bioxcel therapeutics®

Commercial Day

October 18, 2022

Igalmi™
(dexmedetomidine)
sublingual film · 120 mcg, 180 mcg

BioXcel Therapeutics | 555 Long Wharf Drive, 12th Floor | New Haven, CT 06511 | **www.bioxceltherapeutics.com**

Forward-Looking Statements

This presentation includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995.Forward-looking statements in this presentation include but are not limited to: statements regarding BioXcel Therapeutics' commercial plan and strategy for IGALMI™ including expected timelines, expected benefits to providers and patients from treatment using IGALMI™; potential market size and opportunity for products and product candidates; and its future financial and operational results. When used herein, words including "anticipate," "being," "will," "plan," "may," "continue," and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon BioXcel Therapeutics' current expectations and various assumptions. BioXcel Therapeutics believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

BioXcel Therapeutics may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation: its limited operating history; its incurrence of significant losses; its need for substantial additional funding and ability to raise capital when needed; its limited experience in drug discovery and drug development; its dependence on the success and commercialization of IGALMI™, BXCL501, BXCL502 and BXCL701 and other product candidates; the Company has limited experience in marketing and selling drug products; IGALMI™ or the Company's product candidates may not be accepted by physicians or the medical community in general; the failure of preliminary data from its clinical studies to predict final study results; failure of its early clinical studies or preclinical studies to predict future clinical studies; its ability to receive regulatory approval for its product candidates; its ability to enroll patients in its clinical trials; undesirable side effects caused by the Company's product and product candidates; its novel approach to the discovery and development of product candidates based on EvolverAI; its exposure to patent infringement lawsuits; its ability to comply with the extensive regulations applicable to it; impacts from the COVID-19 pandemic; and the other important factors discussed under the caption "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022, as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC's website at **www.sec.gov** and the Investors section of our website at **www.bioxceltherapeutics.com**.

These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this presentation. Any such forward-looking statements represent management's estimates as of the date of this presentation. While BioXcel Therapeutics may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing BioXcel Therapeutics' views as of any date subsequent to the date of this presentation.

Indication and Important Safety Information

INDICATION
IGALMI is indicated for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. Limitations of Use: The safety and effectiveness of IGALMI have not been established beyond 24 hours from the first dose.

IMPORTANT SAFETY INFORMATION
IGALMI can cause serious side effects, including:

- Decreased blood pressure, low blood pressure upon standing, and slower than normal heart rate, which may be more likely in patients with low blood volume, diabetes, chronic high blood pressure, and older patients. IGALMI is taken under the supervision of a healthcare provider who will monitor vital signs (like blood pressure and heart rate) and alertness after IGALMI is administered to help prevent falling or fainting. Patients should be adequately hydrated and sit or lie down after taking IGALMI and instructed to tell their healthcare provider if they feel dizzy, lightheaded, or faint.
- Heart rhythm changes (QT interval prolongation). IGALMI should not be given to patients with an abnormal heart rhythm, a history of an irregular heartbeat, slow heart rate, low potassium, low magnesium, or taking other drugs that could affect heart rhythm. Taking IGALMI with a history of abnormal heart rhythm can increase the risk of torsades de pointes and sudden death. Patients should be instructed to tell their healthcare provider immediately if they feel faint or have heart palpitations.
- Sleepiness/drowsiness. Patients should not perform activities requiring mental alertness, such as driving or operating hazardous machinery, for at least 8 hours after taking IGALMI.
- Withdrawal reactions, tolerance, and decreased response/efficacy. IGALMI was not studied for longer than 24 hours after the first dose. Physical dependence, withdrawal symptoms (e.g., nausea, vomiting, agitation), and decreased response to IGALMI may occur if IGALMI is used longer than 24 hours.

The most common side effects of IGALMI in clinical studies were sleepiness or drowsiness, a prickling or tingling sensation or numbness of the mouth, dizziness, dry mouth, low blood pressure, and low blood pressure upon standing.

These are not all the possible side effects of IGALMI. Patients should speak with their healthcare provider for medical advice about side effects.

Patients should tell their healthcare provider about their medical history, including if they suffer from any known heart problems, low potassium, low magnesium, low blood pressure, low heart rate, diabetes, high blood pressure, history of fainting, or liver impairment. They should also tell their healthcare provider if they are pregnant or breastfeeding or take any medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Patients should especially tell their healthcare provider if they take any drugs that lower blood pressure, change heart rate, or take anesthetics, sedatives, hypnotics, and opioids.

Everyone is encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You can also contact BioXcel Therapeutics, Inc. at 1-833-201-1088 or medinfo@bioxceltherapeutics.com.

Please see full Prescribing Information.

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Agenda and Speakers

- A Disruptive Approach to the Untapped Agitation Market
- Psychomotor Agitation
- The Front Lines of Agitation
- Hospital Process: How the System Works
- IGALMI™ Commercial Overview & Updates
- Panel Q&A Session

Vimal Mehta, PhD
Founder and CEO

Matt Wiley
Chief Commercial Officer

Brenden Schultek
Vice President of Sales

Sheldon Preskorn, MD
President and CEO, World-Wide Clinical Psychopharmacology Consultation

Karen Sands, MSN, APRN-BC, ANP, CCRN, FCCM
Hospitalist Adult Nurse Practitioner

Jacob Hanaie, PharmD, APh, BCPP
Kedren Psychiatric Hospital and Community Mental Health Center

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A Disruptive Approach to the Untapped Agitation Market

Vimal Mehta
Founder & CEO

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Innovation Shaping the Agitation Market

Similar to the Depression Market in the 1980s

Depression Market

The Philadelphia Inquirer

"Drugs now treating depression generate more than a billion dollars in worldwide annual sales, financial analysts say. ***Before Prozac's introduction in 1986, the U.S. anti-depressant market was relatively stagnant****, generating about $280 million in annual sales, estimates." Jerry Brimeyer, a drug analyst for Dean Witter Reynolds (1990)*

THE WALL STREET JOURNAL.

"Psychiatrists say ***clinical depression still is badly underdiagnosed****, suggesting the world-wide anti-depressant market could expand faster than its current annual rate of about 10%." (1992)*

Innovation driving **market creation**

Historically **underdiagnosed and underserved** markets

No commercial precedent or analogs

IGALMI marketing and education efforts are highlighting the undervalued agitation market

Igalmi™
(dexmedetomidine)
sublingual film · 120 mcg, 180 mcg

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Disruption is in our DNA

Building a Unique Biopharma Model

Delivering innovation

First public AI company focused on neuroscience and Immuno-oncology (2018)

Disrupting drug development paradigm

IND to commercial launch of IGALMI™ in under 4 years

First oral film treatment for BPD/SCZ agitation market

Built integrated commercial team and implementing dynamic launch model

OnkosXcel Therapeutics

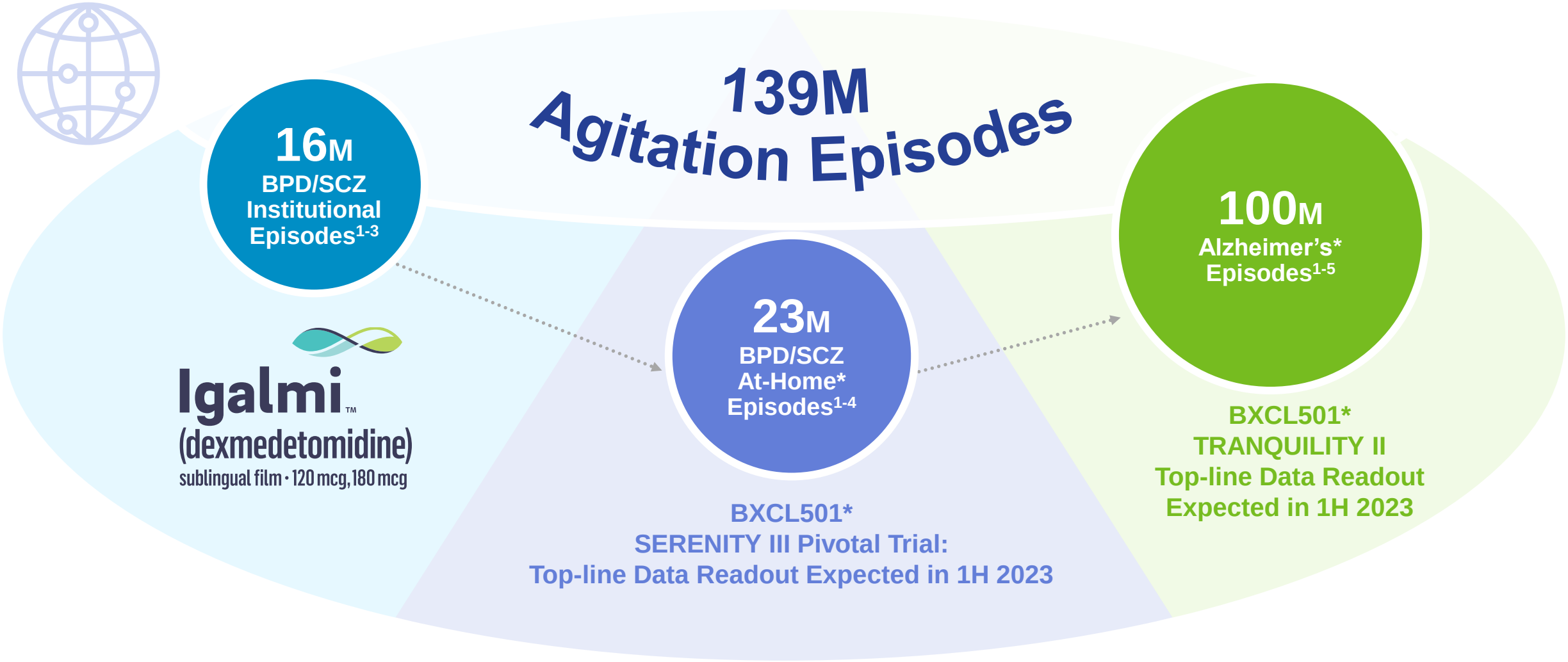
Creative $260m strategic financing in April 2022

Poised to capture 139-million-episode agitation market

Bipolar, Schizophrenia & Alzheimer's related agitation

Well-Positioned to Help Address Significant U.S. Market Opportunity

$15B Potential Market Opportunity[6]



1. Wu, 2006, NAMI 2. NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf 3. Data on File 4. inVibe Patient Agitation Market Research, July 2022 (n=57) 5. Data on File. 6 139M episodes @ $105/episode

*Investigational use; safety and efficacy not established

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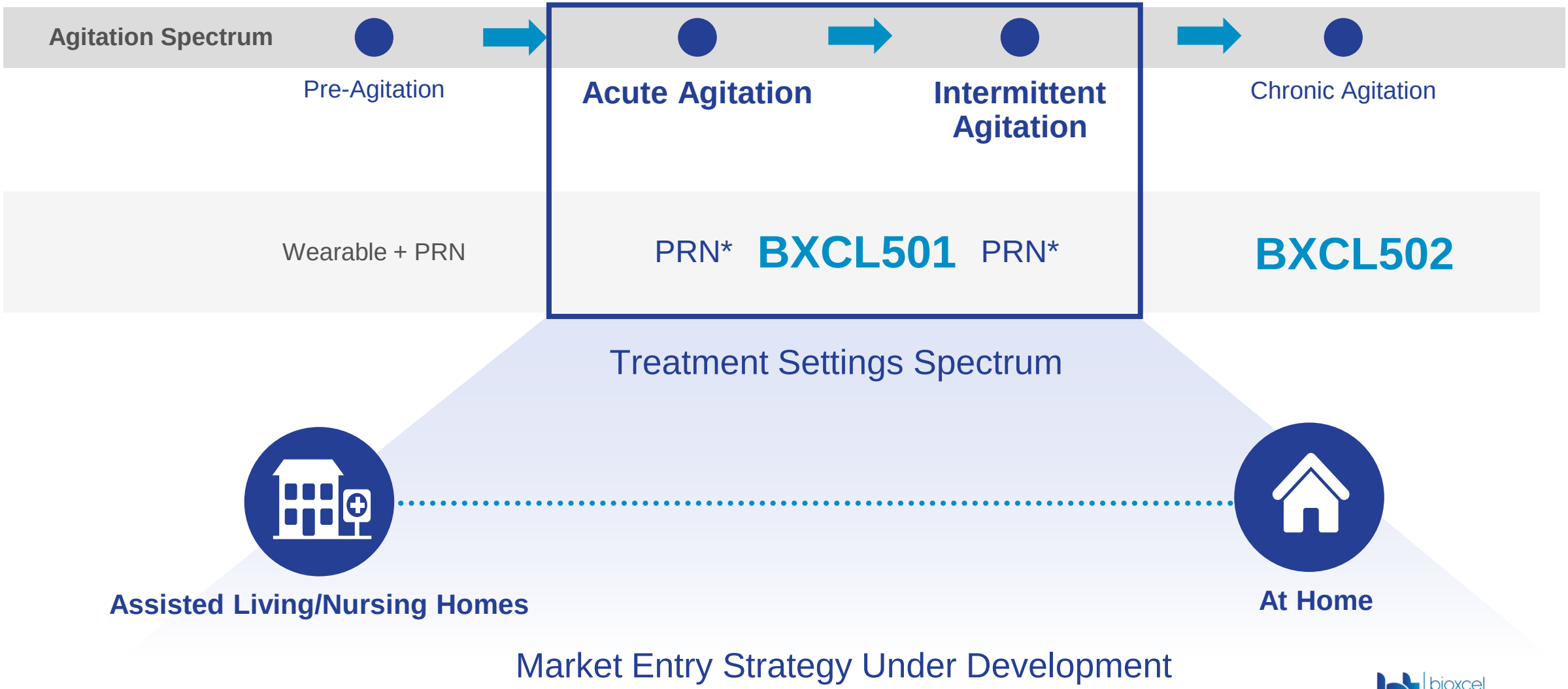
Comprehensive Alzheimer's Disease Program Strategy

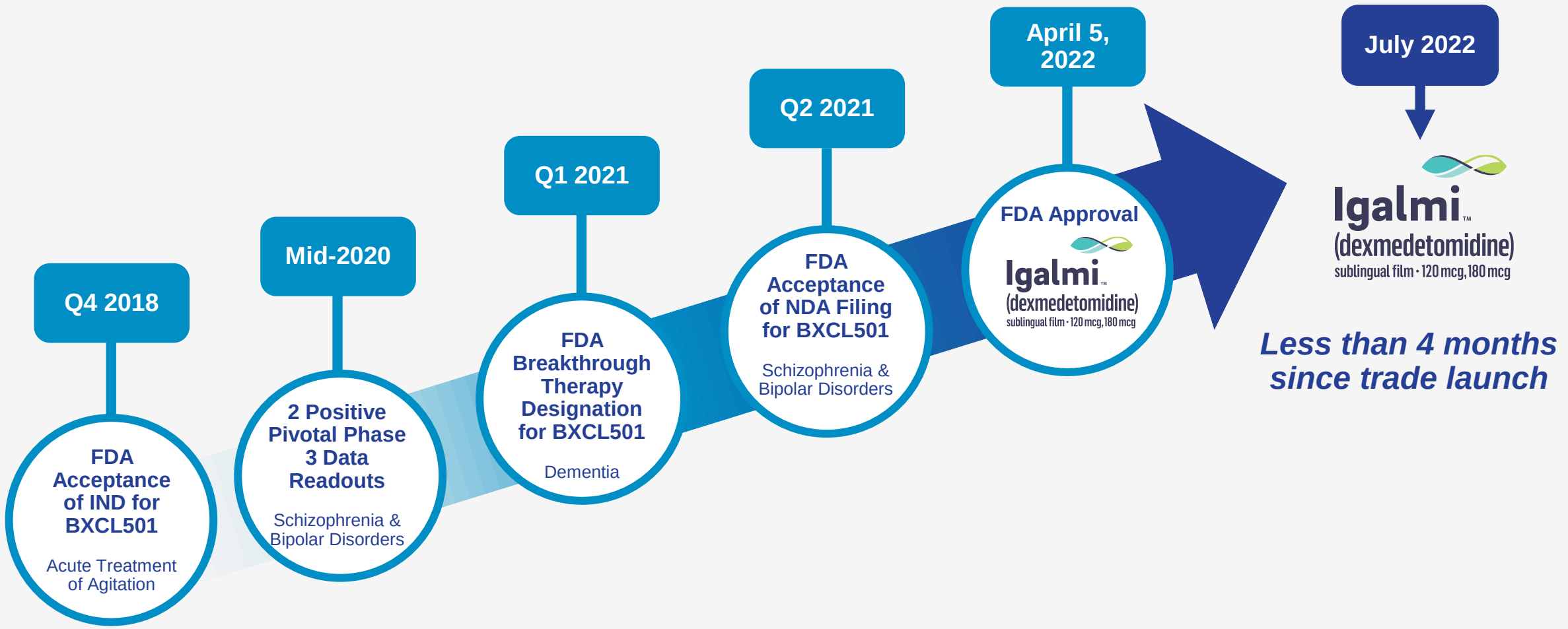
Retail Prescription Market



*As needed

From IND Acceptance to IGALMI™ Launch in 4 Years

First AI-Derived, FDA-Approved Drug With Novel Mechanism of Action



IGALMI™ (dexmedetomidine) Sublingual Film

Approved for Acute Treatment of Agitation Associated with Schizophrenia or Bipolar I or II Disorder in Adults

First and only FDA-approved orally dissolving sublingual film with broad label **covering mild, moderate, and severe agitation**

IGALMI profile represents **significant game-changing market potential**

Limitations of Use: The safety and effectiveness of IGALMI have not been established beyond 24 hours from the first dose.
Please see Important Safety Information and full Prescribing Information at www.igalmihcp.com

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Positive Commercial Momentum in Under 4 Months

Well-positioned to Maximize IGALMI Market Potential

- **Positive market reception** from key hospital stakeholders
- Highly favorable **market dynamics** to IGALMI value proposition
- **Gaining market access** across multiple institutions
- **Expanding national sales team** to cover ~1700 hospitals in 70 geographies

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Psychomotor Agitation

Sheldon Preskorn, M.D.

Speaker is acting on behalf of and is a paid consultant to BioXcel Therapeutics, Inc.
This material is intended for an investor audience only.
The information contained in the following material is intended to provide background and educational information only and does not constitute medical advice. Individual results will vary among patients and depend on many factors. A patient's healthcare provider should consider the circumstances of each patient.

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Personal Experience in the Emergency Department

- Witnessed two firefights in the ER
- Was held hostage in the office at gunpoint
- Suffered a torn ligament restraining an agitated patient who was trying to attack another physician
- Personally knew 10 HCPs who were killed by agitated patients
- Recent experience: 2 patients refused IM injections
  - Would have been good candidates for non-invasive treatment with faster onset of action than oral tablets

Psychomotor Agitation

Associated with Poor Outcomes in Patients with Schizophrenia or Bipolar Disorder

Psychomotor agitation is characterized by motor restlessness and irritability (mild) progressing to aggressive and/or violent behavior (severe)

PREVALENCE

More than 5% of individuals in the United States are diagnosed with schizophrenia or bipolar disorder.

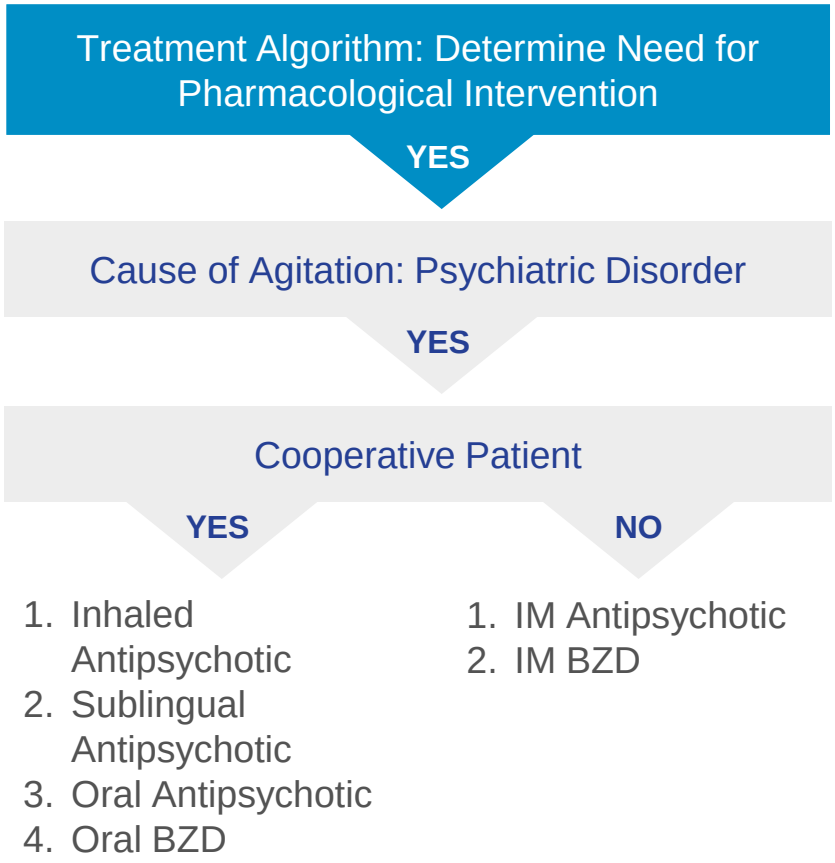
10% to 31%
of all patients with schizophrenia or related psychotic disorders exhibit aggressive or violent behavior.

AGITATION IN HOSPITALS ASSOCIATED WITH:

- Longer hospital stays
- Increased medication consumption
- Higher re-admission rates
- Increased number of violent incidents against staff, other patients, and themselves

Sachs GS. A review of agitation in mental illness: burden of illness and underlying pathology. J Clin Psychiatry. 2006;67 Suppl 10:5-12

Current Treatment Paradigm for Psychomotor Agitation



Martínez-Raga J, Amore M, DiSciascio G, etal. 1st International Experts' Meeting on Agitation: conclusions regarding the current and ideal management paradigm of agitation. Front Psychiatry. 2018;9:54. doi:10.3389/fpsyt.2018.00054

Zeller SL, Citrome L. Managing agitation associated with schizophrenia and bipolar disorder in the emergency setting. West J Emerg Med. 2016; 17(2):165-172. doi:10.5811/westjem.2015.12.28763

Current Treatment Paradigm for Psychomotor Agitation

What are the Unmet Needs?

Characteristics of Drugs Commonly Used For Treatment of Psychomotor Agitation in Patients with Schizophrenia or Bipolar Disorder				
FACTOR	**Oral BZD**	**Oral Antipsychotic**	**IM BZD**	**IM Antipsychotic**
Calm without excessive sedation	NO	NO	NO	NO
Directly targets hyper-arousal mechanism of agitation	NO	NO	NO	NO
Non-invasive, non-traumatic route of administration	YES	YES	NO	NO
Rapid onset of action	NO	NO	YES	YES
Respiratory depression	YES	NO	YES	NO
Motor events	NO	YES	NO	YES

Martínez-Raga J, Amore M, DiSciascio G, etal. 1st International Experts' Meeting on Agitation: conclusions regarding the current and ideal management paradigm of agitation. Front Psychiatry. 2018;9:54. doi:10.3389/fpsyt.2018.00054

Zeller SL, Citrome L. Managing agitation associated with schizophrenia and bipolar disorder in the emergency setting. West J Emerg Med. 2016; 17(2):165-172. doi:10.5811/westjem.2015.12.28763

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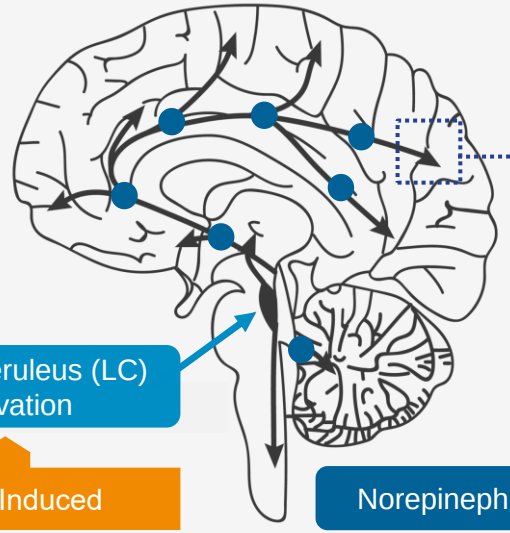
Mechanism of Action of IGALMI (Dexmedetomidine)

Dexmedetomidine has Been Shown to Reduce Hyper-arousal Through Selective Agonist Activity at Alpha-2A Adrenergic Receptors

Hyper-Arousal Physiology



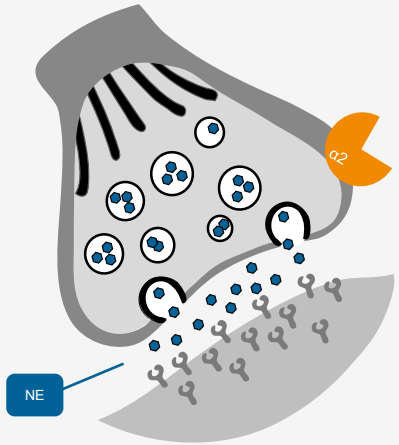
Locus Coeruleus (LC) Activation

Stress Induced

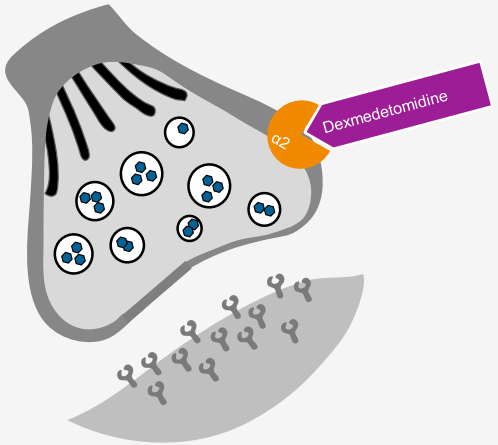
Norepinephrine (NE)

Schizophrenia | Bipolar Disorder | Dementia | Depression

Dexmedetomidine MoA



(+) Agitation



(-) Agitation

Preskorn, SH: Journal of Psychiatric Practice. 28(3):227-233, May 2022
Miller CWT, Hodzic V, Weintraub E. West J Emerg Med. 2020;21(4):841-848. doi:10.5811/westjem.2020.4.45779
IGALMI [package insert]. New Haven, CT: BioXcel Therapeutics, Inc.; 2022.

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Addressing Underlying Biology in Neuropsychiatric Symptoms

- LC neurons fire in a phasic mode. When stressed, LC neurons fire in a tonic mode.
- Tonic firing causes anxiety-related behaviors
- Inhibition of noradrenaline (NA) release potentially reverses this firing pattern and restores phasic activity

McCall JG, Al-Hasani R, Siuda ER et al. Neuron. 2015 Aug 5;87(3):605-20.

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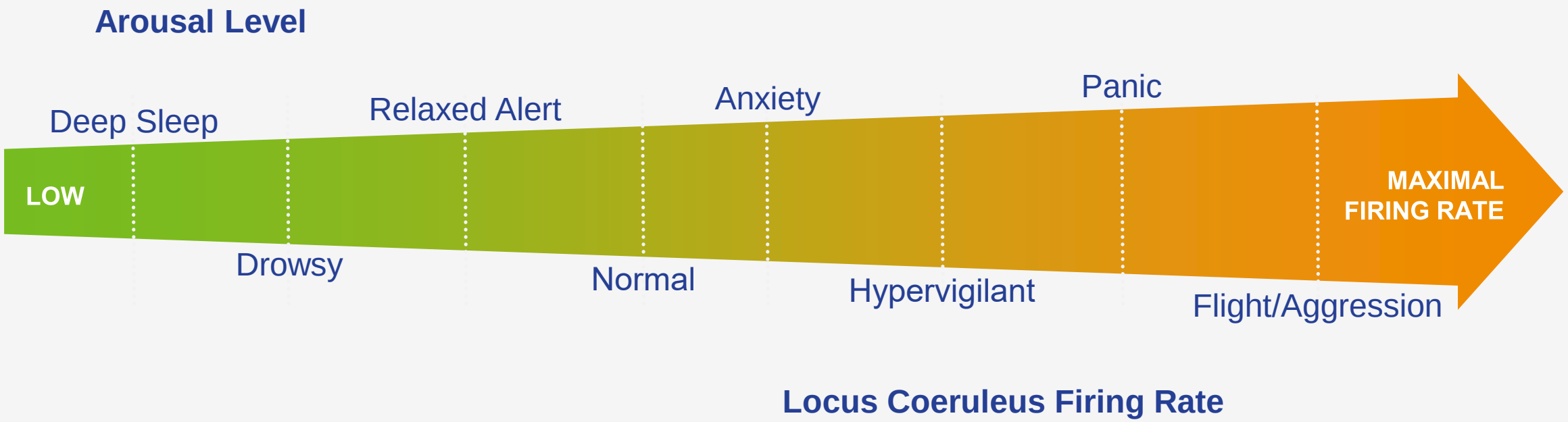
Levels of Arousal and Locus Coeruleus Activity



Preskorn, SH: Journal of Psychiatric Practice. 28(3):227-233, May 2022

DEXMEDETOMIDINE: Compared With Other Clinically Useful Alpha2 Adrenergic Agonists, has Highest Potency and Agonist Efficacy at Alpha-2 Receptors

DRUG	ALPHA-2A		ALPHA-2B		ALPHA-2C	
	EC_{50} (nM)	% Max Activity	EC_{50} (nM)	% Max Activity	EC_{50} (nM)	% Max Activity
DEXMEDETOMIDINE	**3.9**	**89**	**2.8**	**147**	**14**	**110**
Clonidine	25	76	49	49	43	32
Guanfacine	69	78	2010	110	45	72
Lofexidine	17	40	43	97	23	50

Data on File, BioXcel Therapeutics, Inc.

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Further Differentiation Amongst Various Alpha-2 Adrenergic Agonists: Selectivity for Alpha-2 Adrenergic vs. I1-imidazoline Receptors

Radioligand binding properties at I1-imidazoline and α2-adrenergic receptors (Ki, nM)

Drug	1-Imidazoline (1-I)	Alpha2-adrenergic	alpha2/1-I
Clonidine	1	3.8	0.26
Lofexidine	1	6.9	0.14
Guanfacine	2500	2.3	1100
Medetomidine*	14600	2.7	5400

**Racemate of dexmedetomidine*

Adapted from Ernsberger P, Friedman JE, Koletsky RJ. *J Hypertens Suppl.* 1997 Jan;15(1):S9-23

Psychomotor Agitation in Adult Patients with Schizophrenia or Bipolar I or II Disease

Patient Population for IGALMI

Igalmi™
(dexmedetomidine)
sublingual film · 120 mcg, 180 mcg

- Sublingual thin film formulation of dexmedetomidine
- Acts on the pathway of stress-induced agitation (sympathetic hyper-arousal)

Goals of Therapy

- Increase cooperation of mildly agitated patients (shorten time in hospital)
- Prevent escalation of mild to moderate to severe agitation

DEGREE OF AGITATION

	Patient's Feelings	PEC Score
SEVERE	• Aggressive • Violent • Desperate • Confused	31
MODERATE	• Insulting • Frightened • In danger	19
MILD	• Nervous • Tense • Grumpy • Anxious	13

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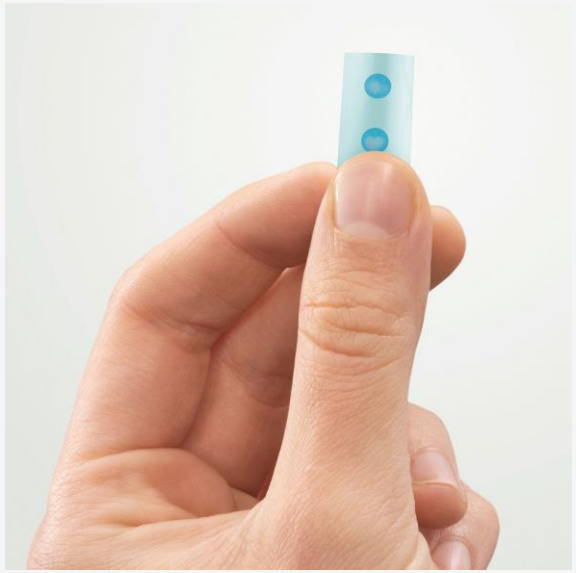
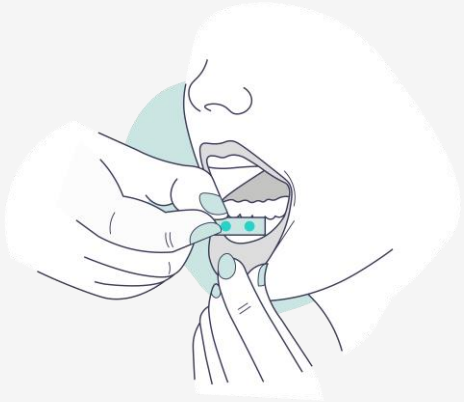
IGALMI: Easy-to-Administer Formulation





Proprietary, Immediate Delivery, Sublingual Thin Film Product

- ✓ Muco-adhesion properties designed for optimizing compliance
- ✓ Adaptable technology enables broad dose range
- ✓ Flexible for potential combination of multiple drugs on a single film
- ✓ Absolute bioavailability; 72% sublingual, 82% buccal
- ✓ Tmax ~ 2 hours; T1/2 = 2.8 hours
- ✓ IGALMI should be administered under the supervision of a healthcare provider, who should monitor vital signs and alertness after administration

IGALMI [package insert]. New Haven, CT: BioXcel Therapeutics, Inc.; 2022.

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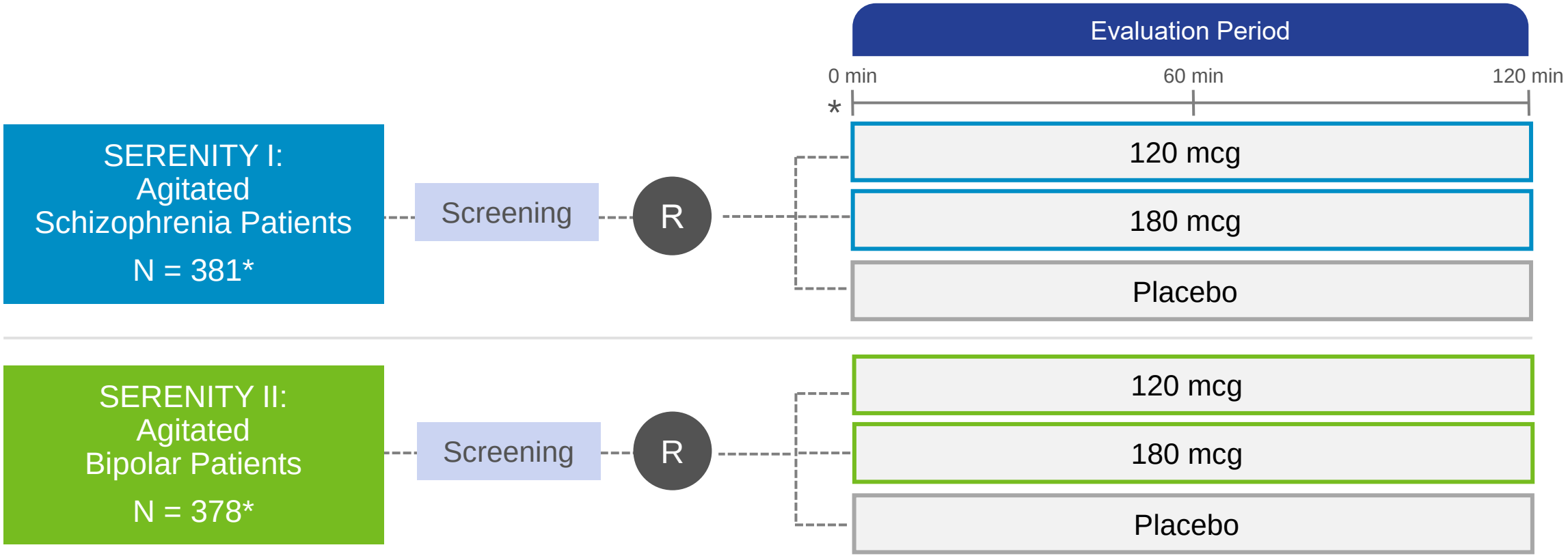
Robust Treatment Effect Observed in Two Phase 3 Studies

- Highly statistically significant improvements in PEC score observed vs. placebo ($p<0.0001$) at two hours in the SERENITY trials for both doses tested
- Statistically significant improvements in PEC score observed as early as 20-30 minutes after treatment
- All exploratory endpoints showed reductions in agitation measures that were durable
- IGALMI was well tolerated with no serious adverse events reported in clinical studies

Preskorn SH, Zeller S, Citrome L, et al. *JAMA*. 2022;327(8):727–736;
Citrome L, Preskorn SH, Lauriello J, et al. *J Clin Psychiatry*. 2022 Oct 3;83(6):22

SERENITY I & II: Two Pivotal Phase 3 Trials of IGALMI



* Patients Dosed

Primary Endpoint: Change from Baseline in PEC Score (PANSS-Excitatory Component) at 2 Hours Secondary Endpoint: Earliest Time Where an Effect on Agitation is Apparent

Preskorn SH, Zeller S, Citrome L, et al. *JAMA*. 2022;327(8):727–736;
Citrome L, Preskorn SH, Lauriello J, et al. *J Clin Psychiatry*. 2022 Oct 3;83(6):22

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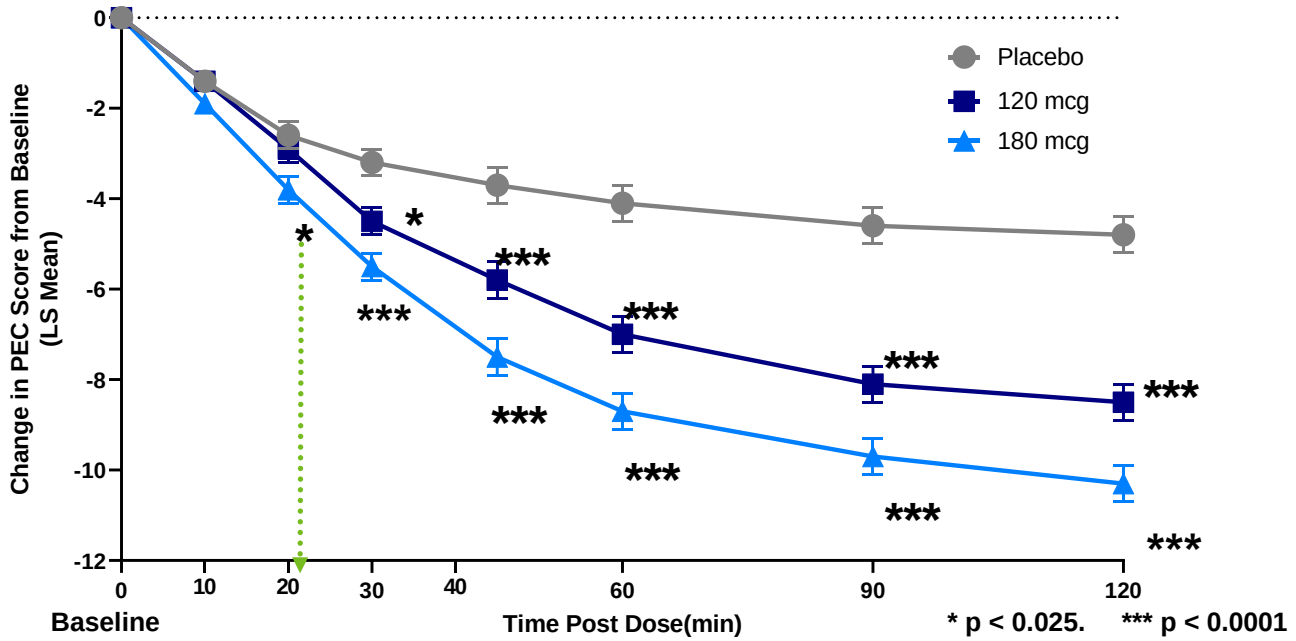
SERENITY I: Rapid Onset of Action Observed



Primary Endpoint at 120 min

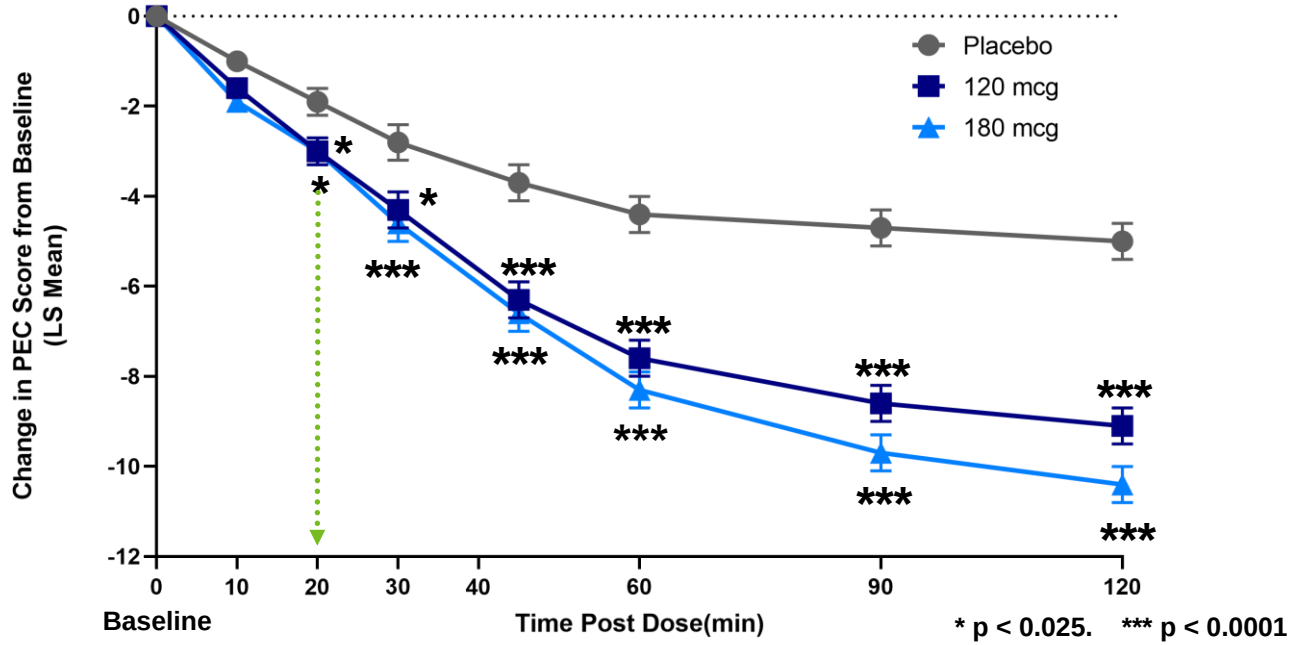
Endpoint (120 min)	Placebo	120 mcg	180 mcg
PEC Total score Change from Baseline	-4.8	-8.5 ***	-10.3 ***
Response°	34%	67%	87%

ITT analysis, Least Square Means +/-SEM analysis, should be interpreted with caution

° Proportion achieving ≥ 40% PEC reduction; pre-specified exploratory analysis, should be interpreted with caution

Citrome L, Preskorn SH, Lauriello J, et al. J Clin Psychiatry. 2022 Oct 3;83(6):22

SERENITY II: Rapid Onset of Action Observed



Time = 120 min (Primary Endpoint)

Endpoint (120 min)	Placebo	120 mcg	180 mcg
Primary: PEC total score change from Baseline	-5.0	-9.1 ***	-10.4 ***
Response°	37%	69%	85%

ITT analysis, Least Square Means +/-SEM analysis, should be interpreted with caution ° Proportion achieving ≥ 40% PEC reduction; pre-specified exploratory analysis, should be interpreted with caution

Preskorn SH, Zeller S, Citrome L, et al. *JAMA*. 2022;327(8):727–736

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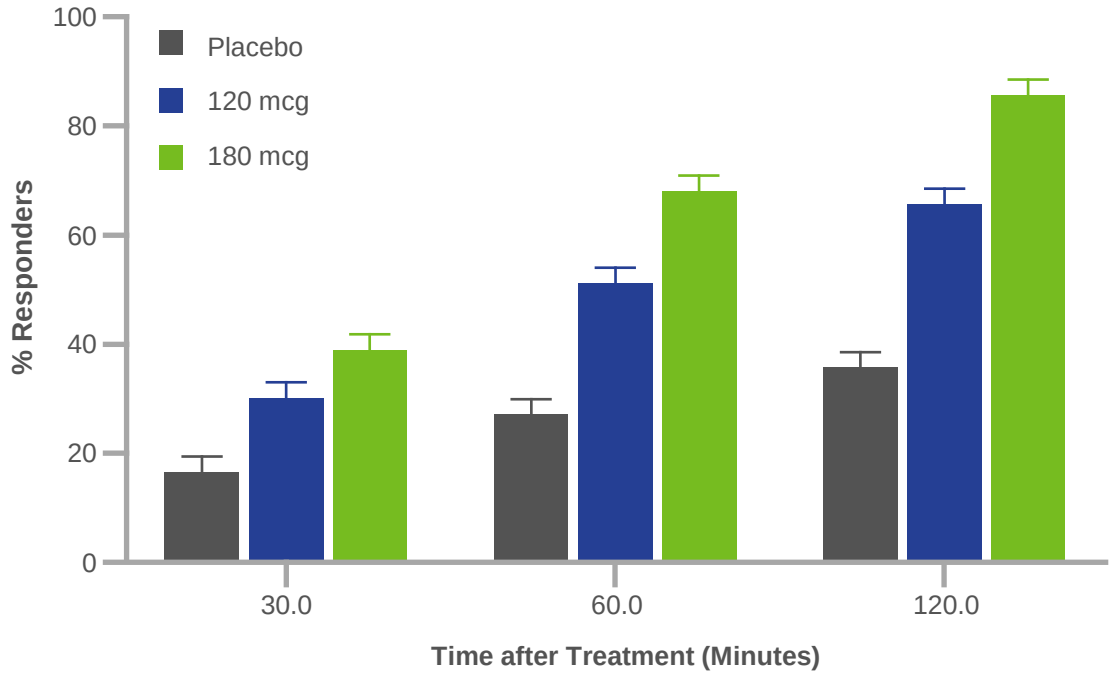
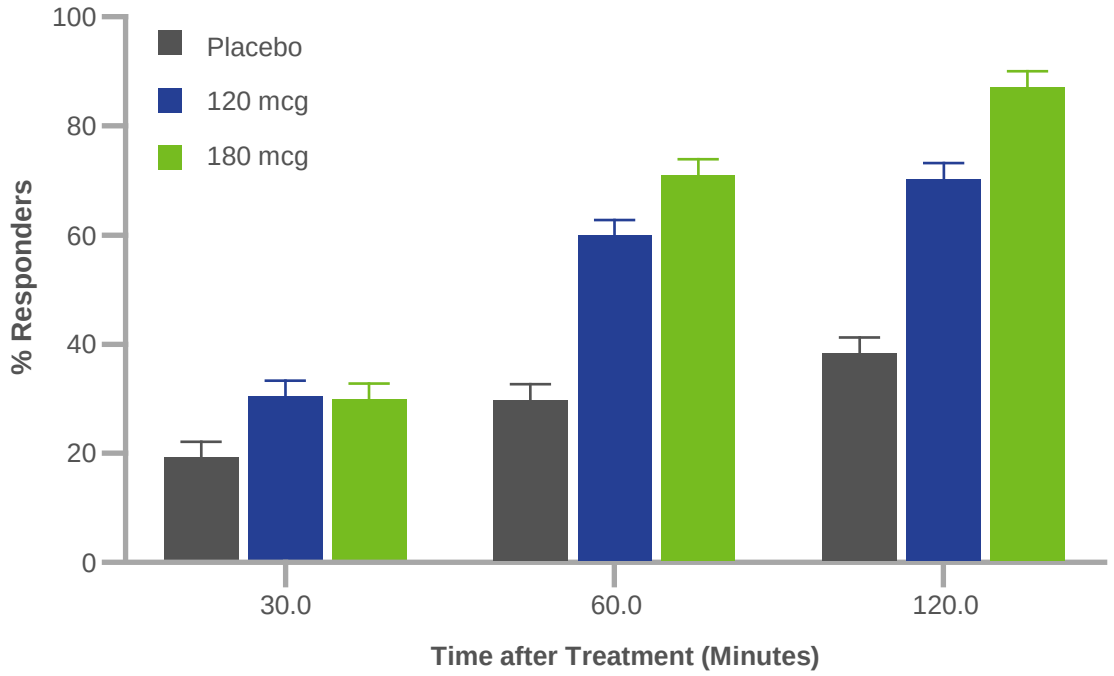
Clinically Meaningful Improvement Confirmed by CGI-I

SERENITY I



SERENITY II



Response Was Defined as "Very Much Improved" or "Much Improved" as Recorded by Study Investigators

The Clinical Global Impression scale – Improvement (CGI-I) is a 7-point scale.

ITT analysis; pre-specified exploratory analysis, should be interpreted with caution

Preskorn SH, Zeller S, Citrome L, et al. *JAMA*. 2022;327(8):727–736
Citrome L, Preskorn SH, Lauriello J, et al. *J Clin Psychiatry*. 2022 Oct 3;83(6):22

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IGALMI Was Well Tolerated with no Serious Adverse Events Reported in Clinical Studies

Integrated Safety Data From the two SERENITY Trials

		180 mcg BXCL501 (N=252)	120 mcg BXCL501 (N=255)	Placebo (N=252)
Somnolence	Mild Moderate	40 (15.9) 16 (6.3)	43 (16.9) 11 (4.3)	15 (6.0) 1 (0.4)
Dizziness	Mild Moderate	13 (5.2) 2 (0.8)	7 (2.7) 3 (1.2)	2 (0.8) 0
Hypotension	Mild Moderate	10 (4.0) 3 (1.2)	10 (3.9) 4 (1.6)	0 0
Orthostatic hypotension	Mild Moderate	9 (3.6) 4 (1.6)	7 (2.7) 0	1 (0.4) 0
Hypoaesthesia oral		12 (4.8)	7 (2.7)	1 (0.4)
Dry mouth		11 (4.4)	19 (7.5)	3 (1.2)
Nausea		7 (2.8)	6 (2.4)	4 (1.6)
Headache		6 (2.4)	12 (4.7)	12 (4.8)
Paraesthesia oral		6 (2.4)	7 (2.7)	1 (0.4)

All subjects self-administered the sublingual film under the supervision of a healthcare professional to monitor vital signs and alertness to prevent falls and syncope.

Treatment Emergent Adverse Events (TEAEs) with >2% incidence rate in one or more treatment groups are included, sorted by decreasing frequency in the order of 180 ug BXCL501, 120 ug BXCL501, Placebo. Subjects counted once at highest severity within each term based on MedDRA (Medical Dictionary for Regulatory Activities) version 23.0

IGALMI [package insert]. New Haven, CT: BioXcelTherapeutics, Inc.; 2022. and Data on File, BioXcel Therapeutics, Inc.

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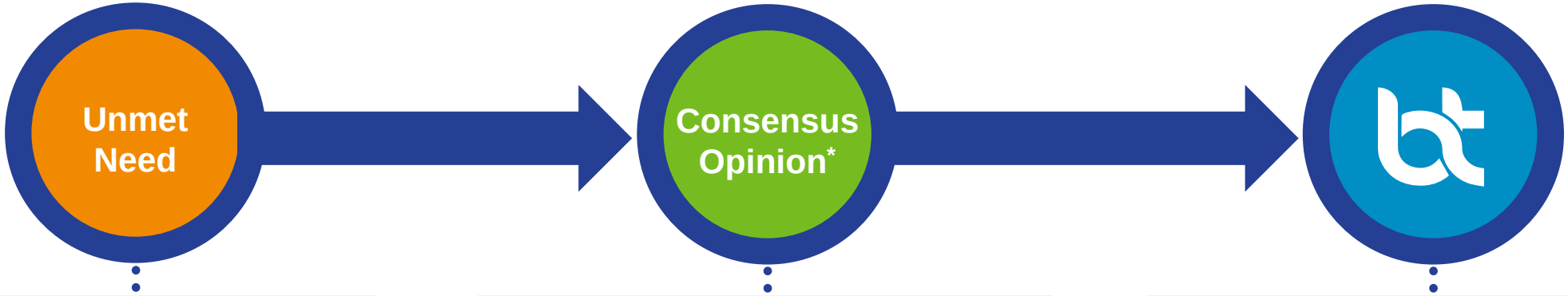
IGALMI: Sublingual Thin Film Dexmedetomidine for Acute Treatment of Agitation in Adult Patients with Schizophrenia or Bipolar I or II Disorder

Agitation: A Growing Global Healthcare Issue ($40B+)



There is a significant unmet need to improve the management of agitation

- ✓ **Non-invasive**
- ✓ **Calmness without unarousable sedation**
- ✓ **Easy to administer**
- ✓ **Rapid onset**
- ✓ **Non-traumatic /non-coercive**
- ✓ **Good safety profile**
- ✓ **Favorable tolerability**
- ✓ **Patient preference**

IGALMI: An Innovative Approach

- ✓ Mechanism of action (MoA) targets an important **pathway mediating psychomotor agitation**
- ✓ Non-invasive, easy to administer **sublingual film** with **onset of action as early as 20-30 min**

*1st International Experts' Meeting on Agitation: Conclusions Regarding the Current and Ideal Management Paradigm of Agitation, Frontiers in Psychiatry 2018

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The Front Lines of Agitation

Karen Sands, MSN, APRN-BC, ANP, CCRN, FCCM

Speaker is acting on behalf of and is a paid consultant to BioXcel Therapeutics, Inc.
This material is intended for an investor audience only.
The information contained in the following material is intended to provide background and educational information only and does not constitute medical advice. Individual results will vary among patients and depend on many factors. A patient's healthcare provider should consider the circumstances of each patient.

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34 Years of Nursing Experience

Career Highlights

Critical Care RN

1988 - 1993

Critical Care Educator

1993 - 2000

Critical Care NP

2000 - 2020

Hospitalist NP

2020 - present

Patient Presentation & Treatment Plan

Rapid Assessment & Diagnosis Needed

Fluctuation or change in mental status

Inattention

- Disorganized thinking
- Altered level of consciousness

PLAN – Determine the cause

- Psychiatric illness
  - Bipolar disorder
  - Schizophrenia
- Medical illness

Transitioning an Agitated Lion to a Calm Kitten!

- Stabilize
- De-escalation
- Rapid Treatment

Treatment Selection Considerations

Team Alliance & Needs

- **Team Needs**
  - **Nursing:** calm, cooperative, and comfort
  - **Pharmacy:** clinical pharmacokinetics and cost
  - **Physician/Advance Practice Provider:** assessable, stable, and transferable
- **Ideal Agitation Treatment Characteristics**
  - Easy to administer
  - Rapid onset of action
  - Effective and predictable dose response
  - Few adverse side effects
  - Lack of drug accumulation
  - Minimal adverse interactions with other drugs
  - Cost effective
  - Supports spontaneous respiration

Lessons Learned Over 3 Decades

- **Avoid Oversedation & Respiratory Depression That Causes:**
  - Hypoxia
  - Aspiration
  - Leads to endotracheal intubation
- **Absolute Goals:**
  - Support respiratory effort and avoid need for adjunctive airway support
  - Maintain hemodynamic stability
  - Maintain functional status on discharge equivalent to baseline
- **Current use of Dexmedetomidine**

Managing Agitation

Challenges and Patient Clinical Factors

Goals & Considerations

- **Hospital Length of Stay can be impacted by drug selection, dosing, and treatments**
- **Treating While Avoiding Over-sedation:**
  - Relieve anxiety and agitation
  - Improve compliance with care
  - Optimize safety
  - Facilitate communication with caregivers and family members
  - Avoid or reduce delirium
  - Minimal side effects

Patient Variables Impacting Treatment

- **Memory loss**
- **Confusion**
- **Medications**
- **Sleep Deprivation**
- **Mechanical Devices**
- **Loss of Control**
- **Constantly Changing Environment**

Autonomic Hyperactivity Resulting From Catecholamine Release During Stress

Symptoms

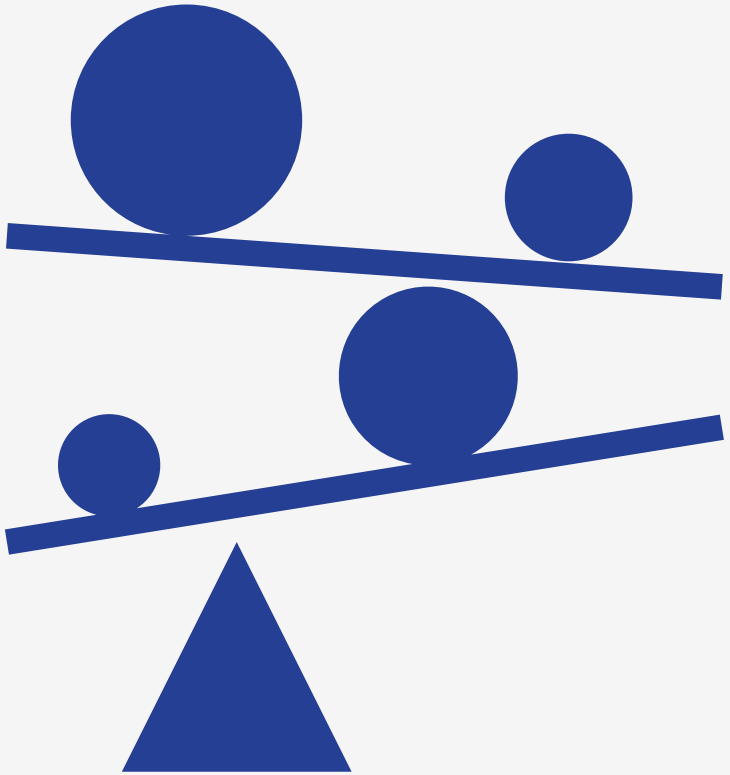
- Tachycardia
- Hypertension
- Diaphoresis
- Tremors
- Hallucinations
- Agitation
- Delusions

Agitation Symptom Management

- Challenging
- Requires frequent and close monitoring with increased level of care
- Extreme resources spent to prevent complications and death

The Balancing Act – Treatment Challenges & Outcomes

Impact of Treatment Oversedation vs. Ideal Patient Comfort



Negative Treatment & Oversedation Impact:

- Increased ICU, ED & Hospital Length of Stay:
  - Increased direct medical care & staffing costs
- Increased risk of complications:
  - Thromboembolic events
  - Healthcare-assisted pneumonia
- Need for additional diagnostic testing
- Increased ventilator use
- Increased risk of death
- Increased patient and staff injuries during treatment

Agitation Treatment Challenges in the ED

Patient Medical Complexities Presenting to the ED

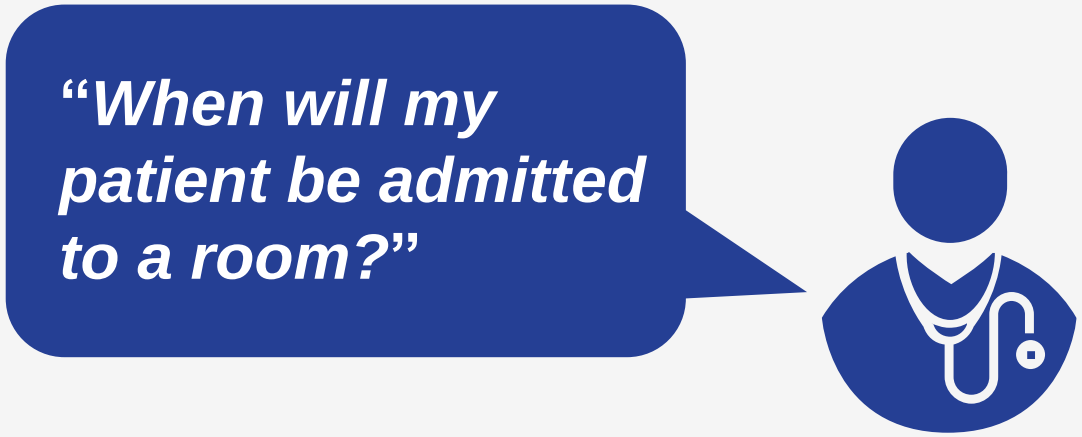
- **Cardiac Event:** Hypertensive Crisis or Myocardial Infarction
- Neurological Event
- Abdominal Catastrophe
- Endocrine Emergency
- Respiratory Failure due to Pneumonia or Viral Illness
- **Polysubstance Self-Medication Abuse:** Tobacco, vaping, alcohol, marijuana, crack cocaine, opiates (oral and IV), methamphetamine
- Medical Noncompliance

ED Challenges

Limitations & Staff Burnout Affecting Patient Care

Logistics Pressures:

- Lack of bed availability at a crisis level
- Staffing shortages limits optimal patient care
- Inadequate monitoring/telemetry beds
- Agitated patient held in ED vs. general floor



Physician Burnout by Specialty *(2021 Survey)*:

Top 4 Reporting Burnout by %

- Emergency Medicine: **60%**
- Critical Care: **56%**
- Obstetrics and Gynecology: **53%**
- Infectious Disease: **51%**

Physician Assistant Burnout *(2021 Survey)*:

Top 4 Reporting Burnout by %

- Critical Medicine: **38%**
- Emergency Medicine: **37%**
- Oncology: **35%**
- Hospital Medicine: **34%**

Case Studies: Safety Risks & Staff Injuries

Safety Risks From Escalation to Physical Aggression

Injuries: Staff & patients

Restraints:

- 10% of patients with schizophrenia and bipolar disorder require confinement and restraints
- Requires enhanced staff, monitoring, and documentation
- Need for security at bedside

Nurse 1	Nurse 2	Nurse 3
• Patient pulled nurse's arm	• Patient took fist and beat the back of nurse's neck • Permanent injury and out on worker's compensation	• Patient bit nurse on the arm • Human bite is as serious as animal bite – *Lab test costs* – *Time off work*

IGALMI™ – Medication Characteristics Desired by ED Staff

Rapid Response Team Option for the Agitated Adult Patient with Schizophrenia or Bipolar I or II Disorder

Ideal Agitation Treatment Characteristics

- ✓ Easy to administer
- ✓ 20-minute onset of action
- ✓ Effective
- ✓ Known safety profile
- ✓ Doesn't suppress respiration

Additional Staffing Needs

- Provider education on IGALMI and appropriate patient selection
- Broad hospital staff education on de-escalation techniques
- Staff education on benefits of IGALMI use

Hospital Process: How the System Works

Jacob Hanaie
PharmD, APh, BCPP

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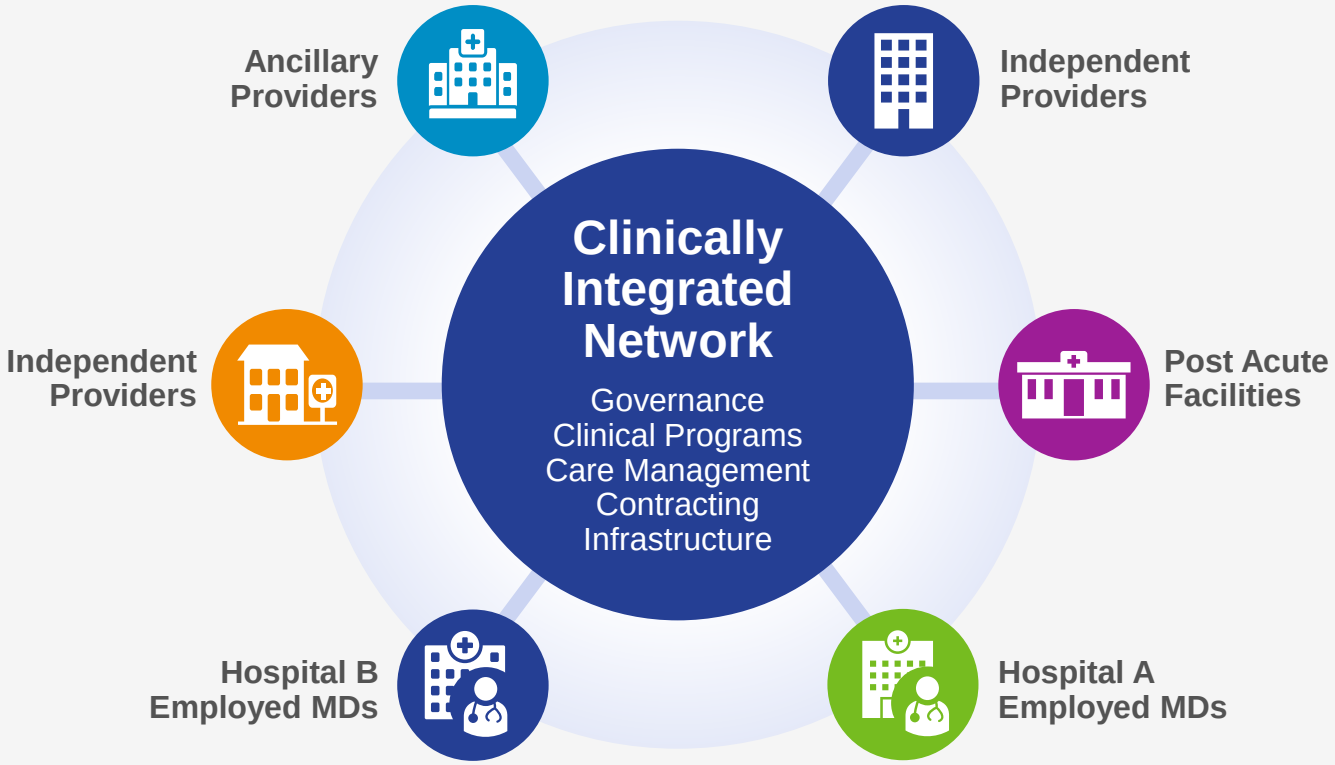
Complex Institutional Structures & Functions

Practice Groups and Hospital Networks



Non-integrated Group Practices & Hospitals

Multi-specialty Group Practices

Accountability Care Organizations (ACOs)

- Groups of doctors, hospitals, and other healthcare providers who come together voluntarily to give coordinated high-quality care to patients

Integrated Delivery Networks (IDNs)

- Health systems that aim to integrate healthcare organizations to consolidate missions and clinical operations
- **Examples:**
  - New York Presbyterian Healthcare System – NY
  - Yale New Haven Health System, New Haven, CT
  - Henry Ford Health System – Detroit, MI

Fully Integrated Delivery & Financing Systems

- **Example:** Kaiser

Complex Institutional Structures & Functions

Purchasing Groups

Group Purchasing Organizations (GPOs)

- Entities created to leverage purchasing power of a group of businesses to obtain vendor discounts based on collective buying power of GPO members
- Funded by administrative fees paid by vendors
- Examples:
  - Vizient
  - Premier
  - Health Trust

What's one thing these all have in common, regarding medication use policies?

Pharmacy and Therapeutics (P&T) Committee: Overview

- Meets regularly to **review newly available drug therapies**
- **Stays abreast of developments** in pharmacy market
- **Manages the formulary**
- Involved in **quality/cost initiatives**

Broad Functional Responsibilities

Policies & Procedures Develops, Reviews & Manages:

- Medication usage, ensuring safe and effective drug utilization
- Compliance with local, state, and federal laws and regulations
- Promoting cost-effective drug therapies
- Overseeing pharma-related relationships
- Treatment guidelines

Reviews, Develops, Oversees & Approves:

- Drug-related educational programs
- Drug-related staff trainings and orientations

Analyzes, Studies & Reports:

- Pharmacoeconomic studies / cost analysis
- Drug procurement
- Wholesaler contracting
- Advises Quality Assurance Department/committees
- Advises Infection Control Committee
- Reports and advises Medical Staff Committee
- Reviews scientific publications

Performance Improvement Focus Areas

PRESCRIBING

- Pharmacist interventions
- Incomplete orders
- PRN orders
- Patient demographics
- Non-formulary orders
- Experimental drug orders
- Verbal/telephone orders

DISPENSING

- Medication distribution/dispensing
- After-hour medication dispensing
- Dispensing error reporting
- Pyxis dispensing
- Compounded dispensing
- Medication cassette fill

ADMINISTRATION

- PRN (as needed) administration
- STAT/NOW (Immediate) order administration
- Administration timeliness
- Med-pass audits
- Pyxis reconciliation reports
- Medication administration record reconciliation

MONITORING

- Medication errors
- Food-drug interactions
- Drug-drug interactions
- Adverse drug reactions
- Black box warning medications
- Medical care evaluations
- Drug use evaluation
- Therapeutic drug monitoring

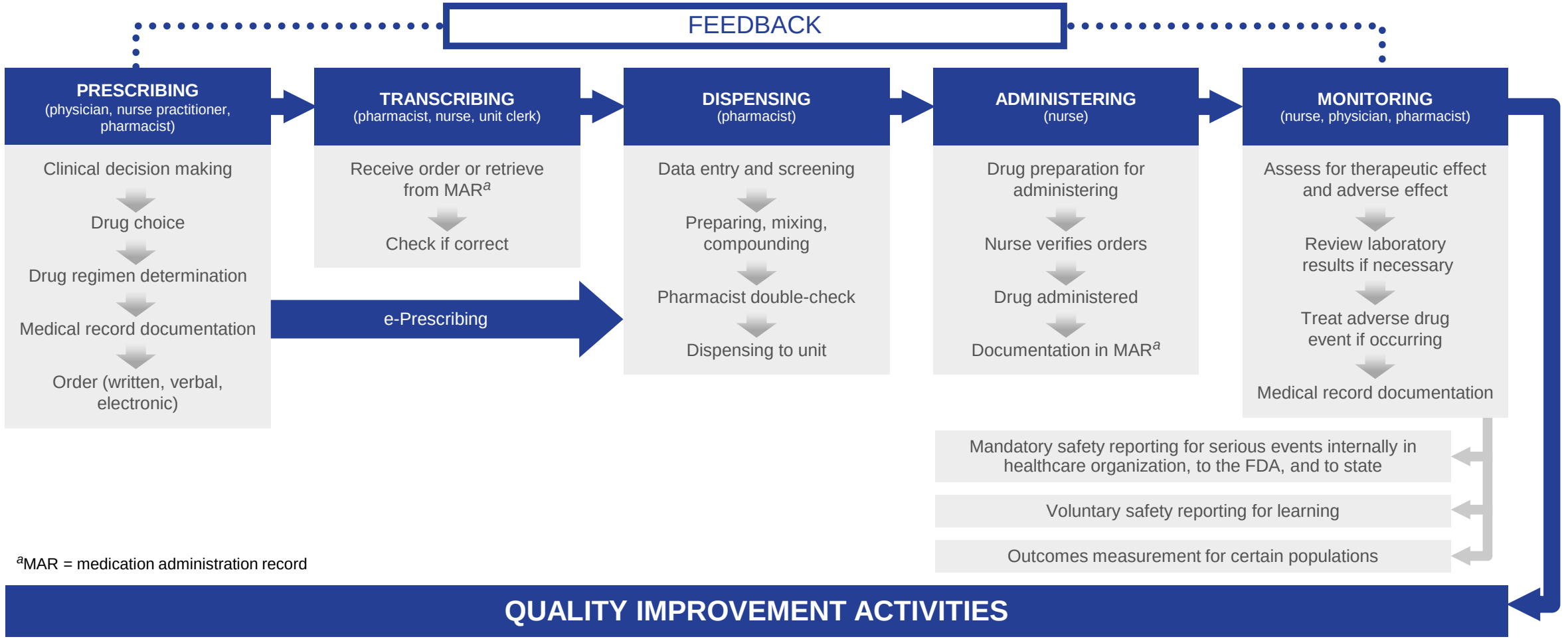
Broad Additional Responsibilities

- Review and redevelop drug monograph
- Coordinate drug recalls
- Develop & revise treatment guidelines
- Member of Medication-assisted Treatment (MAT) Committee
- Communicate with Therapeutic Assessment Committee (TAC)
- Communicate with Value Assessment Committee (VAC)
- Participate in cross-department and hospital-wide studies
- Oversee insurance coverage and prior authorizations

Formulary Medication Management

- New medications (~50 per year)
- Indication expansions
- Changes to package inserts
- Recalled meds (~1,300 per year)
- Compounding medication review
- Experimental drug usage
- Clinical trial studies

Continuous Feedback & Quality Improvement Process



[a]MAR = medication administration record

Any of these steps can affect treatment guidelines

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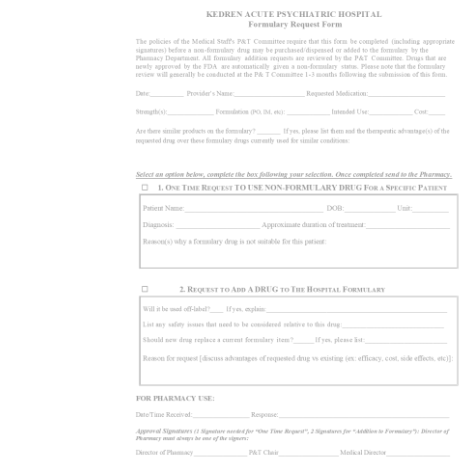
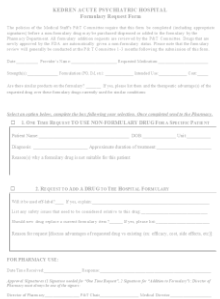
New Drug Formulary Process

Formulary Process: The Request Form





KEDREN ACUTE PSYCHIATRIC HOSPITAL
Formulary Request Form

The policies of the Medical Staff's P&T Committee require that this form be completed (including appropriate signatures) before a non-formulary drug may be purchased/dispensed or added to the formulary by the Pharmacy Department. All formulary addition requests are reviewed by the P&T Committee. Drugs that are newly approved by the FDA are automatically given a non-formulary status. Please note that the formulary review will generally be conducted at the P& T Committee 1-3 months following the submission of this form.

Date:_____ Provider's Name:_____ Requested Medication:_____

Strength(s):_____ Formulation (PO, IM, etc): _____ Intended Use:_____ Cost:_____

Are there similar products on the formulary? _____ If yes, please list them and the therapeutic advantage(s) of the requested drug over these formulary drugs currently used for similar conditions:

Select an option below, complete the box following your selection. Once completed send to the Pharmacy.

☐ **1. ONE TIME REQUEST TO USE NON-FORMULARY DRUG FOR A SPECIFIC PATIENT**

Patient Name:_____ DOB:_____ Unit:_____

Diagnosis: _____ Approximate duration of treatment:_____

Reason(s) why a formulary drug is not suitable for this patient:

☐ **2. REQUEST TO ADD A DRUG TO THE HOSPITAL FORMULARY**

Will it be used off-label?____ If yes, explain:_____

List any safety issues that need to be considered relative to this drug:_____

Should new drug replace a current formulary item?_____ If yes, please list:_____

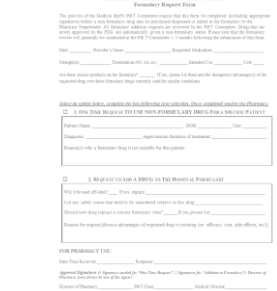
Reason for request [discuss advantages of requested drug vs existing (ex: efficacy, cost, side effects, etc)]:

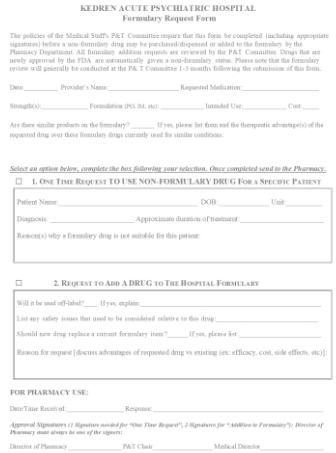
FOR PHARMACY USE:

Date/Time Received:_____ Response:_____

Approval Signatures (1 Signature needed for "One Time Request", 2 Signatures for "Addition to Formulary"): Director of Pharmacy must always be one of the signers:

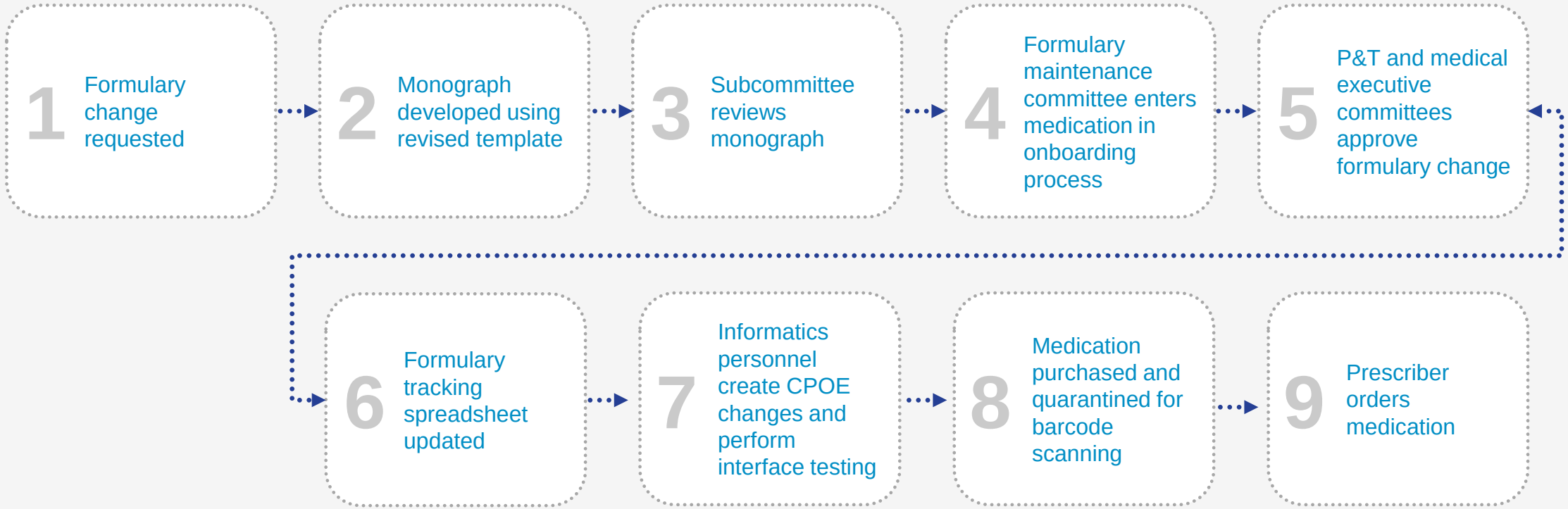
Director of Pharmacy_____ P&T Chair_____ Medical Director_____





From Formulary Change Request to Medication Orders

9-Step Process

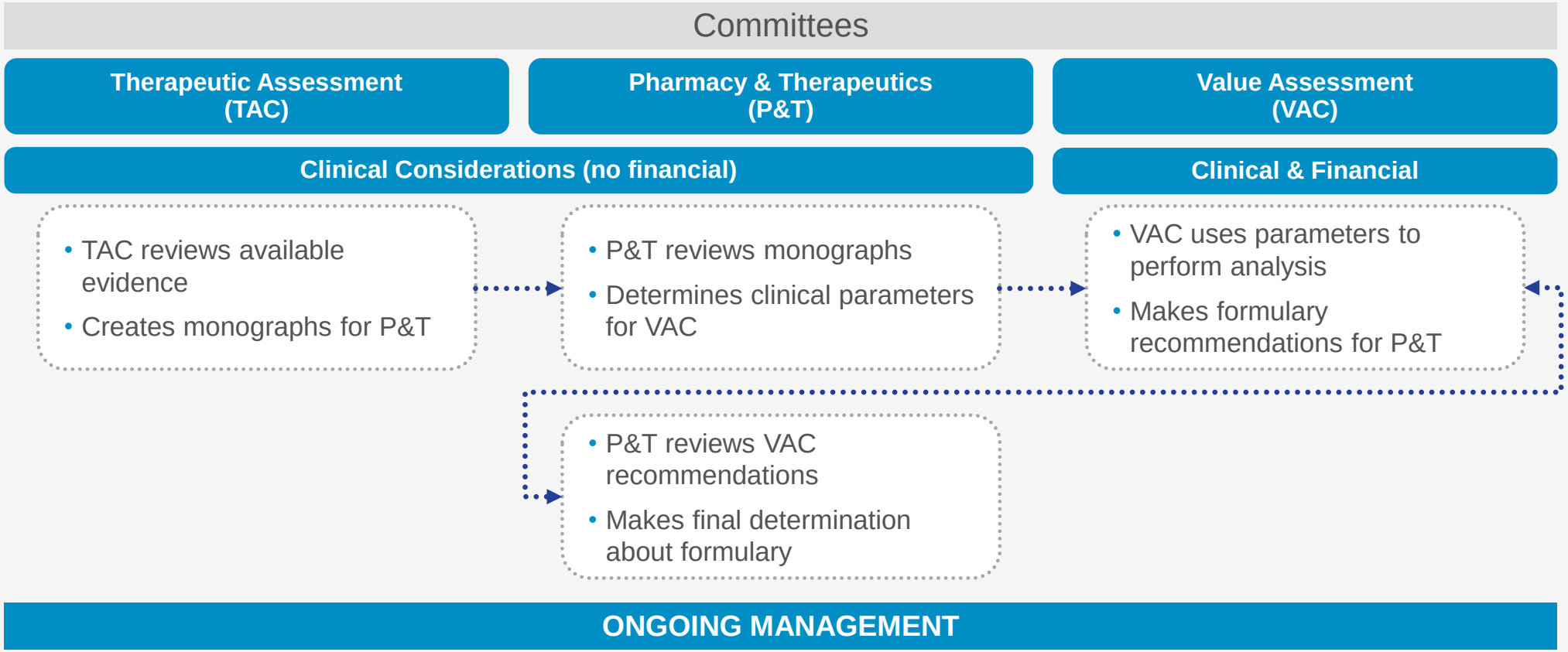


CPOE = Computerized Provider Order Entry

Multiple Committee Perspectives

Clinical & Financial Considerations

Formulary Development Process



COVID-19 Impact on P&T Committee

P&T Committee in Post-COVID-19 Environment

Might meet quarterly *(might not)*

Might meet in person *(might not)*

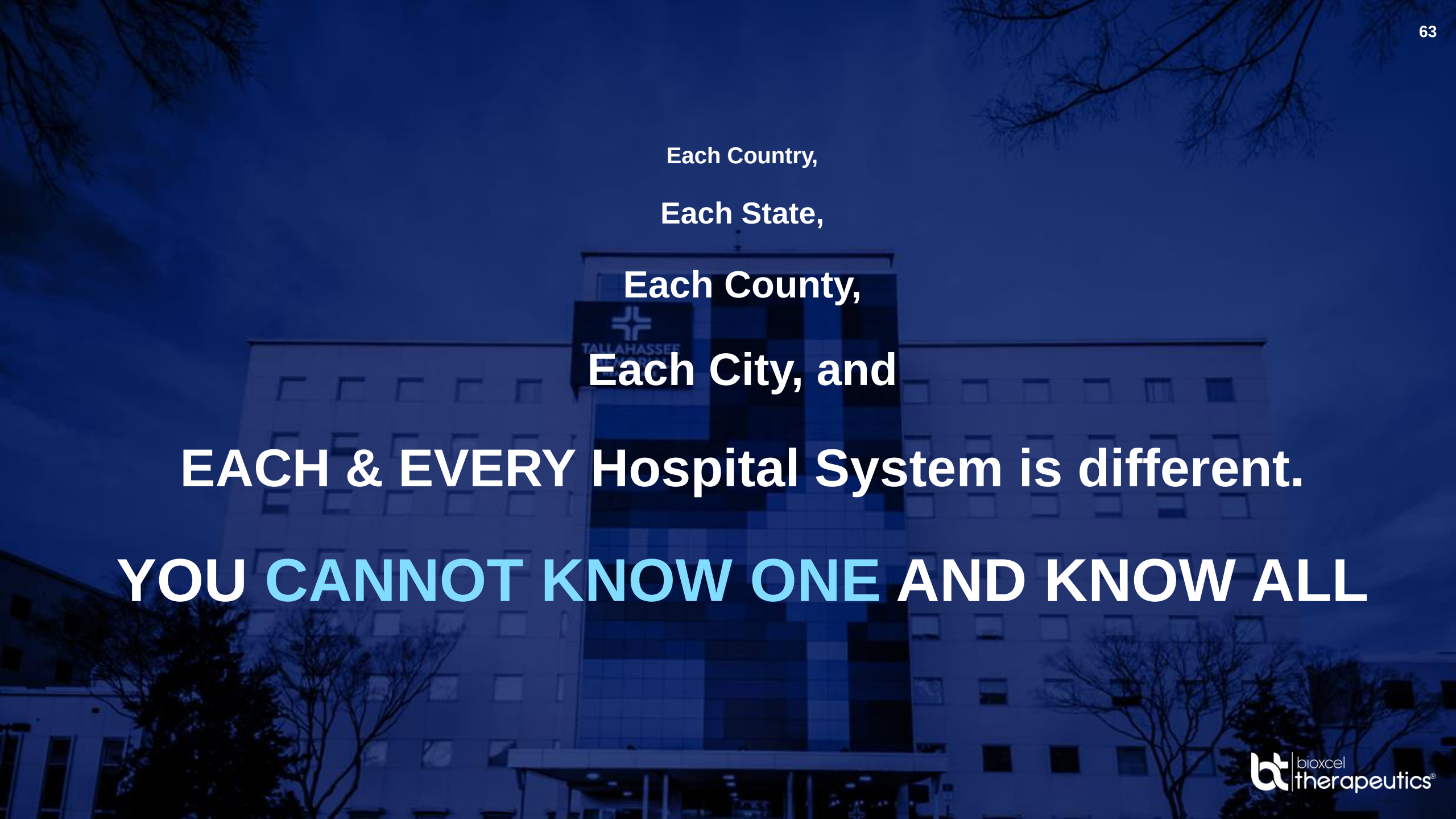
Might have ALL committee members *(might not)*

Extended time discussing COVID, Monkey Pox, infection control, etc.

Budgets have changed and/or shifted

Priorities have changed and/or shifted

Relationship with pharma has changed



Each Country,

Each State,

Each County,

Each City, and

EACH & EVERY Hospital System is different.

YOU CANNOT KNOW ONE AND KNOW ALL

IGALMI™ Commercial Overview and Updates

Matt Wiley
Chief Commercial Officer

bioxcel therapeutics®

Positive Commercial Momentum in Under 4 Months

Well-positioned to Maximize IGALMI™ Market Potential

- **Positive market reception** from key hospital stakeholders
- Highly favorable **market dynamics** to IGALMI™ value proposition
- **Gaining market access** across multiple institutions
- **Expanding national sales team** to cover ~1700 hospitals in 70 geographies

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The Trauma of Agitation: One Patient's Perspective

Patient Background

Bipolar Disorder

- Diagnosed >5 years ago
- 33-year-old female

Agitation Symptoms

- Multiple times per month

Care Summary

- ~35 ED/urgent care visits per year
- Has required inpatient care due to agitation episodes twice in the past 2 years

Image: womenshealth.gov
Source: inVibe Patient Agitation Market Research, July 2022 (n=57)

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The Trauma of Agitation: One Patient's Perspective

"I feel like there is no end to the agitation when it's happening. It's very frustrating because not only do I feel out of place mentally, but I also have physical feelings of nervousness. With the agitation, I get kind of tics where I pick at myself, or I'm trembling and I can't stop, or I'm shaking my leg or my foot. I just feel like it's both physical and emotional, and it's hard to control both at the same time."

–Anonymous Bipolar Patient

Image: womenshealth.gov
Source: inVibe Patient Agitation Market Research, July 2022 (n=57)

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The Evolving Agitation Market

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Agitation in Bipolar and Schizophrenia Represents $4B Market Opportunity

16M Institutional Episodes[1-3]

+

23M At-Home* Rx & Self-Managed Episodes[1-4]

=

39M Agitation Episodes

Igalmi™ (dexmedetomidine) sublingual film · 120 mcg, 180 mcg

SERENITY III Pivotal Trial

*Investigational use; safety and efficacy not established

1. Wu, 2006, NAMI 2. NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf 3. Data on File 4. inVibe Patient Agitation Market Research, July 2022 (n=57) 5. Estimate based on 39M episodes @ $105/episode

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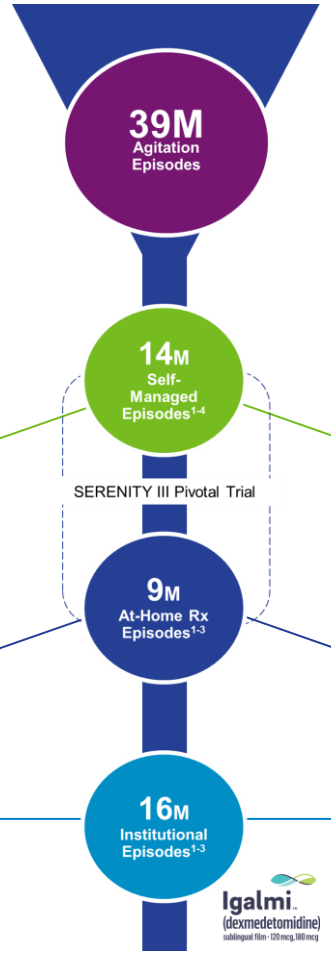
Market Opportunity Segmentation

Amalgamation of Market Research and Epidemiology-based Prevalence Publications

Bipolar Disorders I & II (BPD)	Outcome
US Adult Population (78%)	259,740,000
BPD Prevalence (2.80%)	7,272,720
BPD Dx Total (82.90%)	6,029,085
BPD Agitation Patients (21%)	1,266,108
Self-Managed BPD Episodes (10/year)	**12,661,078**
BPD Agitation Episodes (17/year)	21,523,833
At-Home Rx BPD Episodes (36%)	**7,748,580**
Institutional BPD Episodes (64%)	**13,775,253**
Total BPD Agitation Episodes	**34,184,911**



Outcome	Schizophrenia (SCZ)
259,740,000	Adult Population (78%)
1,636,362	SCZ Prevalence (0.63%)
1,309,090	SCZ Dx Total (80%)
327,272	SCZ Agitation Patients (25%)
1,309,090	Self-Managed SCZ Episodes (4/year)
3,272,724	SCZ Agitation Episodes (10/year)
916,363	At-Home Rx SCZ Episodes (28%)
2,356,361	Institutional SCZ Episodes (72%)
4,581,814	**Total SCZ Agitation Episodes**

1. Wu, 2006, NAMI 2. NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf 3. Data on File 4. inVibe Patient Agitation Market Research, July 2022 (n=57)

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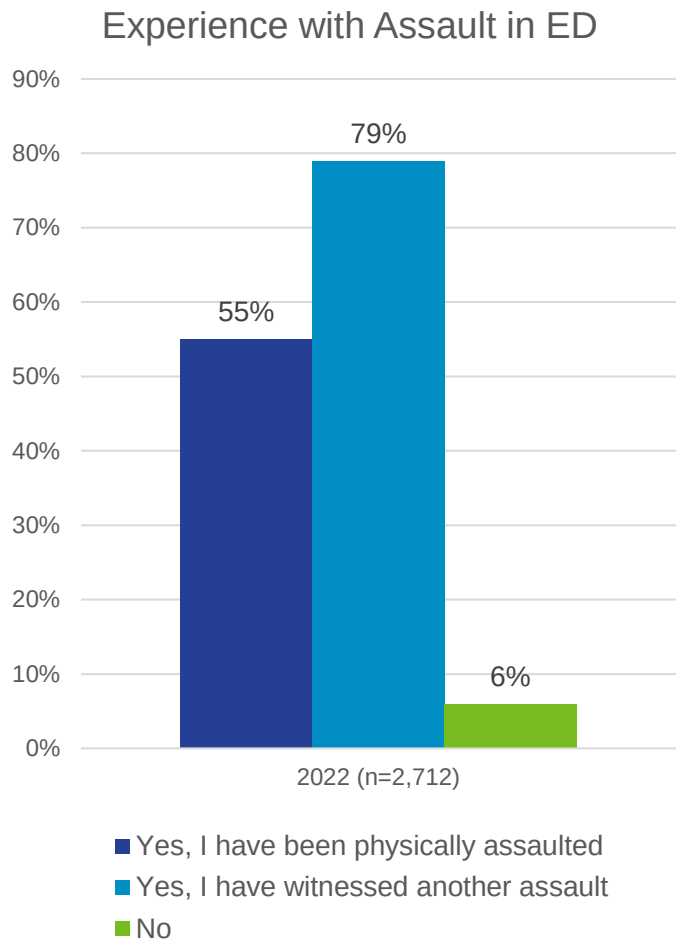
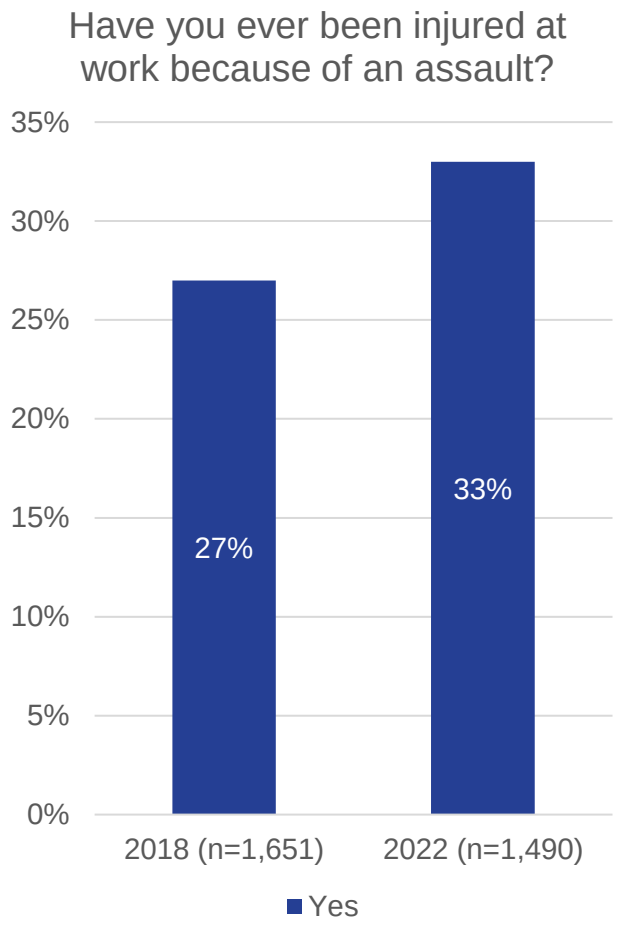
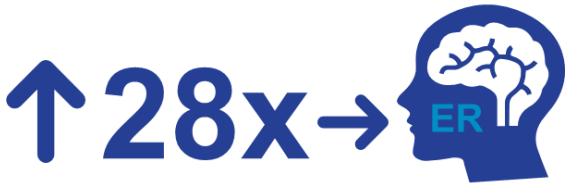
55% of Physicians Surveyed in ACEP Poll* Have Been Assaulted

Assault-related Injuries on the Rise







Increase in odds of assault by patient with diagnosis of schizophrenia, schizoaffective, or bipolar disorder with manic symptoms in psychiatry emergency room

*Source: American College of Emergency Physicians Emergency Department of Violence Poll Results, 2022.
Lawrence RE, et al. J Am Acad Psychiatry Law. 2020; 48(44)8:484-495.

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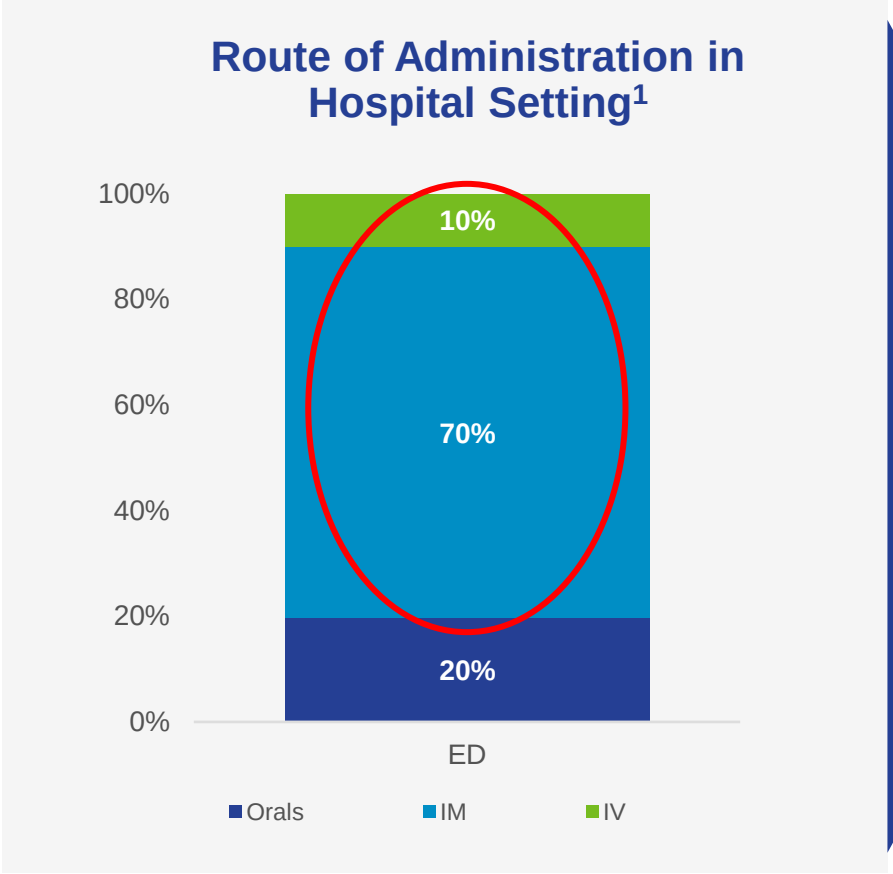
80% of Patients Administered Invasive Treatments for Agitation

Coercive Approach may Escalate Agitation



Patients acknowledge their agitation often escalates while in emergency-care setting[2]

Needle phobic, invasive approach, don't like being touched, "feel like I'm being euthanized," perceptions of being a "guinea pig"

Patients and caregivers alike report many negative emotions associated with physical or chemical restraint

1 Huron Market Landscape 2020 BXCL 501 – Key Insight Generation MR Findings (February 2021),
2 BXCL501 Positioning Study Patients & Caregivers Final Report (April 2021)

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Commercial Infrastructure & Progress

Fully Integrated and Experienced Commercial Team

Designed to Meet Today's Needs and Future Demands

MARKETING

Driving Market Awareness and Interest

MARKET ACCESS

Navigating stakeholder contracting & oversight

SALES

Driving hospital demand and pull-through

ANALYTICS/OPERATIONS

Delivering key insights and enabling productivity

TRAINING

Optimizing commercial skillsets

DISTRIBUTION

Ensuring steady, consistent national supply

Impactful Marketing Messages and Value Proposition

IGALMI™: First and Only Sublingual Film for Acute Treatment of Agitation Associated with Schizophrenia or Bipolar I or II Disorders[1]

Core Message	HCP Benefit
IGALMI reduces norepinephrine release, a key mediator of agitation[1]	Novel mechanism approved for treating agitation
Significantly reduced agitation beginning as early as 20 minutes[1]	Ability to reduce agitation in reasonable and desirous timeframe in non-invasive option
The effects of IGALMI were studied across a spectrum of agitation severity[1]	80 to 90% of all patients responded to treatment at 2 hours
Proven safety profile in clinical trials[1]	No serious treatment-related adverse reactions were seen in clinical trials

Limitations of Use: The safety and effectiveness of IGALMI have not been established beyond 24 hours from the first dose.
See Important Safety Information on slide 3

HCP=healthcare professional.
*Approximately 80-90% of patients who received IGALMI vs. ~40-46% of patients who received placebo were considered PEC responders (achieving ≥40% reduction in total PEC) at 2 hours.
1. IGALMI [package insert]. New Haven, CT: BioXcel Therapeutics, Inc.; 2022. 2. Data on file. BXCL501-301 CSR (SERENITY I). BioXcel Therapeutics, Inc.; January 2021. 3. Preskorn SH, et al. *JAMA.* 2022;327(8):727-736.

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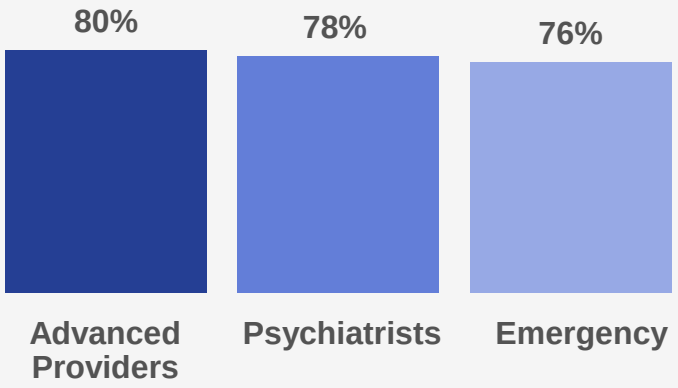
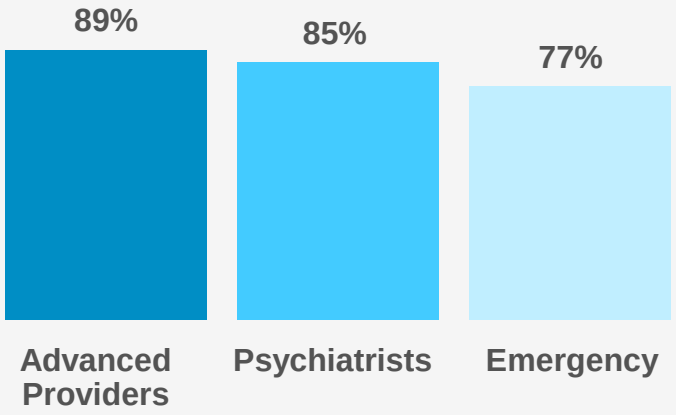
Stated Utilization of IGALMI™ Doubles When Provided Within Context of Promotional Messaging

Product Profile Reactions[1]

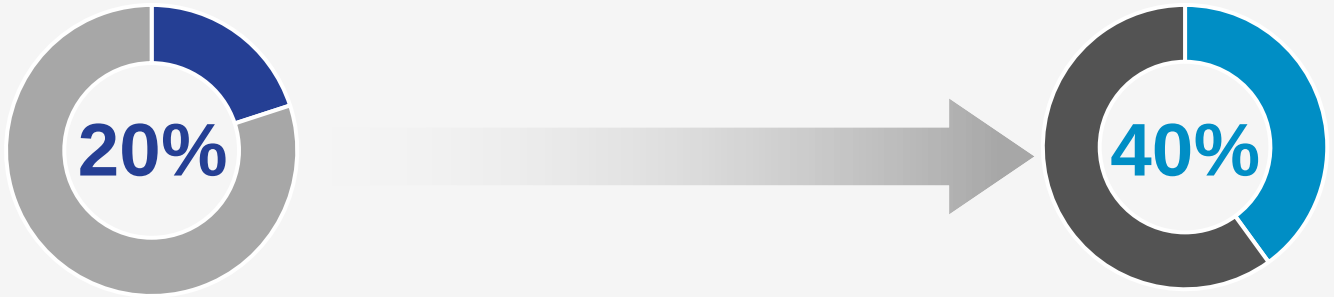
Positive Impressions (Top3 Box)



Detail Aid Presentation Reactions[2]



HCP Stated Utilization



1. HCP ATU Landscape Research, January 2022
2. HCP Quantitative VisAid Testing, December 2021

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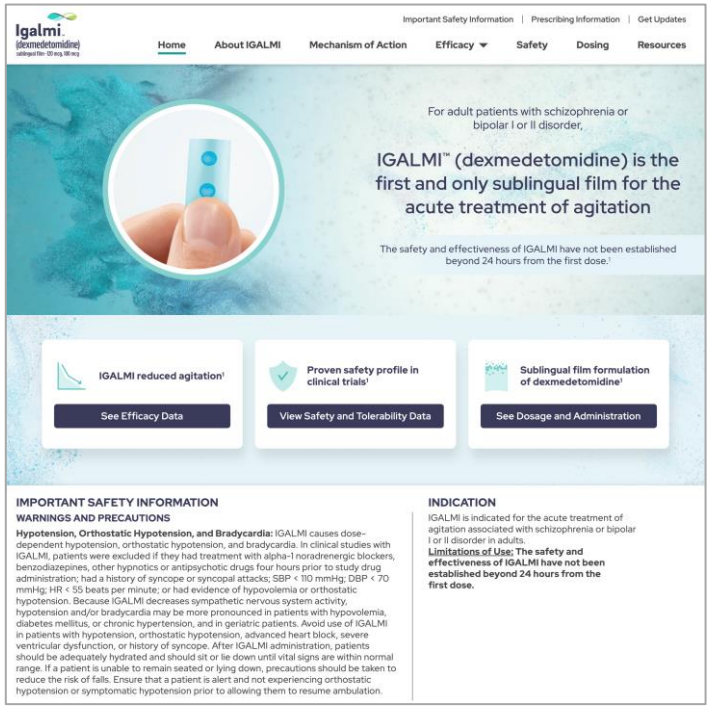
Marketing Efforts are Reaching Providers Through Peer Programs, Conventions, and Digital Media



ashp pharmacists advancing healthcare

AMERICAN PSYCHIATRIC ASSOCIATION

American Psychiatric Nurses Association

American College of Emergency Physicians®

SAEM Society for Academic Emergency Medicine

ENA EMERGENCY NURSES ASSOCIATION

AAEP

Psych Congress

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Market Access

High-priority Focus on Key Stakeholder Groups to Generate Access

GPOs

- Group purchasing organizations (GPOs) contract with manufacturers on hospitals' behalf and provide pass-through discounts

IDNs

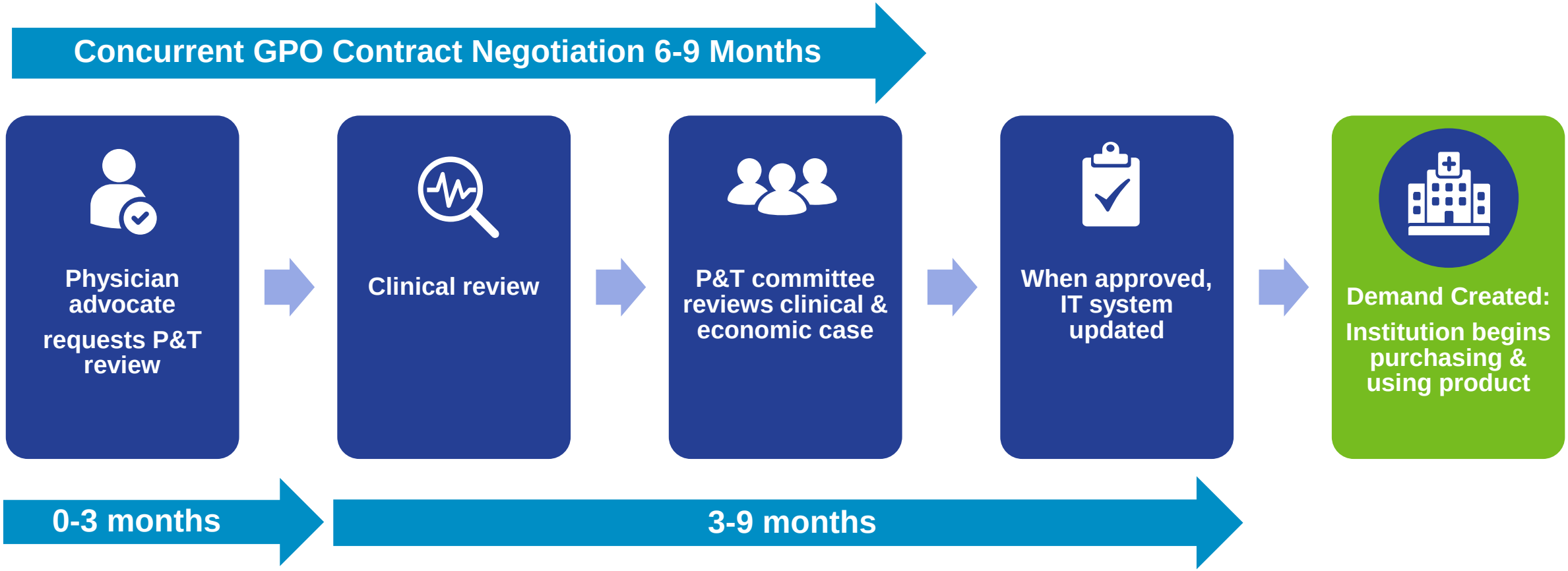
- Integrated delivery networks (IDNs) are a network of providers that deliver coordinated and integrated care within a geographic area

HCOs

- Healthcare organizations (hospitals) have their own Pharmacy and Therapeutics (P&T) committee and access barriers

Working to Gain Hospital Formulary Access and Drive Demand

Navigating Contracting and P&T Process



Source: BioXcel Therapeutics Market Research, Data on File

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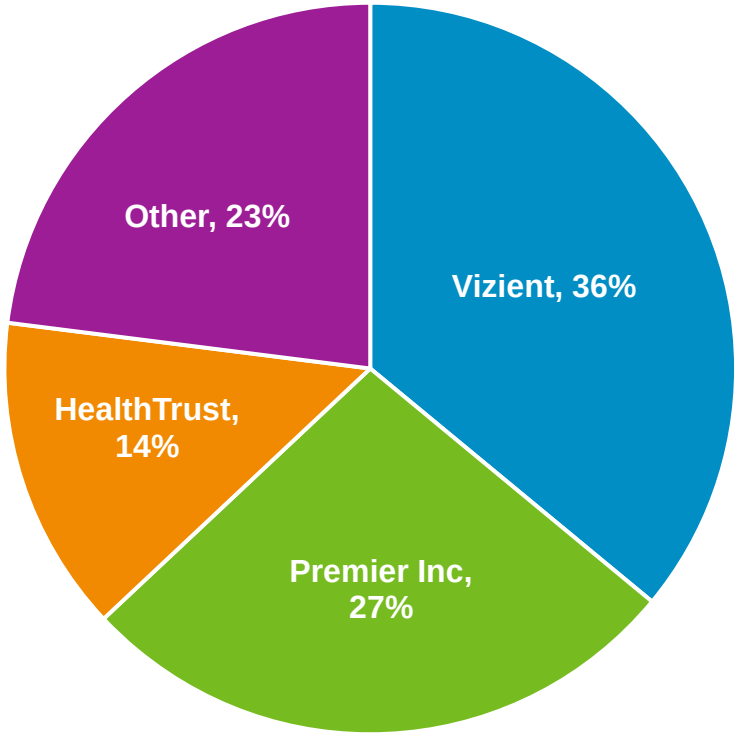
IGALMI™ Now Contracted with Nearly Half of Targeted U.S. Hospital Beds

Top 3 GPOs Influence 77% of Staffed Beds in the U.S. and >90% of IGALMI Target Beds

Bed Volume by GPO



GPO Contracting Process

- **Vizient contract executed and effective October 1, 2022**
- **~46% of all target hospital beds now covered**
- Other GPOs in advanced stages of engagement

Data from Definitive Healthcare matched to BTAI target model. Data accessed September 2022

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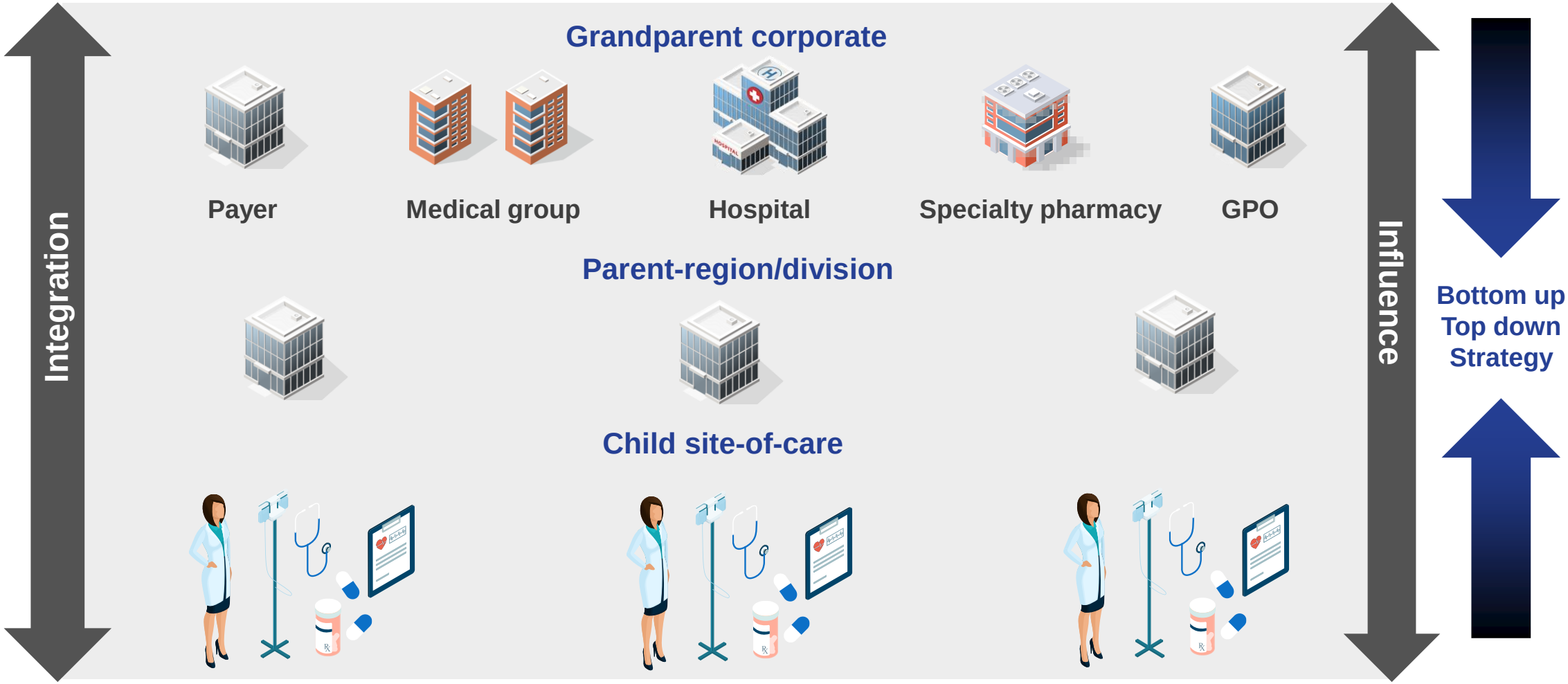
Corporate IDNs Have Varying Degrees of Control and Influence

Key Focus for Corporate Account Directors



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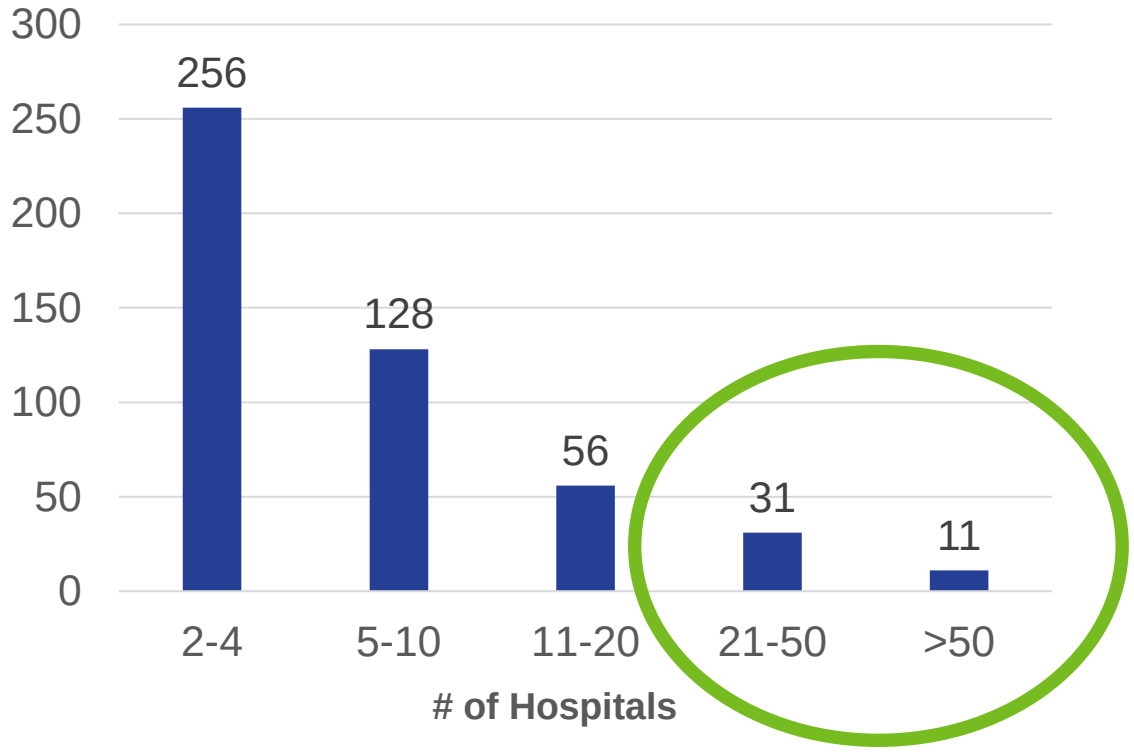
~10% of IDNs Control Majority of IDN-affiliated Hospitals in U.S.

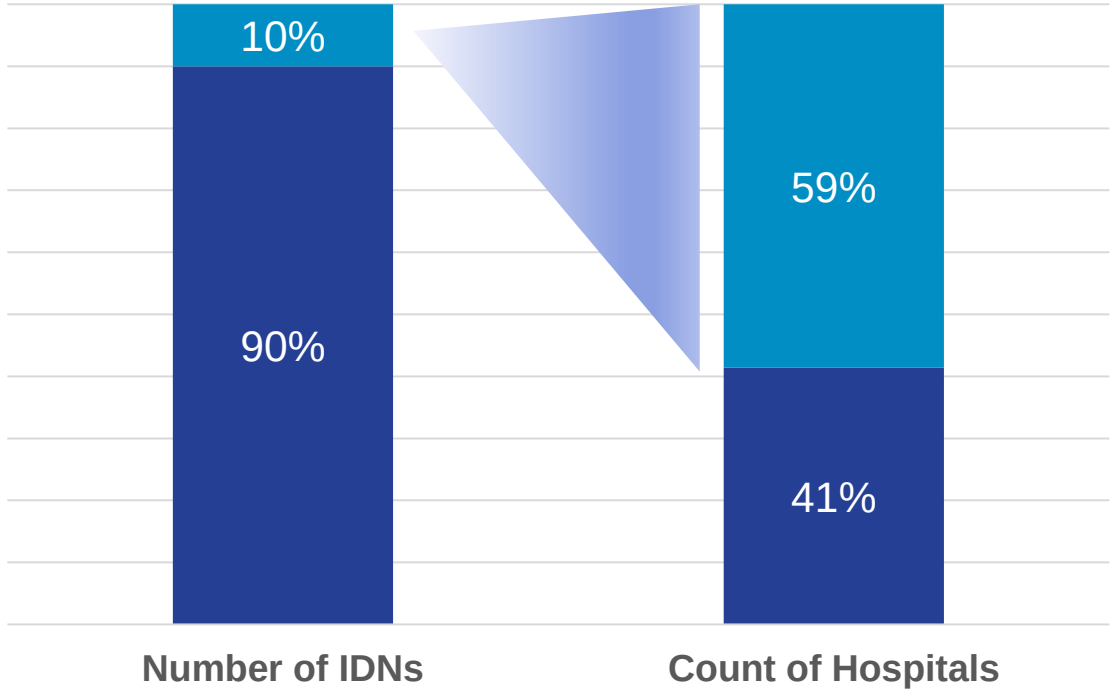
Core Execution Focus

Most IDNs are Small and Regional



Distributions of IDNs by # of Hospitals

Top 10% of IDNs control ~60% of IDN affiliated Hospitals



Source: Veeva Open Data, July 2021; Symphony Source Non-Retail, July 2021

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59 IDNs Represent One-Third of Target Hospital Beds

Can Affect Protocols and Pathways in Additional Network Hospitals

★ Large High controlling IDNs (Priority)

★ Large High controlling IDNs (Tier 2 Targets)

Corporate Account Team Focus

- Corporate Account Director (CAD) Team deployed to engage with target IDNs in 3Q
- Coordination between sales and CAD team designed to drive interest and adoption of these systems
- Key Metrics:
  - 33% of all targeted beds
  - 37% of all targeted agitation episodes
  - 38% of all targeted agitation patients

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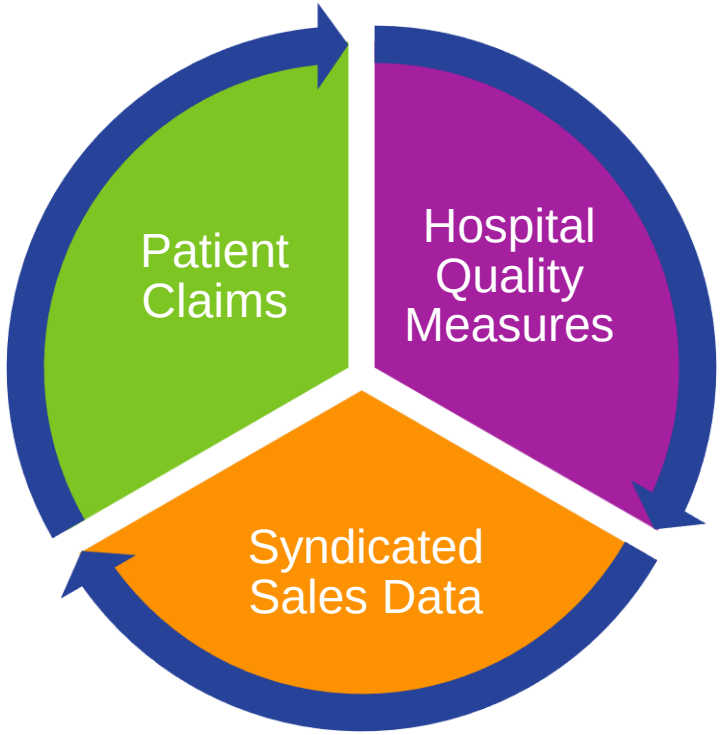
Unique Precision Targeting Using 81B Record Data Lake

Refined Priorities for Sales Force Expansion

Factors include hospital beds, antipsychotic utilization, agitation episodes, repeat patient visits, among others



Key Targeting Metrics

- ~1700 priority target hospitals
  - Represents majority of bipolar or schizophrenia agitation episodes and patient volume
  - Represents ~80% of total psych beds

Sources: 1. American Hospital Association. 2. Clarivate claims data..

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Sales Force Deployment and Field Intelligence

Brenden Schulek
Vice President, Sales

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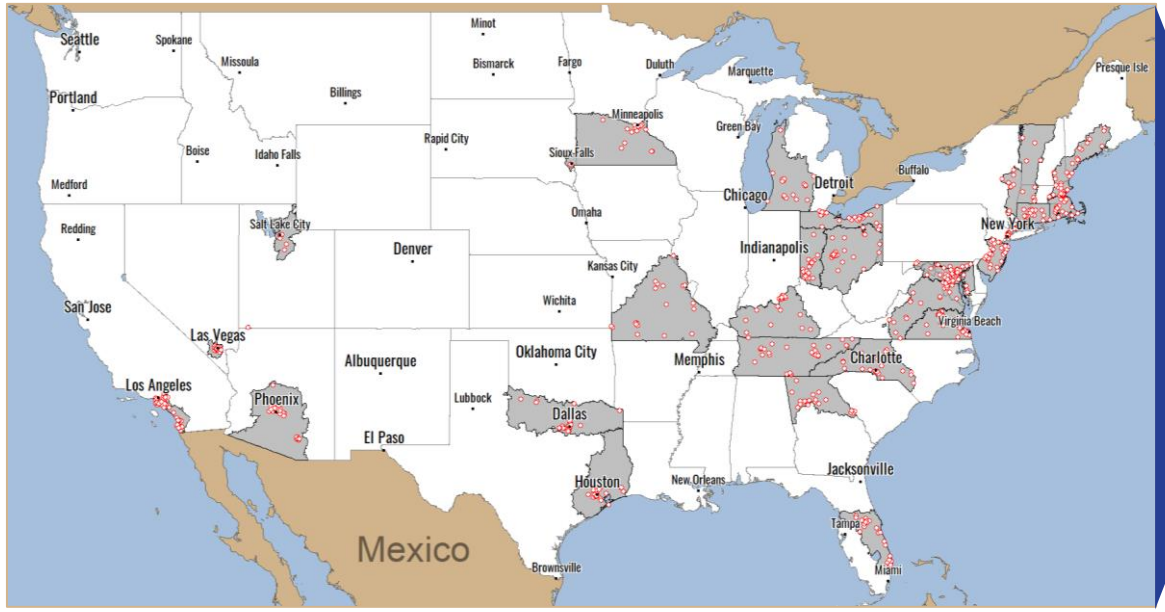
Field Force Expansion Nearing Completion; Plan to Mobilize Sales Efforts Against ~1,700 Target HCOs

Representing ~70% of Commercial Opportunity; Covers all Major U.S. Population Centers

Wave One Target Coverage: 37%

2022



Wave Two Target Coverage: 100%

2023

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Institutional Specialists Have In-depth Hospital Experience & Expertise

Averaging 8 Commercial Launches Each

22 year average experience in **pharma/biotech sales**

14.5 year average experience in **hospital sales**

8.5 year average selling in **emergency setting**

6.5 year average selling in **CNS market**

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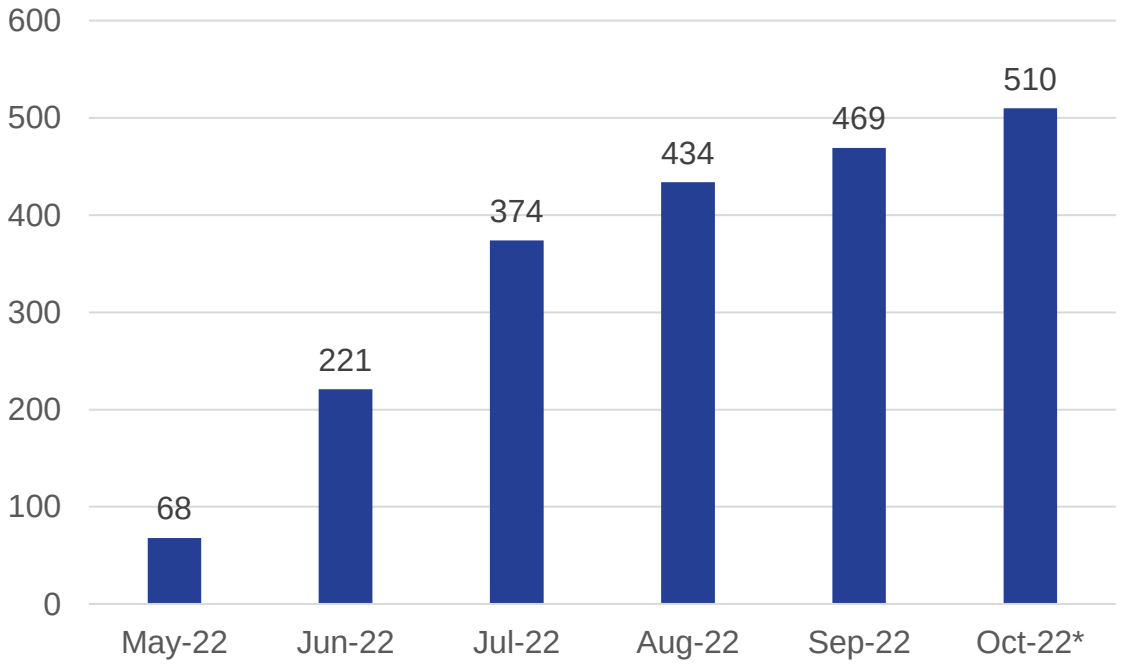
First Wave Sales Team has Penetrated Two-Thirds of Target Universe and Continues to Expand Reach

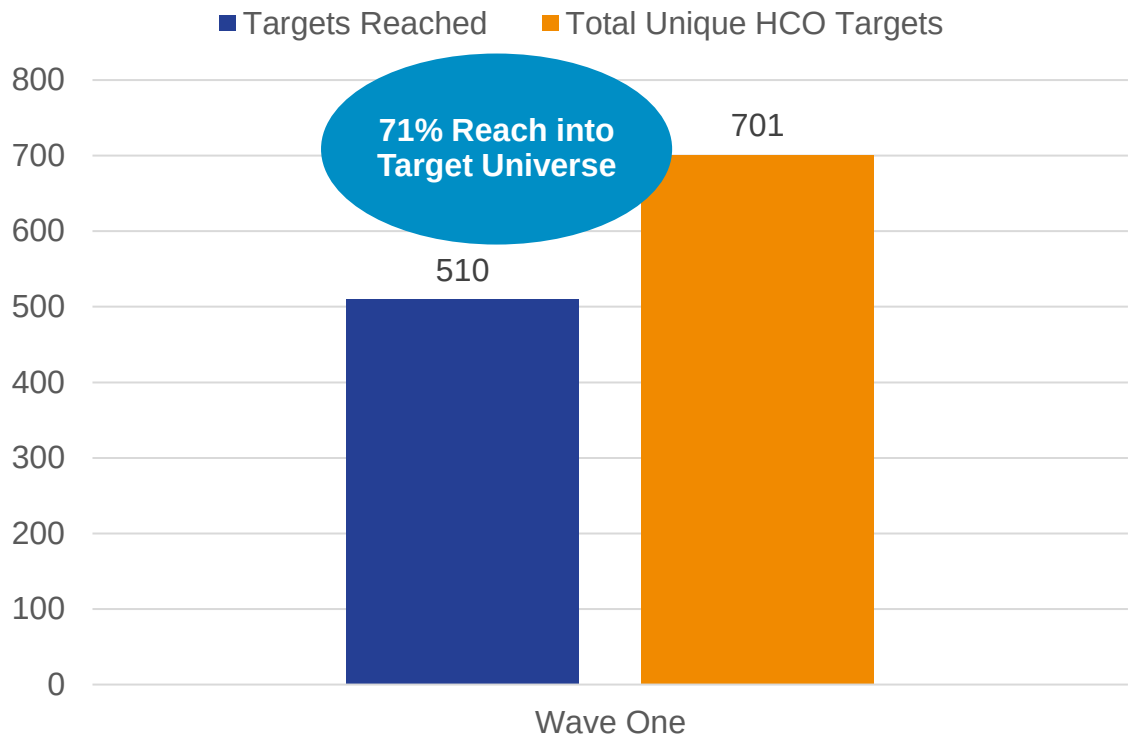
Cumulative Unique Target Hospital Reach



*October MTD (10/11/22)

Target Hospital Reach to Date

Target account depth/penetration has doubled in the last 2 months



Source: Data on file

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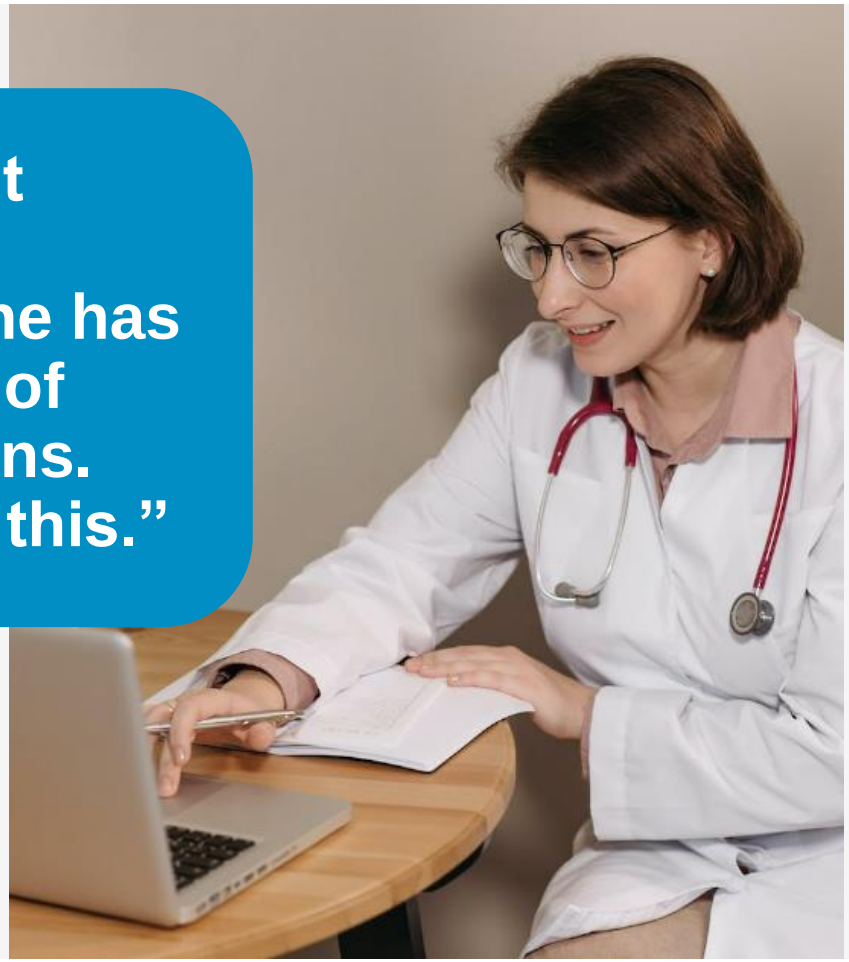
Providers are Enthusiastic About IGALMI™

"I could have used this today!"

– RN Response after ED Inservice - Large Community Hospital

"I'm a psychiatrist and my mom is a schizophrenic. She has PTSD from years of force and injections. I can't wait to get this."

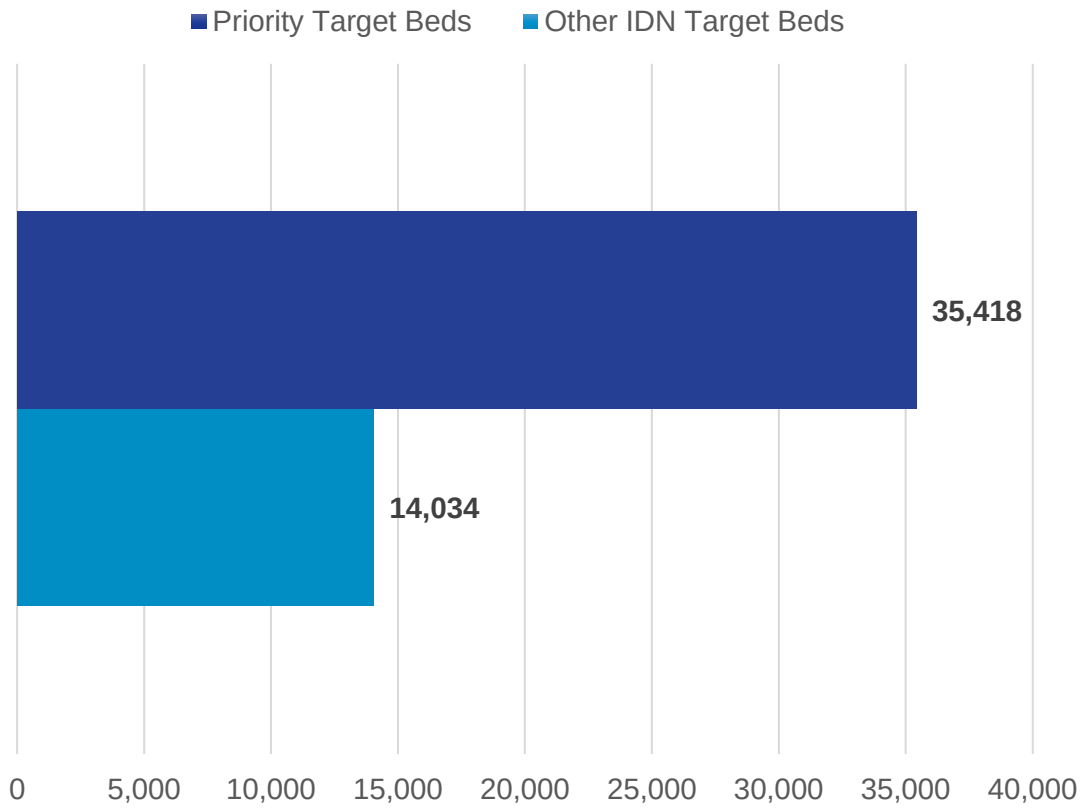
– Psych MD, Hospital and Office Practice

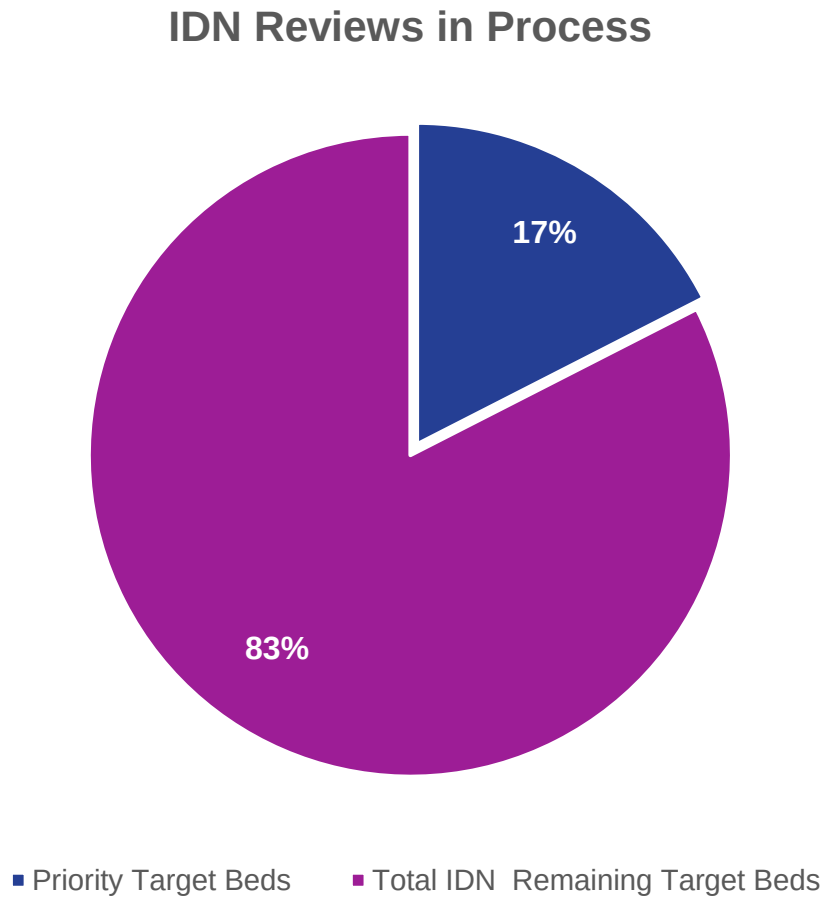


Key Performance Indicators

Early Votes at Multiple IDNs Expected in 2022 Representing 17% of Target Beds and ~50k Total Beds

Additional Voting in Process with Child Accounts in Larger Systems

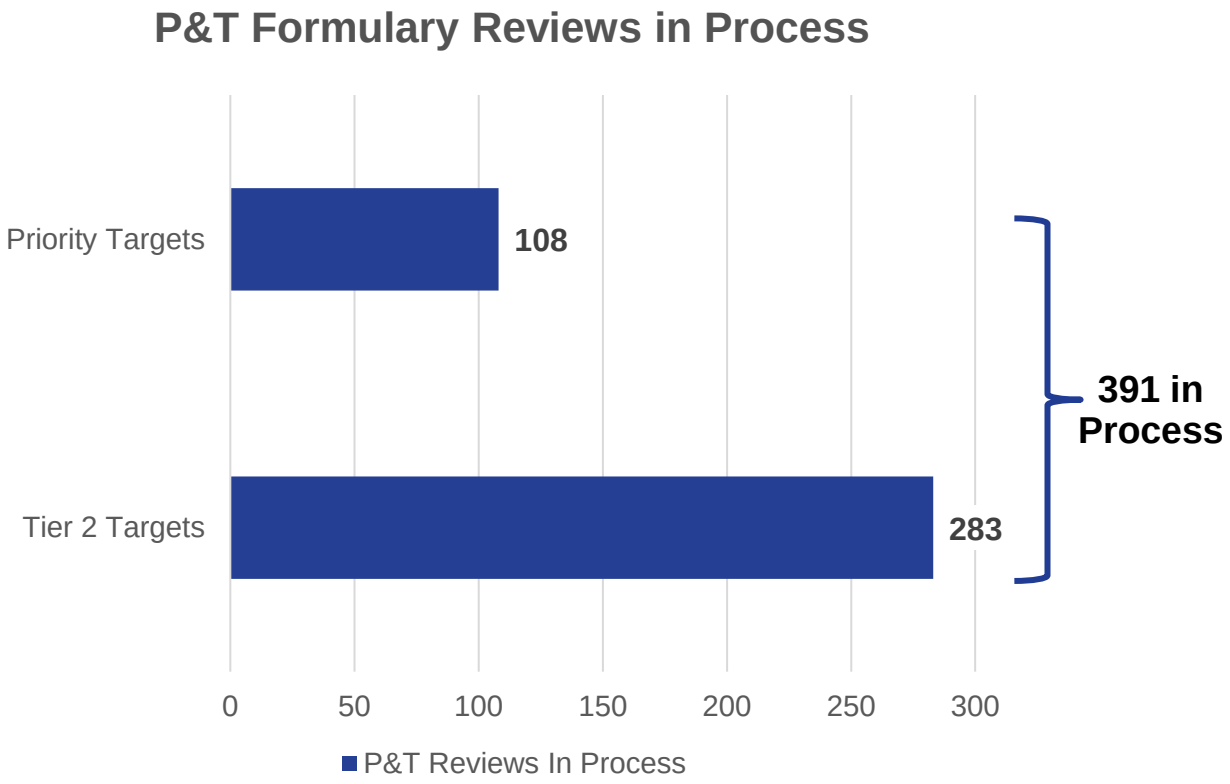


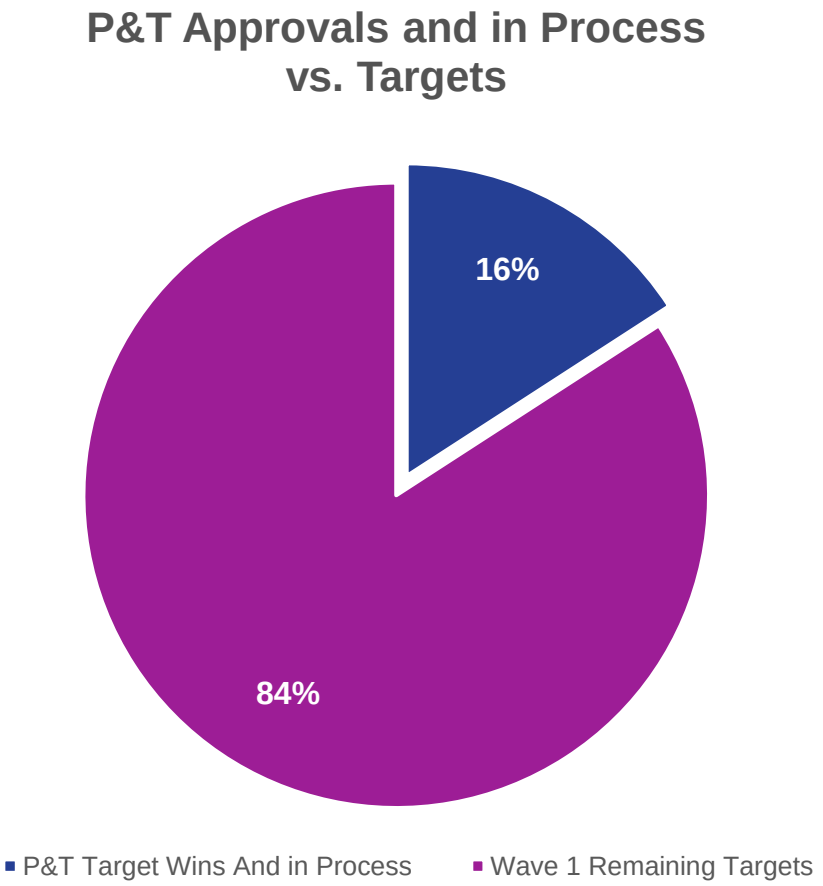


Source: Data on file

Early Votes Indicate Strong Interest, with Over a Dozen Formulary Approvals and ~400 Votes in Queue

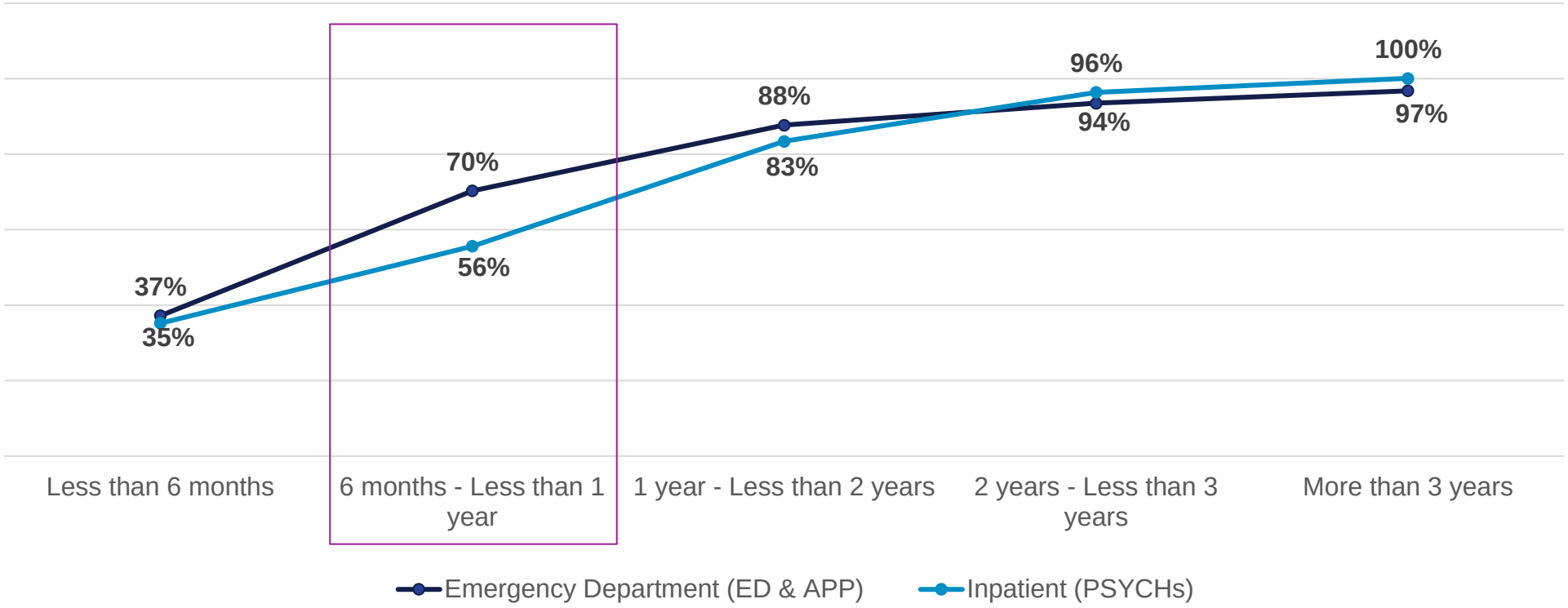
16% of First Wave Targeted Hospitals in Process in Less Than 4 Months





Source: Data on file

Clinicians Anticipate Usage Within First Year Post-Formulary Approval



Source: HCP ATU Landscape Research, January 2022; If PRODUCT X were available to you and on formulary, when would you most likely first try it from time of launch

Environment Favors Growth in 2023

- **Fully integrated commercial team built and sales team expansion under way**
- **Market dynamics evolving and favorable** to IGALMI demand
- **Sales interaction very positive** with 71% reach and early use yielding expected results
- **Market access momentum building** with 46% of GPO beds under contract and 17% of total target IDN beds in process

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Thank you!

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