	Company defined	XML De Facto standards ad hoc
Regulatory	Published regulations, with comment	Primarily Scientific data Some write up	Regulatory inspection	Defined by regulations	XML De Facto standards
Patents	Case law Federal Rules of evidence etc.	Primarily Experiment write up Some data	Adversarial	~ 10 years before first come under scrutiny Retain for 50 -100 years	PDF Paper Microfilm

Regulatory Compliance

- Regulatory authorities want you to work in a certain way and require proof that you did
- They also want to be assured you're creating the records that are needed to diagnose/trace/fix issues

Regulators

- Medical, e.g. FDA and other national counterparts
- Environmental, e.g. EPA
- Employment, Health, etc.

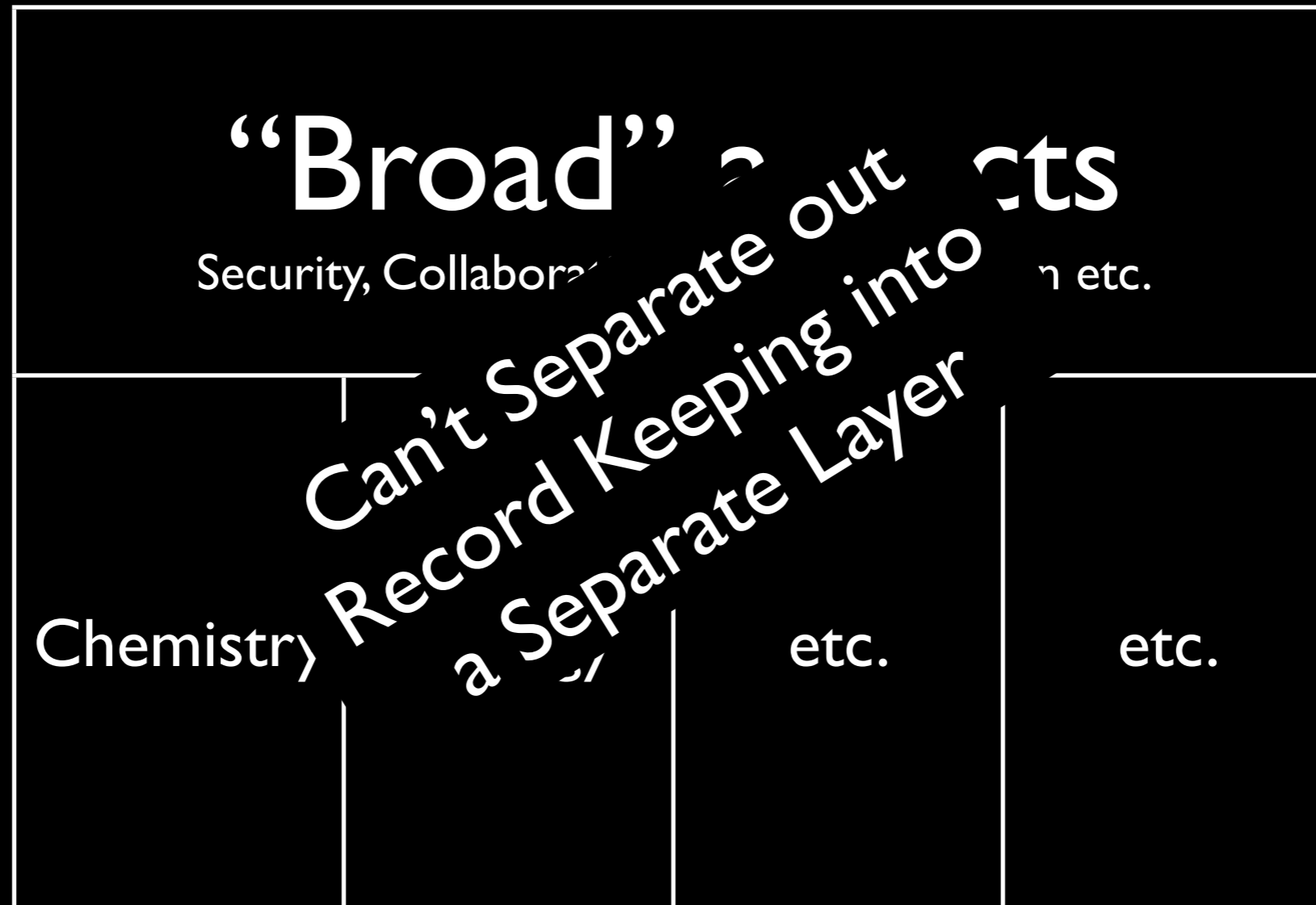
Regulators

- Generally the people who are performing a regulated activity are intimately away of their regulatory responsibilities
- There will often be an individual or group within the organisation who are responsible for your relationship with the regulator

ELNs in a Regulated area

- The regulator is generally interested in what you did and how
- It is impossible to split the record keeping layer and the activity

Regulated areas

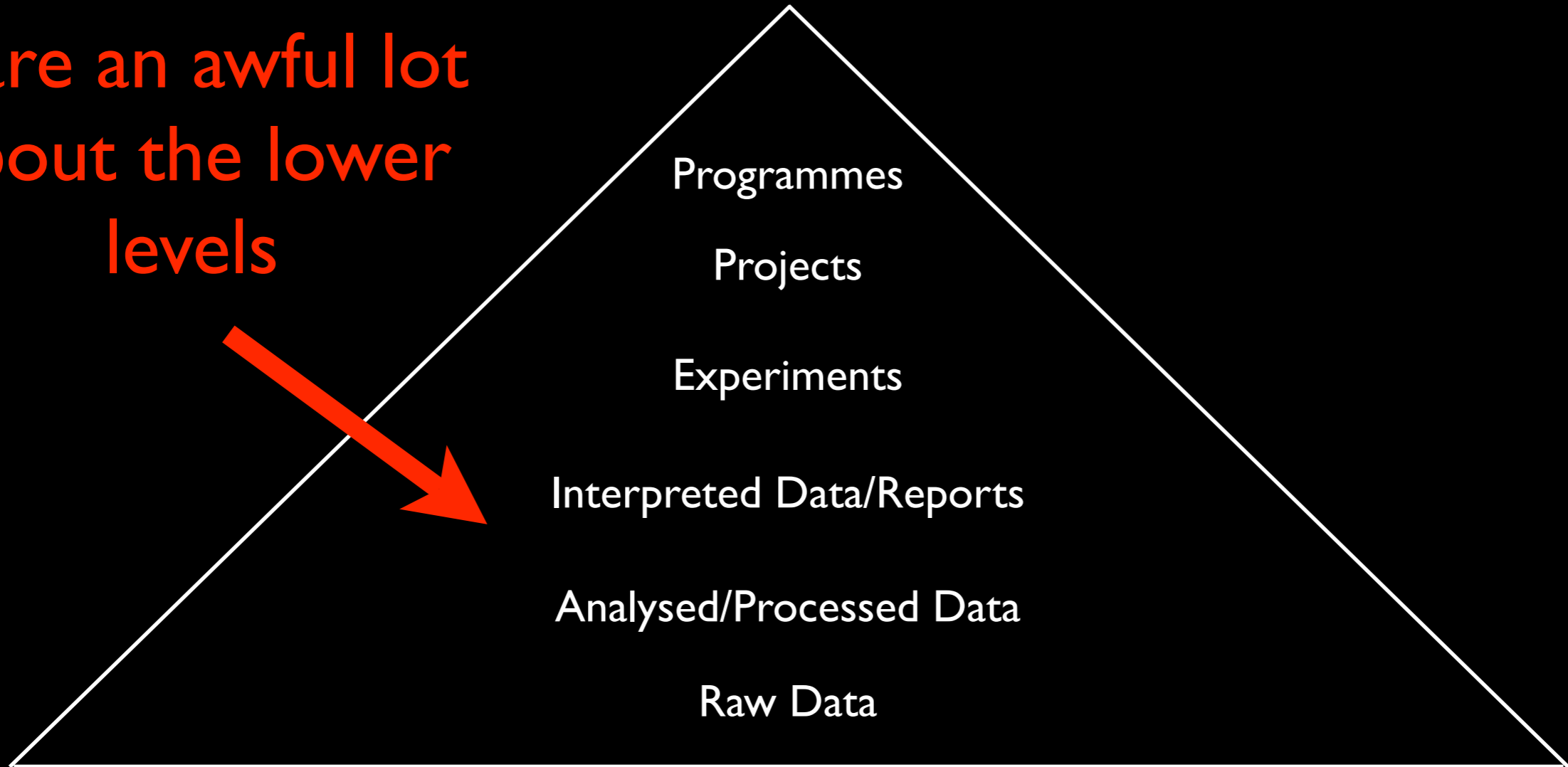


Have to do this

Chemistr	<i>Record keeping is part of the "Deep", specific functionality</i>	etc.
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Different types of stuff

Care an awful lot
about the lower
levels



ELNs in a Regulated Area

- “Generic” ELNs are rare in a regulated area
- Often, the thing that replaces your Paper Notebook may not even be called an “ELN”

Paper Notebook Replacements

- SDMS
- Compliance Management Systems
- LIMS

Keeping Lawyers Happy

- In Discovery, at some point you're going to have a clever idea
- Your lawyers will want to patent it

Patents and Records

- You get a patent primarily for what happened in someone's brain
- Hopefully you have some record of that
- Which you then take into court

Patents and Records

- Unfortunately a patent case is conducted in a court of law
- This makes it somewhat of a blood sport
- Your records have to survive adversarial scrutiny
- Ideally you haven't got anything hanging around which causes you a problem

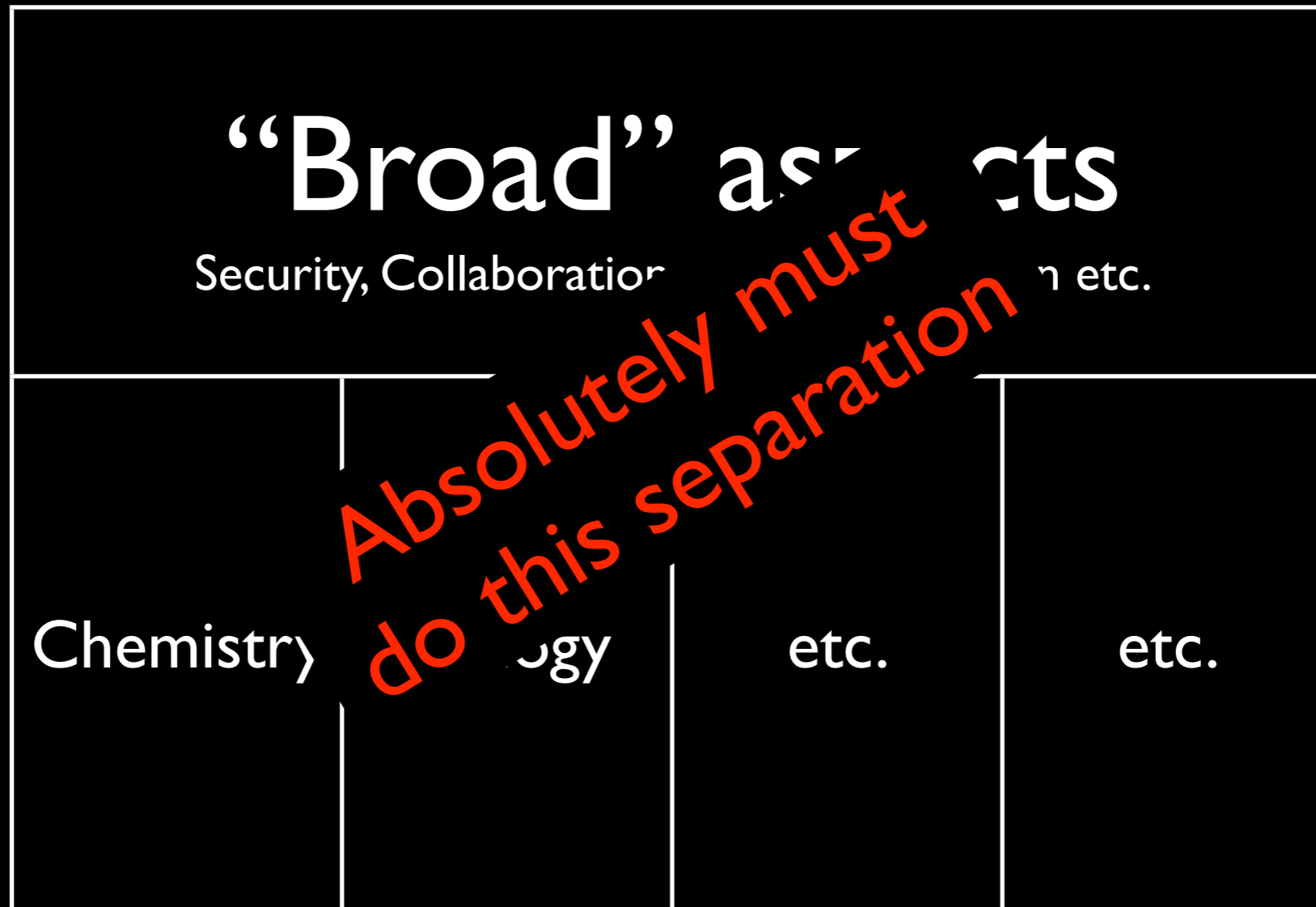
Keeping Lawyers Happy

- Some kind of Patent Evidence Creation & Preservation Process/System
- Will take records from all systems
- Author Signed, and Witnessed
- Long retention periods for the experiment writeups
- Get rid of everything else

Surviving Court

- Designing Patent Evidence Systems is an interesting game
- Lots little interdependencies
- Technology is only a small part of it
- In fact, the less technology the better!
- All about simplicity and reliability

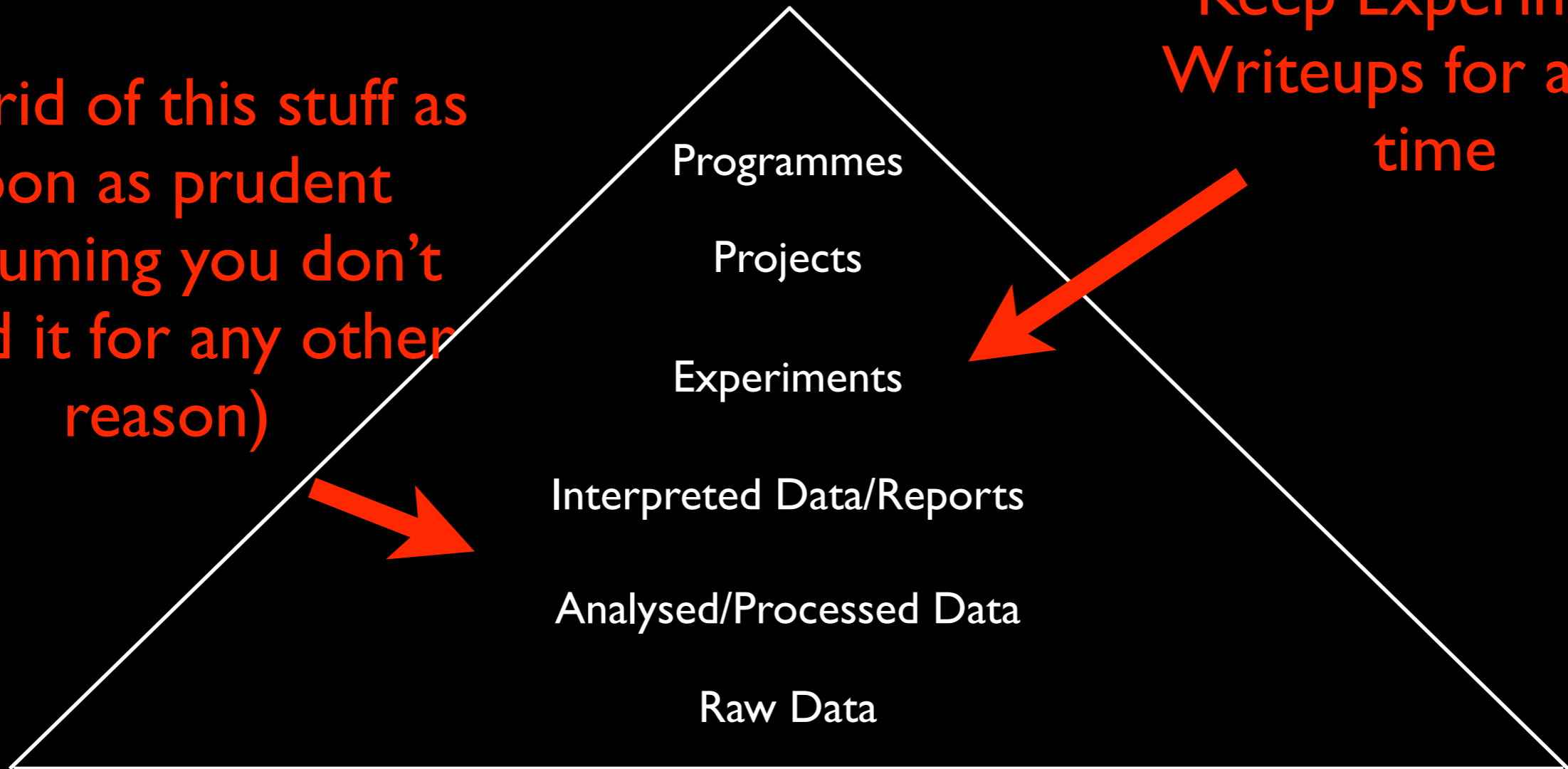
Keeping Lawyers Happy



Different types of stuff

Get rid of this stuff as soon as prudent (assuming you don't need it for any other reason)

Keep Experiment Writeups for a long time



Interesting Thoughts

- A lot of people in Discovery aren't keeping the right stuff in their notebooks
 - Sometimes too detailed, sometimes not enough
 - Sometimes the people keeping the best notebooks don't need to keep them
 - Sometimes the people who should aren't!

Interesting Thoughts

- The lawyers don't want to torture you
- Really, honestly
- You can create good patent evidence reasonably painlessly
 - Decent front-end system
 - Good backend

Interesting Thoughts

- Scientists are happy and productive
- You don't spend all that much money (good ROI!)
- Lawyers get a reliable process and good evidence

Questions?

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