MDICx – Overview of the CDRH 510(k) Improvement project
Overview of 510(k) Program Improvement Project

Jeff Slutsky
NSigma Solutions Inc.
Overview

• MDUFA\(^1\) IV (2017) set goals for average TTD\(^2\) for 510(k) submissions
  – 108 days beginning with FY2022 cohort
  – Several FDA initiatives were begun to help meet the shared goals
    • 510(k) Improvement project- CDRH\(^3\)-Office of Device Evaluation (ODE)
    • Lean Six Sigma-CDRH-Office of Quality Management and Organizational Excellence (QM/OE)

• This presentation describes the 510(k) Improvement project, its current state and ties to Case for Quality (CfQ)

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1 MDUFA- Medical Device User Fee Amendments  
2 TTD- see definition at end of presentation  
3 CDRH- Center for Devices and Radiological Health
Approach

• The approach followed the lean six sigma method
  – A TIM WOOD(S)³ focus on inventory(WIP/workload), movement, waiting, over-processing

• The approach was augmented by the use of an Arena⁴-based simulation model allowing;
  – sensitivity analysis of 510(k) program performance
    • e.g. effect of #holds on FDA days, effect on TTD of the ratio of special, 3rd-party, traditional and abbreviated submissions
  – “what if” scenarios to be “tried” before actually piloting
    • e.g. what if the #consults decreased/increased by x%?
  – determination of conditions necessary to achieve MDUFA goals
    • Useful before/during/after MDUFA negotiations

3 TIM WOOD(S)-transportation, inventory, movement, waiting, over-processing, over-production, defects, (skills)
4 Arena- discrete-event simulation software from Rockwell Automation
Approach

- Construction of 510(k) process flow maps
  - Detailed process maps were created from receipt of submission in the White Oaks/Landover mailrooms to SI decision

- Capture of historic performance and parameter data

- Capture of behaviors of people as they perform their tasks
  - Lead reviewers (LR) and consultants interviewed regarding work priority, task switching, time on task, availability, etc.

- Construction of simulation models using this information
  - Validation of model against historic FY15-FY18 performance
Model Input Data

Major 510(k) process steps: Receive Submission, Refuse to Accept, Substantive Review, Final Review

Each 510(k) submission is a unique arrival to the system, with randomly assigned parameters that affect its flow e.g. trad./spec./abb./3rdparty, procode, etc.
The simulation “plays out” on a daily cadence
  – Distribution of 510(k) submissions per day for FY’15
How well does the model work?

- The performance of the model was evaluated against actual FY15 and FY16 cohorts
- Included are, % submissions with PI*/SE** at the SI decision, % Specials, and % 3rd Party

<table>
<thead>
<tr>
<th></th>
<th>FY15 (Historical)</th>
<th>FY15 (Model)</th>
<th>FY16 (Historical)</th>
<th>FY16 (Model)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SI Decision = PI</td>
<td>12.2%</td>
<td>12.2%</td>
<td>7.8%</td>
<td>7.8%</td>
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<tr>
<td>SI Decision = SE</td>
<td>7.4%</td>
<td>7.4%</td>
<td>6.1%</td>
<td>6.1%</td>
</tr>
<tr>
<td>Specials</td>
<td>13.5%</td>
<td>13.5%</td>
<td>13.4%</td>
<td>13.4%</td>
</tr>
<tr>
<td>3rd Party</td>
<td>1.7%</td>
<td>1.7%</td>
<td>1.3%</td>
<td>1.3%</td>
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<tr>
<td>TTD Performance</td>
<td>133.0</td>
<td>134.9</td>
<td>140.5</td>
<td>139.8</td>
</tr>
<tr>
<td>Confidence Range</td>
<td>N/A</td>
<td>+/- 1.1 days</td>
<td>N/A</td>
<td>+/- 2.0 days</td>
</tr>
</tbody>
</table>

Model performance is acceptable (+/- 2d) for both FY15 and FY16

*PI- Proceed Interactively, **SE- Substantially Equivalent

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How well does the model work?

- How well does the model estimate actual FY16 TTD using actual FY15 statistics and actual FY16 arrival data?

<table>
<thead>
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<th>FY15/FY16 (Model)</th>
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<td>SI Decision = PI</td>
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</tr>
<tr>
<td>3rd Party</td>
<td>1.3%</td>
<td>1.3%</td>
</tr>
<tr>
<td>TTD Performance</td>
<td>140.5</td>
<td>141.7</td>
</tr>
<tr>
<td>Confidence Range</td>
<td>N/A</td>
<td>+/- 1.5 days</td>
</tr>
</tbody>
</table>

Adequate (+/- 2d) estimation of historic FY16 TTD
Model Demonstration

• Demo of model...
• Play [video]
A “What If” Scenario

The following were varied;

%PI, %SE at SI, %Specials, %3rd Party

<table>
<thead>
<tr>
<th>Process Changes</th>
<th>FY16 (Historical)</th>
<th>FY17</th>
<th>FY18</th>
<th>FY19</th>
<th>FY20</th>
<th>FY21</th>
<th>FY22</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td>6.9%</td>
<td>8.0%</td>
<td>16.67%</td>
<td>17.50%</td>
<td>18.33%</td>
<td>19.17%</td>
<td>20.00%</td>
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<tr>
<td>SE at SI</td>
<td>11.9%</td>
<td>10.0%</td>
<td>14.33%</td>
<td>14.75%</td>
<td>15.17%</td>
<td>15.58%</td>
<td>16.00%</td>
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<tr>
<td>PI / SE at SI Total</td>
<td>18.8%</td>
<td>18.0%</td>
<td>31.0%</td>
<td>32.25%</td>
<td>33.5%</td>
<td>34.75%</td>
<td>36.0%</td>
</tr>
<tr>
<td>Specials</td>
<td>13.4%</td>
<td>12.0%</td>
<td>17.0%</td>
<td>19.75%</td>
<td>22.5%</td>
<td>25.25%</td>
<td>28.0%</td>
</tr>
<tr>
<td>3rd Party</td>
<td>1.3%</td>
<td>2.0%</td>
<td>2.0%</td>
<td>5.0%</td>
<td>8.0%</td>
<td>11.0%</td>
<td>14.0%</td>
</tr>
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</table>

Results from the simulation

<table>
<thead>
<tr>
<th>Measurements (all in days)</th>
<th>FY16 (Historical)</th>
<th>FY17</th>
<th>FY18</th>
<th>FY19</th>
<th>FY20</th>
<th>FY21</th>
<th>FY22</th>
</tr>
</thead>
<tbody>
<tr>
<td>TTD</td>
<td>139.8</td>
<td>136.7</td>
<td>125.4</td>
<td>122.8</td>
<td>120.0</td>
<td>116.8</td>
<td>113.8</td>
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<td>TTD – FDA</td>
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<td>75.5</td>
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<td>71.1</td>
<td>69.2</td>
<td>67.7</td>
<td>65.7</td>
</tr>
<tr>
<td>TTD – Industry</td>
<td>63.7</td>
<td>61.2</td>
<td>52.9</td>
<td>51.8</td>
<td>50.8</td>
<td>49.1</td>
<td>48.1</td>
</tr>
</tbody>
</table>

Would not meet MDUFA IV TDD goals with only these changes
Another “What If” Scenario

Use FY18 cohort performance and proposed new initiatives
Reduce AINN, Implement Quik Reviews, Increase #Specials

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Simulated Results for All FYs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submissions</td>
<td>FY17</td>
</tr>
<tr>
<td>% AINN</td>
<td>4035</td>
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<tr>
<td>% Quik Review</td>
<td>71%</td>
</tr>
<tr>
<td>% Specials</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>12.3%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th>FY17</th>
<th>FY18</th>
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<th>FY20</th>
<th>FY21</th>
<th>FY22</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA Days</td>
<td>72.0</td>
<td>68.3</td>
<td>69.1</td>
<td>66.6</td>
<td>64.8</td>
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<tr>
<td>IND Days</td>
<td>61.5</td>
<td>54.0</td>
<td>54.5</td>
<td>51.3</td>
<td>48.4</td>
<td>47.4</td>
</tr>
<tr>
<td>TTD (in days)</td>
<td>133.5</td>
<td>122.3</td>
<td>123.6</td>
<td>117.9</td>
<td>113.2</td>
<td>110.6</td>
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<tr>
<td>MDUFA Goal</td>
<td>128</td>
<td>124</td>
<td>124</td>
<td>120</td>
<td>116</td>
<td>112</td>
</tr>
</tbody>
</table>

Can meet MDUFA IV TDD goal with these changes

AINN- Additional Information Needed

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Conclusions

• Changes to 510(k) were identified and investigated
  – The changes were simulated and their effect on TTD estimated
  – Results indicate that FDA could meet its portion of MDUFA goals
  – The improvements are only incremental

• The project demonstrated that revolutionary improvement would require different approaches
  – CfQ is one of those approaches (which had already been started)
Innovation in 510(k) Modifications to CfQ VIP in 2019

Cisco Vicenty
Office of Compliance (OPEQ Strategic Initiatives Staff)
Center for Devices and Radiological Health
What do we need?

Visibility & Information
- Responsiveness
- Control
- Information at the right time

Least burdensome
- Simplification
- Reduce error
- Improve information exchange
- Increase value

Innovation & Safety
- Accelerate improvement
- Accelerate new technologies
- Improve patient outcomes
Think past the current processes!
Seeking the revolutionary

A new paradigm
Thank you
Q&A

Please use the chat box feature on Zoom to ask your question
Connect with MDIC

• Next MDICx webinar – Update on the CFQ VIP, May 15: https://mdic.org/event/update-on-the-case-for-quality-voluntary-improvement-program-cfq-vip/

• Next Case for Quality Forum is June 20 in Arlington, VA. Details at: https://mdic.org/project/case-for-quality-forums/

• Interested in the CFQ VIP initiative? Learn more at: https://mdic.org/project/cdrh-quality-pilot/