CDER Office of Compliance
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
<table>
<thead>
<tr>
<th>No-Care Culture</th>
<th>Blame Culture</th>
<th>Compliance Culture</th>
<th>Ownership Culture</th>
<th>Way of Life</th>
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</thead>
<tbody>
<tr>
<td>Accidents Happen</td>
<td>Prevent a similar accident</td>
<td>Prevent accidents before they occur</td>
<td>Tune systems through ownership of mistakes</td>
<td>Risk Management at the core of business culture</td>
</tr>
<tr>
<td>REGRESSIVE</td>
<td>REACTIVE</td>
<td>COMPLIANT</td>
<td>PROACTIVE</td>
<td>RESILIENT</td>
</tr>
<tr>
<td>NO RISK ASSESSMENT</td>
<td>REACTIVE RISK ASSESSMENT</td>
<td>REGULAR RISK ASSESSMENT</td>
<td>PROACTIVE RISK ASSESSMENT</td>
<td>INTEGRATED RISK ASSESSMENT</td>
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<tr>
<td>POOR INVESTIGATION</td>
<td>LIMITED INVESTIGATION</td>
<td>CAUSAL INVESTIGATION</td>
<td>OPEN CAUSAL INVESTIGATION</td>
<td>PROACTIVE INVESTIGATION</td>
</tr>
</tbody>
</table>

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
10. Role as Clinical Investigator v. Physician
Thank You

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