	Office of Sponsor and Regulatory Oversight	Document #: <b>F03-205-S01</b>
	<b>Risk-Based Assessment for Pharmacy Monitoring Plans</b>	Revision #: <b>1</b>
		Effective Date: <b>15FEB2024</b>

OSRO is implementing a risk-based assessment to help generate pharmacy monitoring plans. The pharmacy monitoring assessment is part of the Clinical Monitoring Plan (CMP).

The following assessment table should be considered as a guideline. Utilized assessment factors may change from those listed if OSRO deems it warranted.


### Pharmacy Monitoring Assessment

The *Risk Score* calculated in Table 1 determines the frequency of pharmacy monitoring visits assigned to the protocol. The three visit intervals are listed in Table 2.

For protocols utilizing multiple investigational products, the stringiest IP score across all products will be used; e.g., if one of three investigational products is stored in the freezer and the other two are stored at room temperature, the IP score will be 3.

**Table 1. Investigational Product Monitoring Assessment**

Investigational Product (IP) Factor	IP Assessment	IP Score	Risk Score
Investigational Product storage	Room Temperature	1	
	Refrigerator	2	
	Freezer	3	
Product dosing	Fixed dose	1	
	Calculated dose	2	
More than one investigational product	No	0	
	Yes	2	
Temperature excursions within the last 3 months based on where products are stored ( <i>across all sites</i> )	No	0	
	Yes	2	
NIH-manufactured product	No	0	
	Yes	2	
Product provided under an agreement	No	0	
	Yes	2	
Product Sterility (dosage form)	Non-Sterile	0	
	Sterile	2	
<b>Minimal Risk Score: 2</b> <b>Median Risk Score: 7</b> <b>Maximal Risk Score: 15</b>	<b>Total Risk Score =</b>		

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**Table 2. Pharmacy Monitoring Visit Frequencies**

Risk Score	Monitoring Visit Interval	
	Active Phase <sup>1</sup>	Follow-Up Phase <sup>2</sup>
<b>2-5</b>	Every 12 months +/- 4 weeks	Not Applicable – A Pharmacy Close-out Visit (COV) will be conducted
<b>6-9</b>	Every 6 months +/- 2 weeks	
<b>10-15</b>	Every 4 months +/- 2 weeks	

<sup>1</sup> Enrollment and Treatment phases.

<sup>2</sup> Begins after Treatment phase has been monitored.

Note: If no drug accountability records exist for a protocol utilizing commercial products, accountability records may be reviewed remotely. All other pharmacy visits will be conducted onsite.