



Background

- In order to minimize waste and cost, clinical review of oral oncolytics often warrants sending partial fills due to scans, laboratory measures, or dosing regimen changes.
- It is important to consider the stability and appropriate storage of medications to ensure the patient is still receiving a viable product.
- Manufacturer labeling often has limited information, making it difficult to extrapolate the true necessity to keep medications in the original container.
- This project was designed to help oncology pharmacists better assess when it is appropriate to open bottles and/or packages to prevent waste and minimize cost.
- Thorough analysis of each medication via tertiary drug references, package labeling, and outreach to manufacturer will occur as applicable to identify best practice for each individual product.

Objectives

- To create a systematic workflow for the specialty pharmacy to utilize in determining whether a medication may be opened

Methodology

Identify Medications	<ul style="list-style-type: none"> Initial phase was to conduct a retrospective review of all the medications that the pharmacy had historically opened
Conduct Research and Outreach	<ul style="list-style-type: none"> Various students, residents, and pharmacists worked to compile data over time Resources included: <ul style="list-style-type: none"> Package insert Medication guide or patient guide Outreach to manufacturers Requested written correspondence from manufacturers, if available, or alternatively documented phone calls Assess whether medication contains a desiccant, any open dish studies, and any literature regarding use outside of the original container (with and/or without desiccant put into the alternative source)
Compile Findings	<ul style="list-style-type: none"> All medications were put into a consolidated spreadsheet

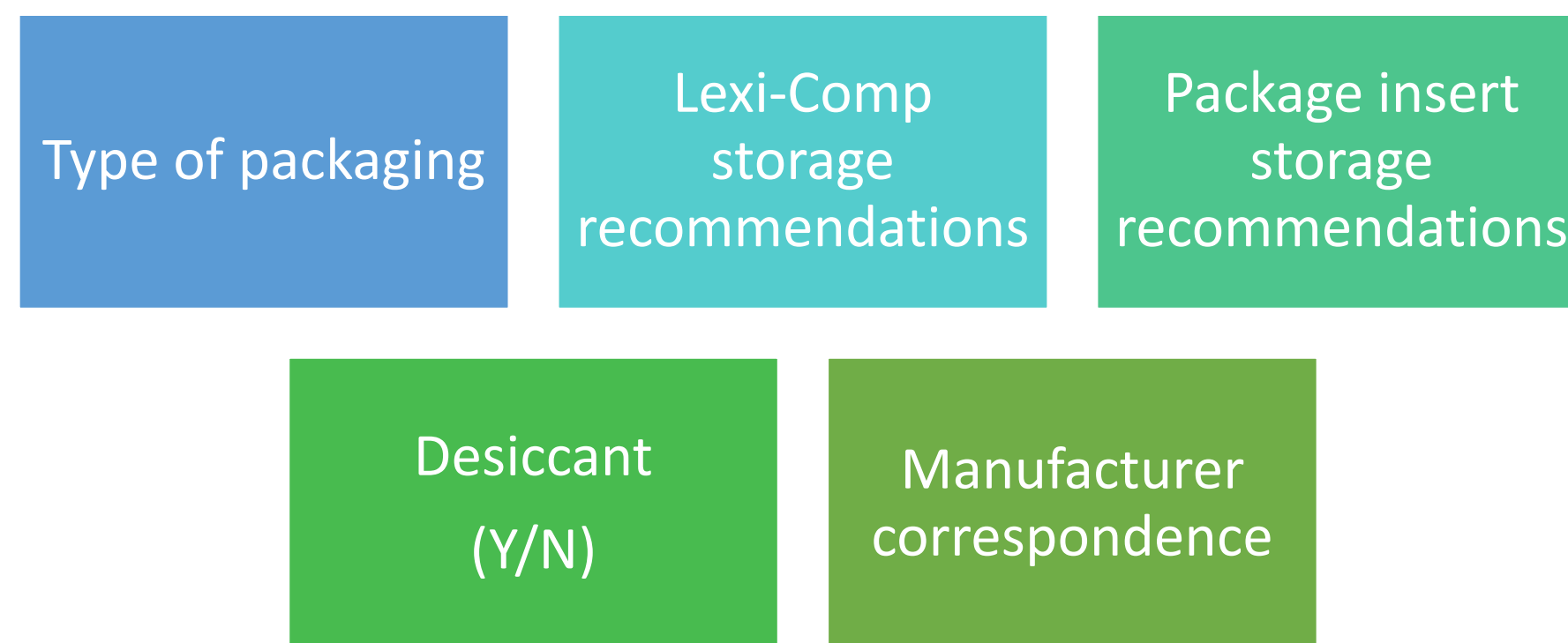
Medication Use Evaluation (MUE)

- MUE identified over 160 medications to review
- 50% of applicable medications had been historically opened
- Equivalent to 36% of hematology/oncology medications

Initially reviewed and approved:

Apalutamide (Erleada)
Axitinib (Inlyta)
Dabrafenib (Tafinlar)
Enzalutamide (Xtandi)
Pacritinib (Vonjo)
Venetoclax (Venclexta)

Data Collection

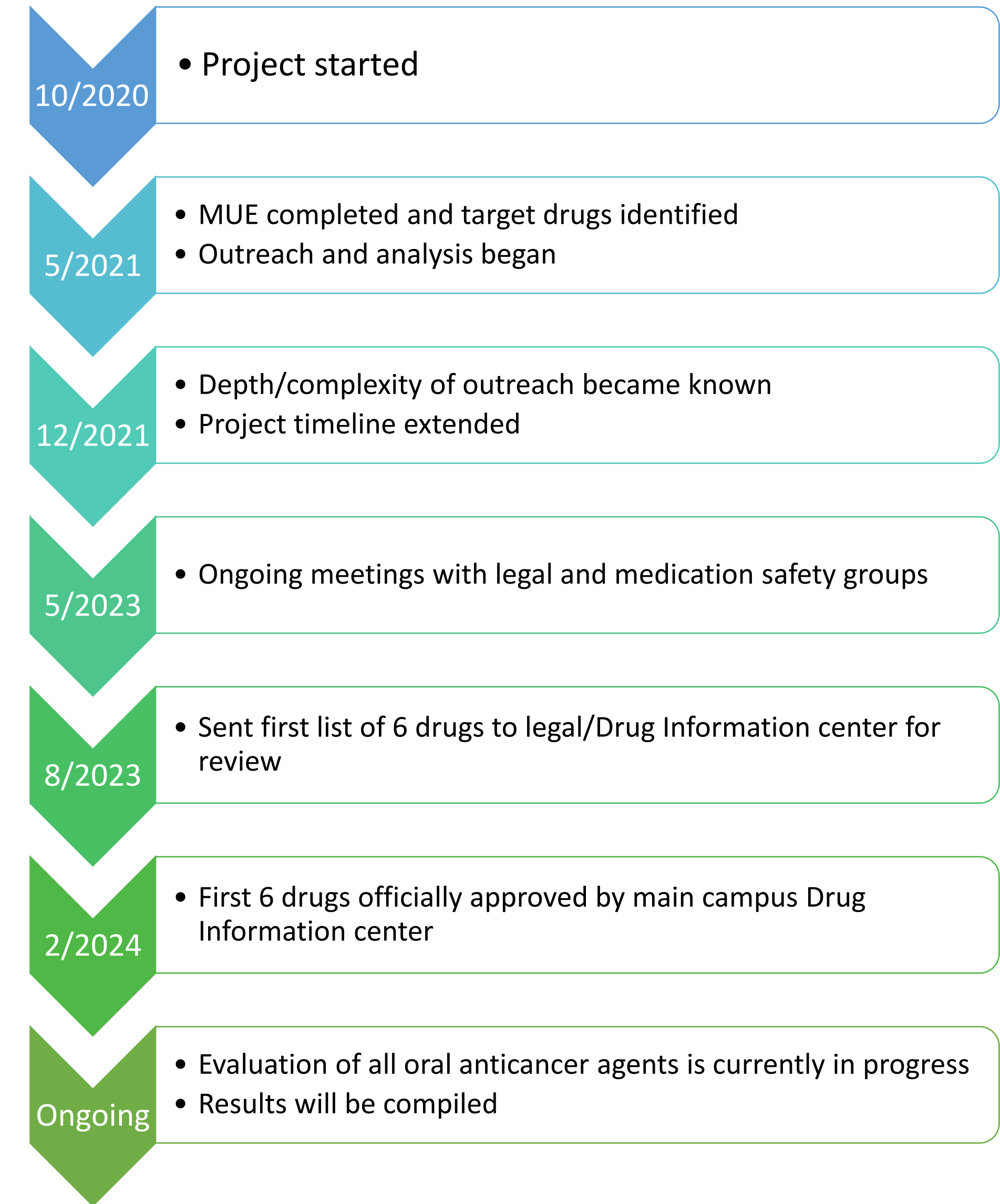


Prescribing Information and Excel Template

Storage and Handling
 Store at 20 °C to 25 °C (68 °F to 77 °F); excursions permitted to 15 °C to 30 °C (59 °F to 86 °F) [see USP Controlled Room Temperature].
 Store in original package to protect from light and moisture. Do not discard desiccant.

Brand Name	Generic Name	Desiccant (Y/N)	Additional Comments	Package Size	Historically Opened Bottle (MUE) / uneven multiple of blister pack	Recommendations - OK TO OPEN?
Erleada	Apalutamide	Y	Only good for 10 days in pill boxes ; advise against this based on manf correspondence and studies conducted	#120	Y	Y - BUT NOT PILL BOXES

Timeline



References

- Erleada® (apalutamide) [package insert]. Horsham, PA: Janssen Pharmaceutical Companies; 2019, revised 2024.
- Akgöl K, van Merendonk LN, Barkman HJ, van Balen DE, van den Hoek HL, Klous MG, Hendriks JJ, Huijtema AD, Beijnen JH, Nuijen B. Redispensing of expensive oral anticancer medicines: A practical application. *J Oncol Pharm Pract.* 2024 Apr;30(3):519-526. doi: 10.1177/10781552231176199. Epub 2023 May 16. PMID: 37192749.
- Waterman KC, MacDonald BC. Package selection for moisture protection for solid, oral drug products. *J Pharm Sci.* 2010 Nov;99(11):4437-52. doi: 10.1002/jps.22161. PMID: 20845442.
- Sato K, Inaoka N, Kodama Y, Muro T, Nakamura T, Sasaki H, Kitahara T. [Influence of Storage Conditions after One-dose Packaging on Stability of Magnesium Oxide Tablets]. *Yakugaku Zasshi.* 2018;138(11):1435-1441. Japanese. doi: 10.1248/yakushi.18-00024. PMID: 30381651.
- Trovato JA, Tuttle LA. Oral chemotherapy handling and storage practices among Veterans Affairs oncology patients and caregivers. *J Oncol Pharm Pract.* 2014 Apr;20(2):88-92. doi: 10.1177/1078155213479417. Epub 2013 Mar 19. PMID: 23512268.
- Zerillo JA, Goldenberg BA, Kotecha RR, Tewari AK, Jacobson JO, Krzyzanowska MK. Interventions to Improve Oral Chemotherapy Safety and Quality: A Systematic Review. *JAMA Oncol.* 2018;4(1):105-117. doi:10.1001/jamaoncol.2017.0625