MED-MSL-TD-US-0180 v3

RxKinect: An Observational, Electronic Patient Survey Study

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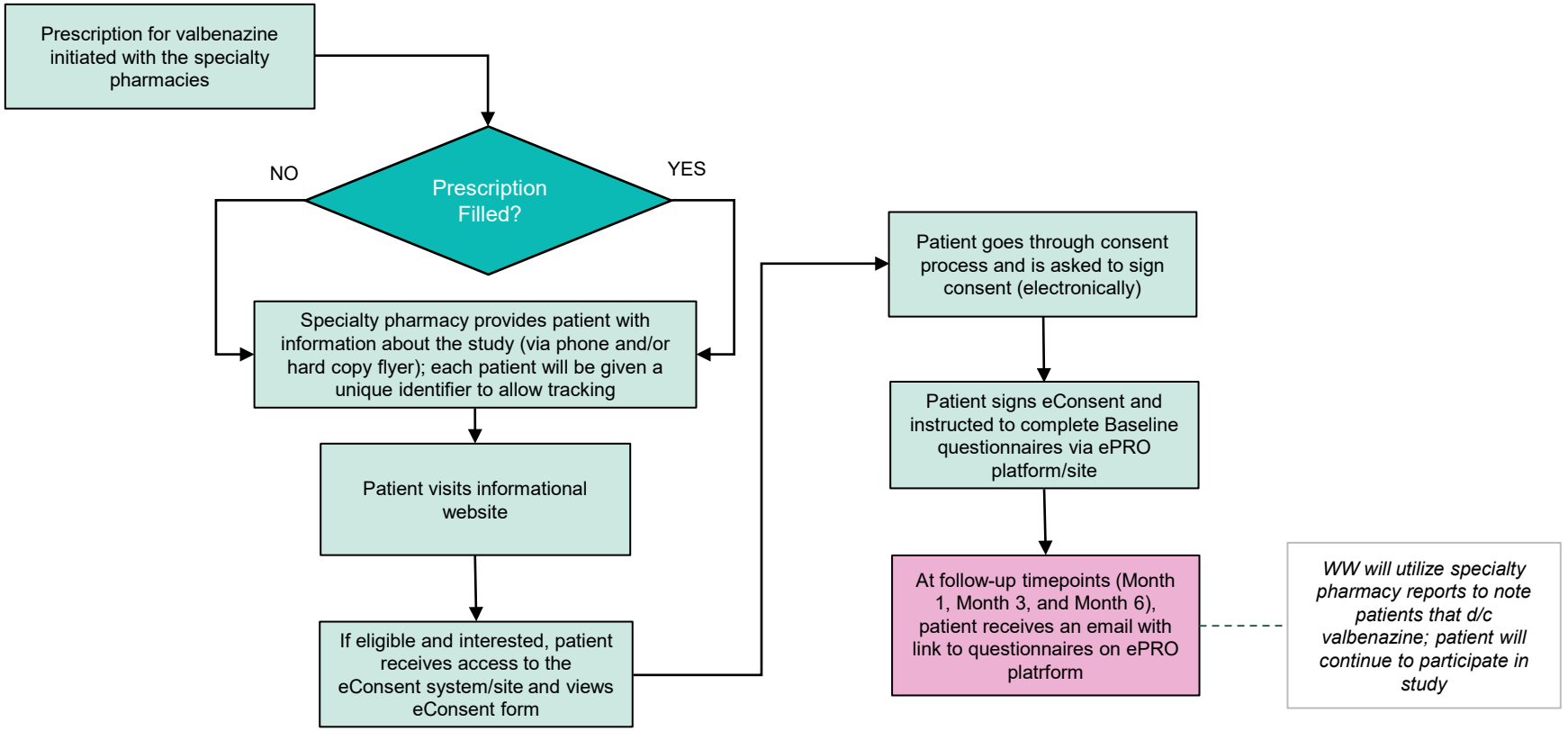
RxKinect: Study Overview

Understanding the patient perspective for treatment of tardive dyskinesia with valbenazine capsules: An observational, electronic patient survey study (RxKinect)	
Study Design	• This is an observational, two-arm, 6-month longitudinal study surveying patients receiving an initial prescription of valbenazine. • The selected specialty pharmacies will identify patients who meet study inclusion criteria to enroll in this electronic survey study. • Patient-reported outcomes, patient satisfaction, and HRQoL will be assessed at scheduled times throughout the study. • The study is direct-to-patient and will not include PIs/sites.
Target Population	• Patients diagnosed with tardive dyskinesia (TD) and being newly prescribed valbenazine, irrespective of whether patients decide to take valbenazine for their TD.

RxKinect STUDY

Data on File. Neurocrine Biosciences, Inc.

RxKinect: Study Design



RxKinect STUDY

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RxKinect: Study Objectives

- To understand patients' perspectives of health status, wellness, and functionality when treated with valbenazine
- To assess TD symptom treatment relief, patient satisfaction, and health related quality of life (HRQoL) in patients who are offered treatment with valbenazine
- To describe perspectives of health status, wellness, and functionality in TD patients when offered but not treated with valbenazine

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RxKinect: Patient Eligibility Criteria

Inclusion Criteria

1. Patients receiving new prescription of valbenazine for on-label treatment of TD
2. Patient must be cognitively capable to respond to questions in English or Spanish
3. Patient must be able to complete electronic patient-reported outcome (ePRO) instruments with or without the assistance of a caregiver*
4. Patient must have provided electronic consent (e-consent)

Exclusion Criteria

1. Patients with a known hypersensitivity to valbenazine or any components of valbenazine
2. Patients taking medications for which concomitant use with valbenazine is not recommended
3. Patient receiving valbenazine for off-label treatment
4. Patient received prior treatment with valbenazine

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*Caregiver assistance is solely for the input of patient responses

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RxKinect Outcomes: Patient Characteristics and Treatment Patterns

Baseline Characteristics

- Demographics
- TD history
- Comorbid conditions
- Medications of interest
- Current use of antipsychotics

Valbenazine Treatment Patterns

- Initial dose
- Changes in dose
- Time to stable dose
- Time to discontinuation
- Reason for discontinuation

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RxKinect Outcomes: PROs

Patient-reported outcomes

- Baseline and Follow-up time points (Months 1, 3, and 6) will include the following:
  - Tardive Dyskinesia Impact Scale (TDIS-PRO)
  - Primary body region(s) of TD symptoms with "severity"
  - Patient Global Impression - Severity (PGI-S) scale
  - Total Health VAS
  - Neuro-QoL Short Form v1.0 - Ability to Participate in Social Roles and Activities
  - Patient perception of TD symptoms
  - Perceived ability to manage health conditions
  - Likelihood to initiate (at baseline) or continue valbenazine treatment
  - Social network/support structure (define as Caregiver, Family, Group Home, and Long-Term Care Facility)
- Caregiver
  - Follow-up time points will include the following:
    - Caregiver Global Impression - Severity (CaGI-S) scale

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RxKinect: Statistics

Descriptive statistics will be employed to address the objectives of this study, such as a description of demographic characteristics, valbenazine utilization, and PROs. In general, all continuous measures will be presented by descriptive statistics (means, standard deviations, standard error, minimum/maximum values, medians, interquartile ranges, and 95% confidence intervals). All nominal or categorical measures will be presented in terms of frequencies, proportions, and 95% confidence intervals

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