
SECTION: Research/Clinical Research
SUBJECT: Compassionate Use

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REVISION: V1
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Compassionate Use

PURPOSE

To comply with the 21st Century Cures Act (2016) requirement that manufacturers of investigational drugs for serious conditions make publicly available their policy on evaluating and responding to requests for expanded access.

SCOPE

This policy applies to all InterveXion products in clinical trials of Phase 2 or beyond.

POLICY

At InterveXion, we are dedicated to developing therapies for patients with substance use disorders, particularly those with methamphetamine use disorder. We respect and support people fighting to overcome addiction, and are committed to our work to develop our product candidates as efficiently as possible.

We also understand that from time to time patients and their families may be interested in accessing our investigational products prior to completion of our development program, and outside of one of our clinical trials, through compassionate use, "right to try", extended access, or other such pre-approval access programs. There are many factors that influence consideration of such requests, including risk:benefit profile for each agent and patient, practical supply chain considerations, effect of such requests on our clinical trial programs, and overall feasibility.

Because of all of these considerations, after careful analysis, InterveXion has determined that at this time we are unable to offer a systematic program to provide any of our product candidates to patients on a pre-approval basis. We are committed to the most rapid, efficient means to achieve potential regulatory approval, and if successful, access for the greatest number of patients, and believe that this can best be achieved through completion of our ongoing and future clinical trials as safely and quickly as possible.

We appreciate the participation of patients, families, and the addiction community in our development efforts. For further information about the status of our development programs, please review the information on our website at www.intervexion.com, or contact us via www.intervexion.com/contact.