## Pharm Risk Approach Plan

<table>
<thead>
<tr>
<th>Countermeasure Options</th>
<th>Medication Characterization &amp; Prioritization</th>
<th>Data Mining &amp; Synthesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharm-101: Perform market analysis of packaging/storage options</td>
<td>Pharm-201: Exploration Candidate Formulary (ECF) v1.0</td>
<td>Pharm-301: Define a process for assigning medications to colors on the stoplight chart.</td>
</tr>
<tr>
<td>ExMC Decisions for Study Arms</td>
<td>Pharm-201: ECF 2.0</td>
<td>KDP Acceptance of Process</td>
</tr>
<tr>
<td></td>
<td>Pharm-201: ECF 3.0</td>
<td>KDP Study Medication Selector</td>
</tr>
<tr>
<td></td>
<td>Pharm-201: ECF 4.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pharm-401: Further study the safety and effectiveness of medications determined to be yellow on the most current version of the Stoplight Chart (concurrent with gaps Pharm-201 and Pharm-301). Also consider interaction with packaging/storage from gap Pharm-101.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>New ECF versions based on evidence update and new conditions</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Pharm-101**
- Perform market analysis of packaging/storage options

**Pharm-201**
- ECF v1.0
- ECF 2.0
- ECF 3.0
- ECF 3.x
- ECF 4.0

**Pharm-301**
- Define a process for assigning medications to colors on the stoplight chart.
- ECF 1.0 Stoplight-Baseline
- ECF 2.0 Stoplight
- ECF 3.0 Stoplight
- ECF 3.x Stoplight
- ECF 4.0 Stoplight

**Data Mining & Synthesis**
- KDP Acceptance of Process
- KDP Study Medication Selector

**Legend**
- Analog
- Flight environment
- Cross Element Integration
- Anticipated PRR Color Change

**Note:** Milestone ( ) and Gap Closures ( ) are Program reviews with defined entry/exit criteria.

* This one-pager depicts strategy for only the stability portion of the pharm risk. PK/PD and pharmacogenomics strategy is forthcoming.

**External Deliverables**
- Propose Risk Closure
- New ECF versions based on evidence update and new conditions

**HRR Gap: research logic description**
- Pharm-101: Perform market analysis of packaging/storage options
- Pharm-201: Exploration Candidate Formulary (ECF) v1.0
- Pharm-201: ECF 2.0
- Pharm-201: ECF 3.0
- Pharm-201: ECF 4.0
- Pharm-401: Further study the safety and effectiveness of medications determined to be yellow on the most current version of the Stoplight Chart (concurrent with gaps Pharm-201 and Pharm-301). Also consider interaction with packaging/storage from gap Pharm-101.

**High LxC**
- 9/30/24 - 10/1/20

**Mid LxC: Requires Mitigation**
- 9/30/24 - 9/30/25

**KDP Acceptance of Process**
- KDP Study Medication Selector

**Flight Study Augmentation?**
- Maturation
- Exploration Formulary

**ExMC Decisions for Study Arms**

**New ECF versions based on evidence update and new conditions**

**KDP: Exploration Formulary**
- v3.0 + Stoplight Chart
- 9/30/24