

# CDER Office of Compliance Office of Scientific Investigations



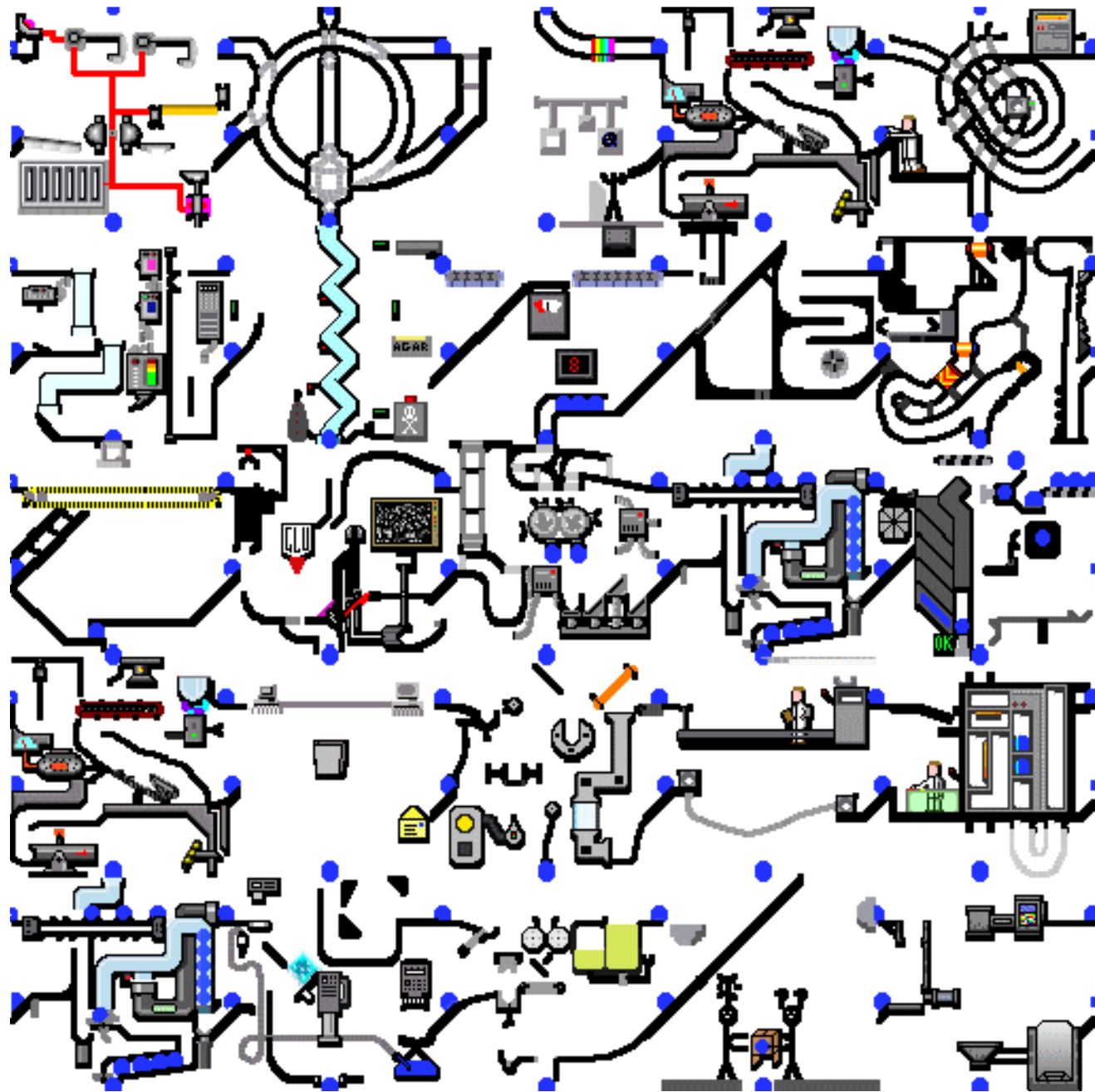
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Acting Director, Office of Scientific Investigations

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# Observations Related to Clinical Investigator Participation

- My observations of clinical investigators who stop after one study, compared to others who conduct research as a central part of their practice
  - Note: anecdotal perceptions only



# The “Top 10” List



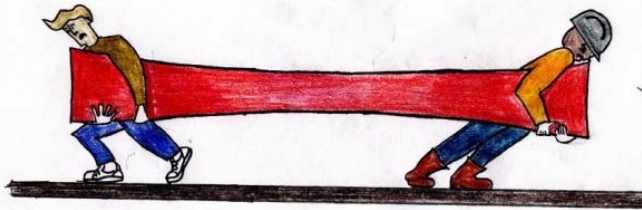
# 10 – Clinical Investigator v. Physician

- Change in mindset
- Follow a protocol v. full treatment flexibility
- Hippocratic Oath – Do no harm
- Team member v. absolute authority



## 9 – Interests v. Needs

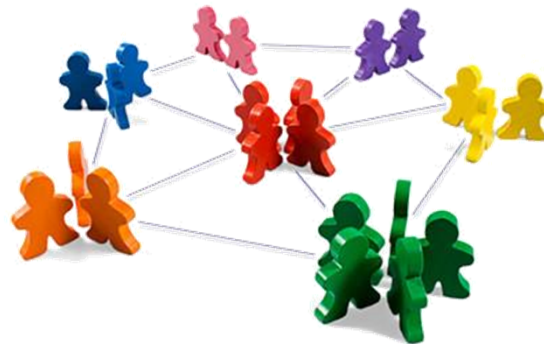
- Interests of the sponsor/applicant compared to the needs of the clinical investigator



- Macro operations across hundreds of sites compared to day-to-day visits with individual subjects
- Investigator understanding of responsibilities

## 8 – Operational Tension

- Delicate balance between operational tensions
  - Speed and “efficiencies” compared to quality and specificity



- Subjects lives involved, and they are receiving medical treatment – but that treatment must be provided in a very specific and regimented manner

## 7 – Output v. Process

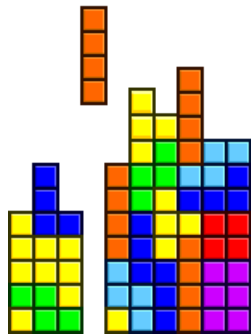
- Individual sites with individual process (and people)
- Economies of scale v. medical practice (and work-around)
- Why → How → What



## 6 – Math (the universal language)



- If you “spend money to make money”
- And you believe “time = money”
- Then you must – spend time to make time
- Change in perspective



## 5 – Rules of Tetris

- If Tetris has taught me anything, it is that errors pile up, but accomplishments disappear
- Just like running a clinical study & following a protocol
- Must understand the rules of the game

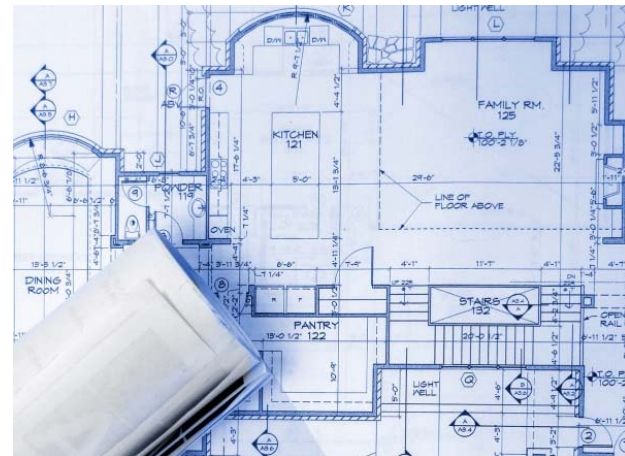
## 4 – Influence and Trust

- Fact pattern:
  - Research site owned by third party
  - Clinical Investigator employed by sites
  - Site “responsible” in CI’s eyes – CI responsible under the regulations
- Make and manage a reliable network of commitments
- Read documents before signing them!



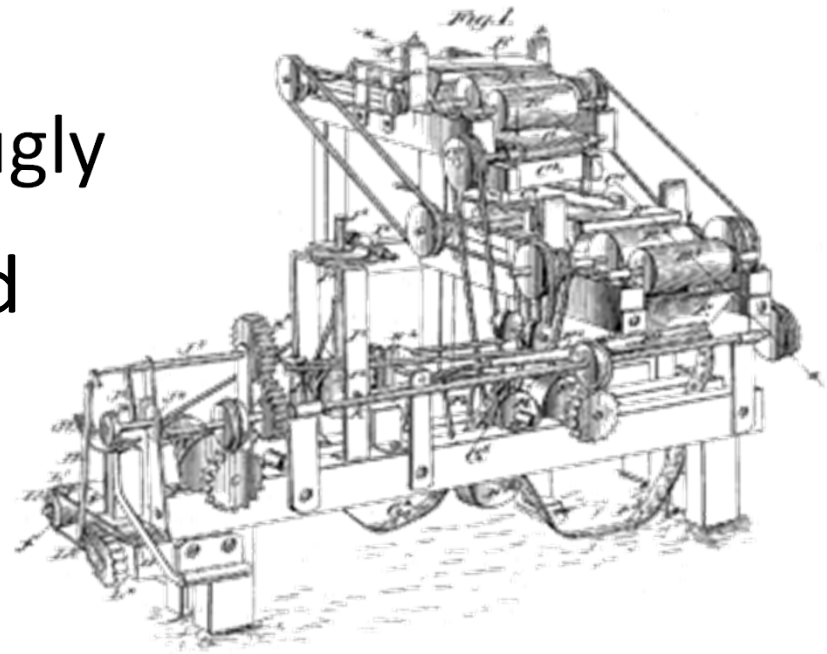
## 3 – Protocol as the blueprint

- Wide variation
  - Inclusion/exclusion
  - Endpoint assessments
  - Timeline requirements
- Should/may/request versus shall/must/required
- Driver of the user (CI) experience



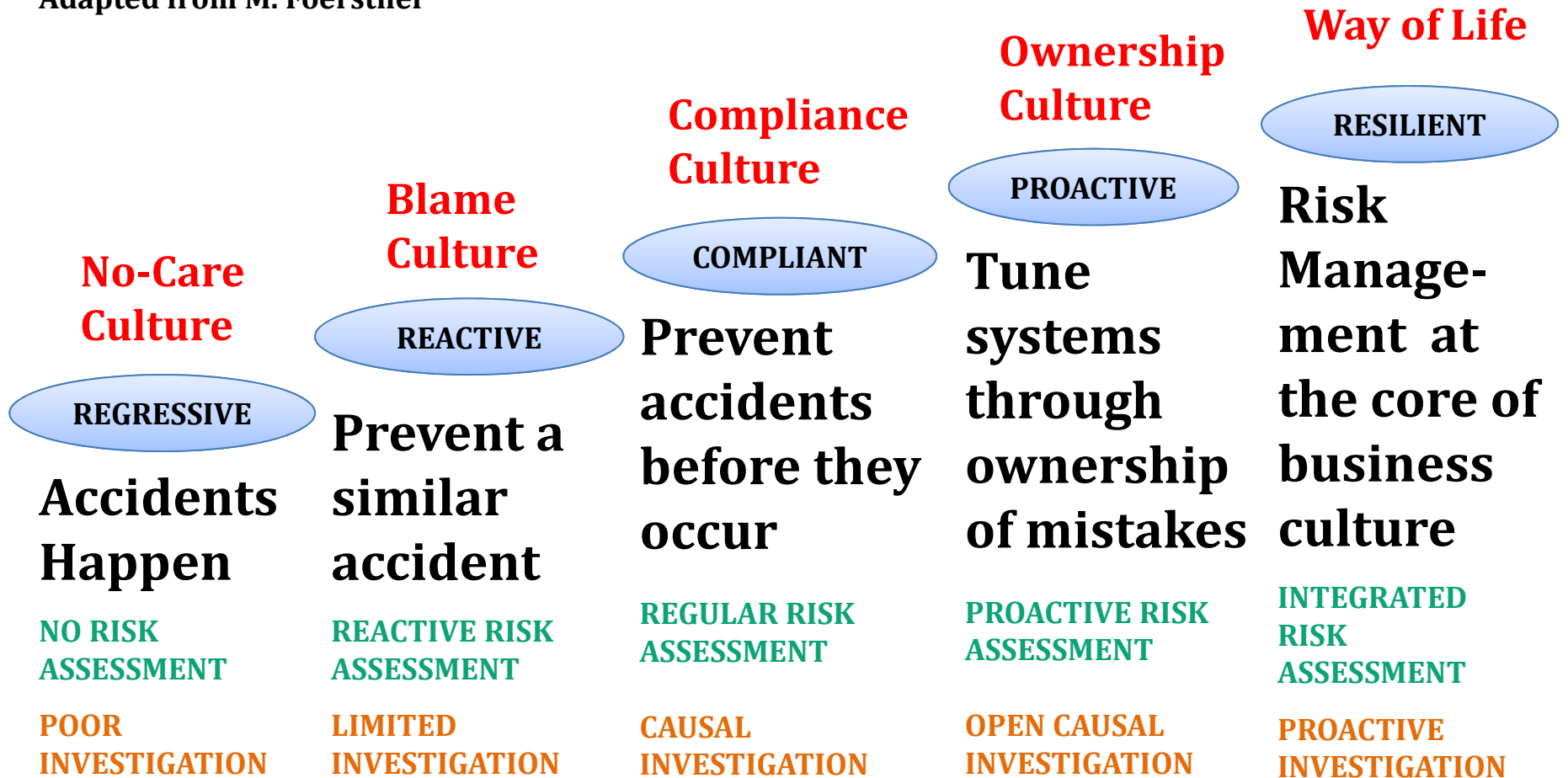
## 2 – Systems

- Clinical investigators who serve in a facility/practice that has a robust culture supporting research
- The good, bad, and the ugly
- Quality system compared to no system



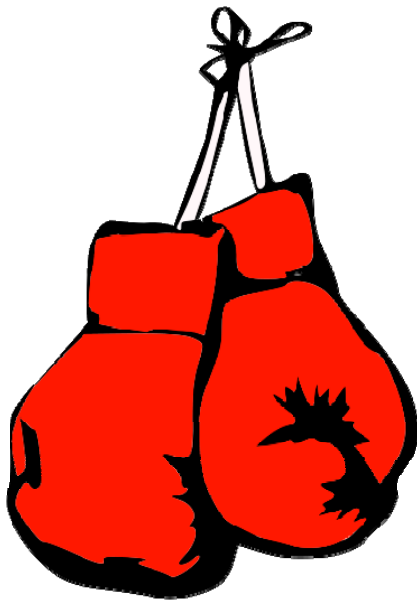


Adapted from M. Foerstner



# 1 – Awareness and Understanding

***“Everyone has a plan until they get punched in the face” – Mike Tyson***



- Perfection v. resilience
- Aware of rules/regulations
- Aware of process, and responsibilities
- System and relationships supporting success



# The “Top 10” List

1. Awareness and understanding
2. Robust systems
3. Protocol as the blueprint
4. Influence and trust of (and with) others
5. Rules of Tetris
6. Math (the universal language)
7. Output v. Process
8. Operational tension
9. Interests v. Needs
10. Role as Clinical Investigator v. Physician



# Thank You

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# Strategic Goals to Achieve OSI's Mission



## User Fee Review Requirements

Providing high-quality, timely inspection reviews to support the Office of New Drugs (OND) and the Office of Generic Drugs (OGD) in meeting user-fee goal dates for the approval of CDER-regulated products.

[www.fda.gov](http://www.fda.gov)



## Responsible Stewardship

Contributing responsibly to the continuous improvement of Bioresearch Monitoring (BIMO) compliance programs by providing substantive input into law, regulation, policy, and guidance development at the Agency level. In addition, OSI will continue to promote internal and external training to foster operational and programmatic excellence across all OSI programs.



## Global Context

Exchanging information with foreign regulatory bodies and participating in collaborative inspections to increase OSI's effectiveness and enhance OSI's decision making in compliance actions. OSI will support the continuing development of collaborations with its foreign regulatory counterparts.



## Stakeholder Engagement

Continuing to engage internal and external stakeholders and building strong partnerships to sustain excellence in OSI's mission-critical functions.



## Rights, Safety, and Welfare

Protecting the American public through the strategic administration of pre- and postmarket compliance programs, which enable OSI to protect human subjects and consumers through safety and efficacy assessment of CDER-regulated products.