anavex LIFE SCIENCES Corp.™

Developing targeted therapies for neurodevelopmental and neurodegenerative diseases

Analysis of ANAVEX™2-73 Phase 2a Data

October 2017

Nasdaq: AVXL

Safe Harbor

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Executive Summary

- ANAVEX2-73 focuses on a new target relevant to Alzheimer's disease and other neurological diseases
- Sophisticated design of ANAVEX 2-73-002 trial with multiple dosing and availability of longitudinal PK/PD data enables detailed responder analysis
- Initial study and in depth data analysis using ARIANA technology demonstrates
  - Relationship between ANAVEX2-73 measured exposure and dose (PK) are consistent across study periods
  - Strong drug concentration / response relationship revealed for key Alzheimer's disease trial endpoints cognition and function, MMSE and ADCS-ADL (PK/PD). This relationship is consistent across multiple time periods
  - Same applies for the brain activity biomarker ERP (PK/PD)
  - Systematic analysis using KEM® identifies actionable parameters enabling a precision medicine approach to include best responders in follow-up Phase 2/3 study
- Additional data to be incorporated
  - DNA, RNA and gut microbiota
  - Advanced data analytics will enable "targeted therapy" design for new trial

The Sigma-1 Receptor (S1R): From Gene to Therapeutic Target

Sigma-1 Receptor is an integral membrane protein involved in cellular homeostasis which targets restoration of neuroplasticity and cellular stress response[2,3]

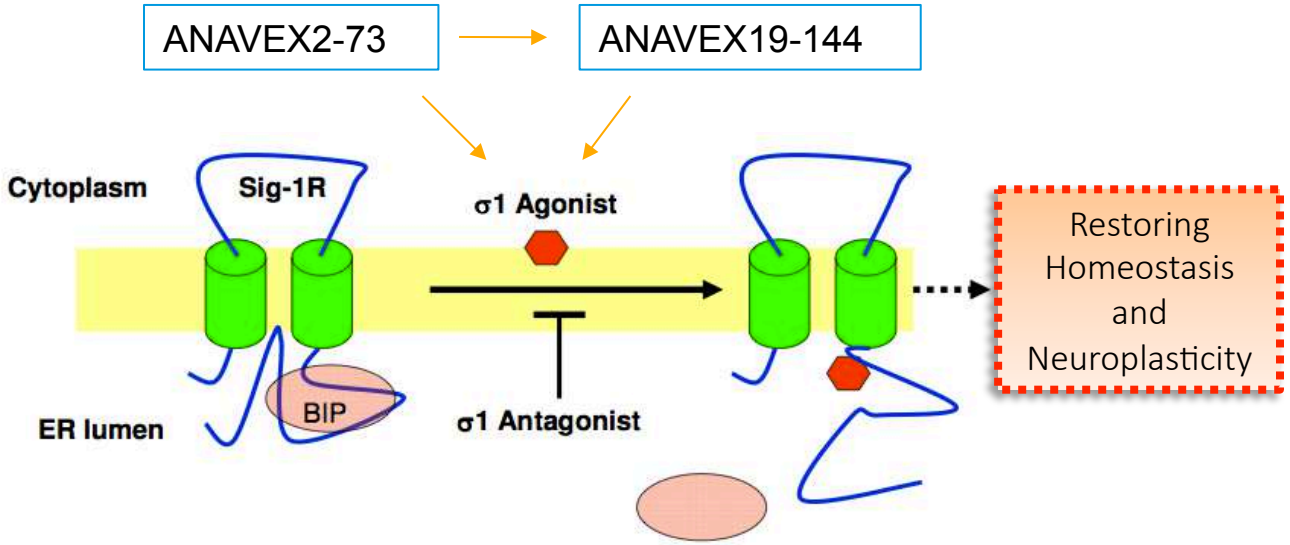
Endogenous S1R agonists activate the Sigma-1 Receptor under conditions with cellular stress[4,5,6]

ANAVEX2-73 is a S1R agonist and activates the Sigma-1 Receptor

Enhancing Activation of endogenous S1R with ANAVEX2-73 improves disease symptoms and underlying pathophysiology

1) Mavlyutov TA et al. Neuroscience. 2013 Jun 14;240:129-34. 2) Su TP et al. Trends Pharmacol Sci. 2016 Apr;37(4):262-78.
3) Ruscher K et al. J Pharmacol Sci. 2015 Jan;127(1):30-5. 4) Dhir A et al. J Psychopharmacol. 2008 Aug;22(6):691-6.
5) Yabuki Y et al. Brain Res. 2015 Oct 5;1622:102-13. 6) Urani A et al. Brain Res. 1998 Jul 13;799(1):64-77.

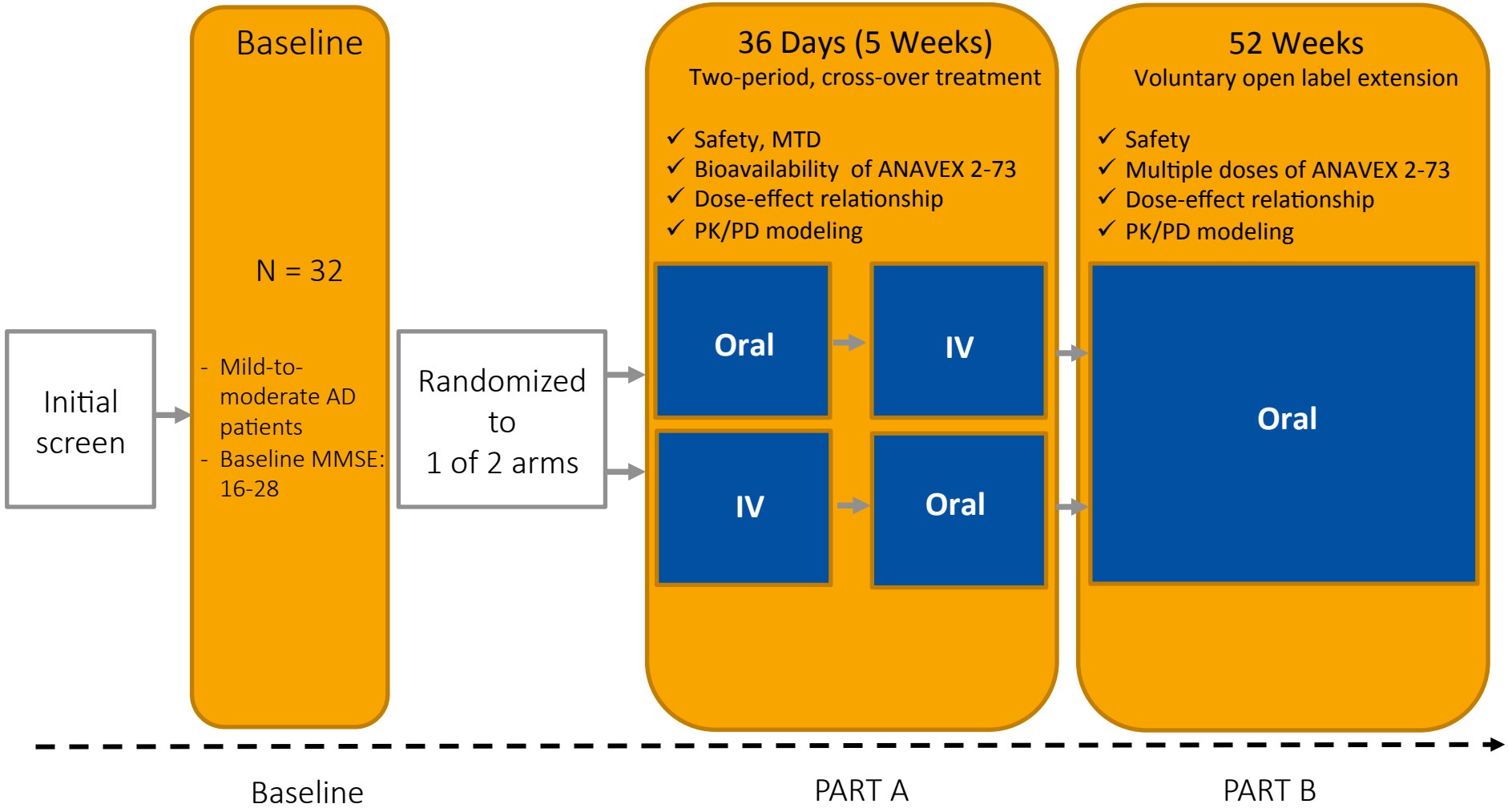
Sigma-1 Receptor Activation of ANAVEX2-73 Extended with Active Metabolite



- ANAVEX2-73 is metabolized into the pharmacologically active metabolite, ANAVEX19-144
- Metabolite also acts as sigma-1 receptor agonist with neuroprotective action like ANAVEX2-73, restoring homeostasis and neuroplasticity
- The apparent elimination half-life of the metabolite (21.45 hr) is approximately twice that of ANAVEX2-73 (10.71 hr) hence the active metabolite result in extended activation of the sigma-1 receptor

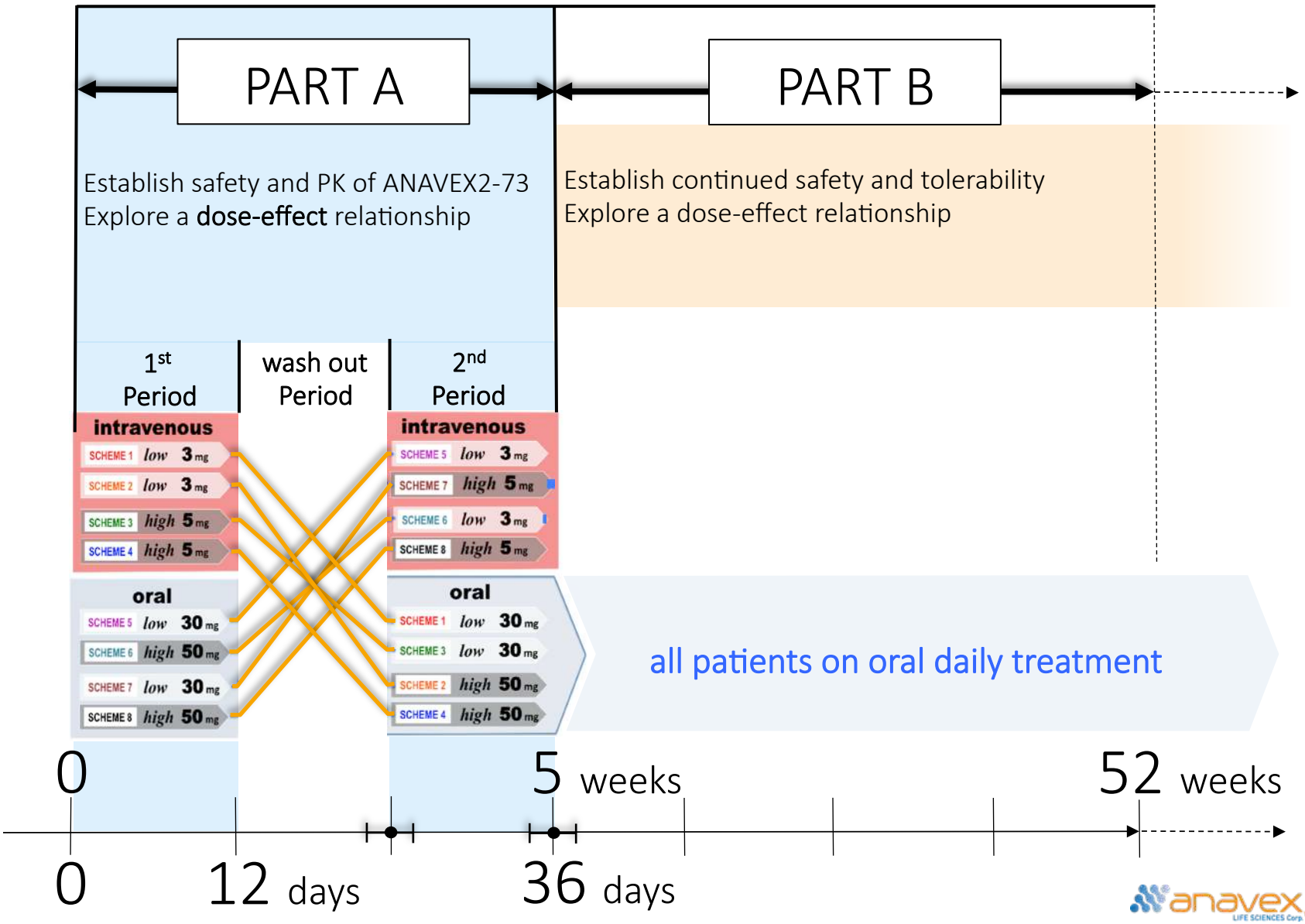
ANAVEX 2-73 Phase 2a Alzheimer's Disease

Randomized, Crossover Assignment, Open Label Study of ANAVEX 2-73 (ANAVEX™2-73-002 Study#)

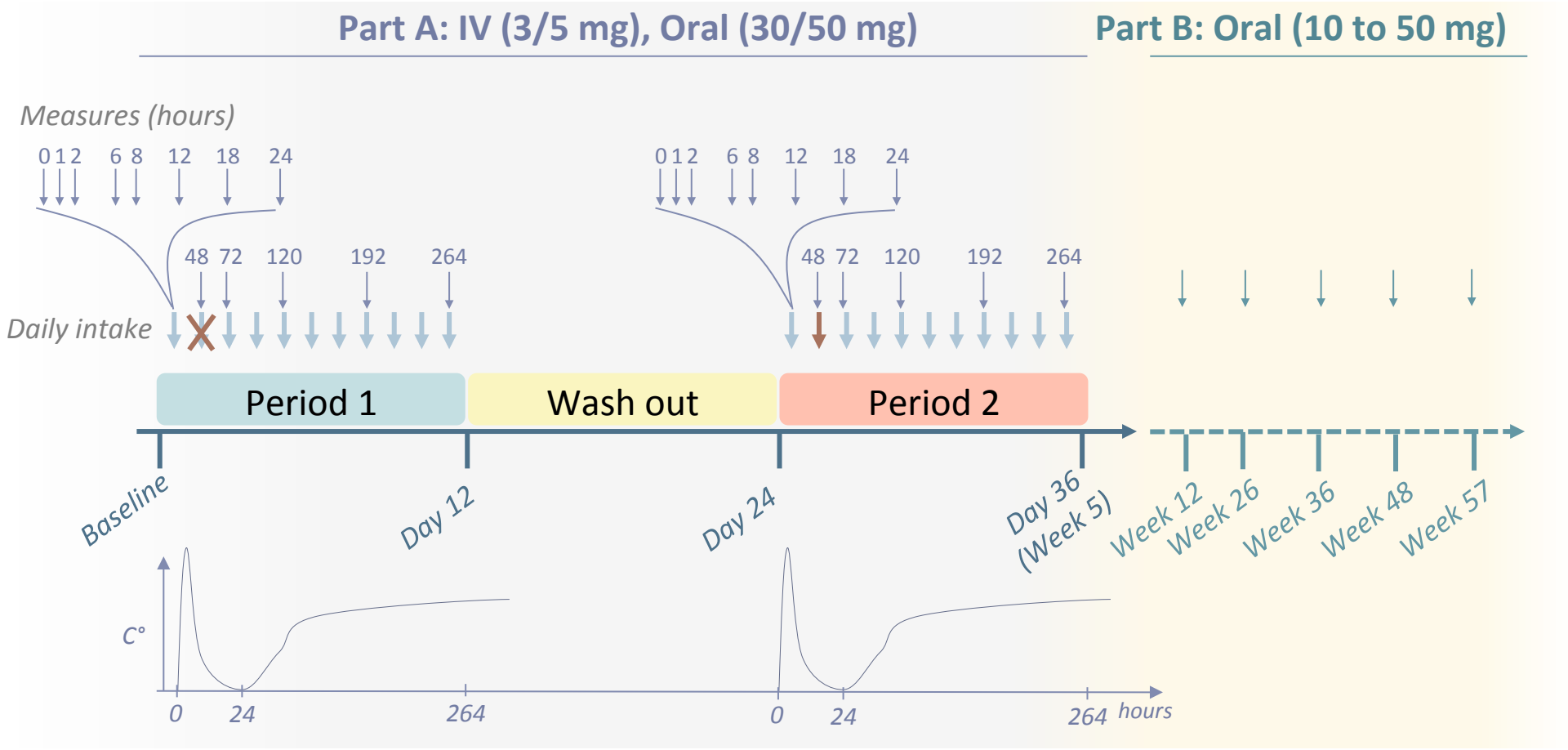


ClinicalTrials.gov Identifier: NCT02244541

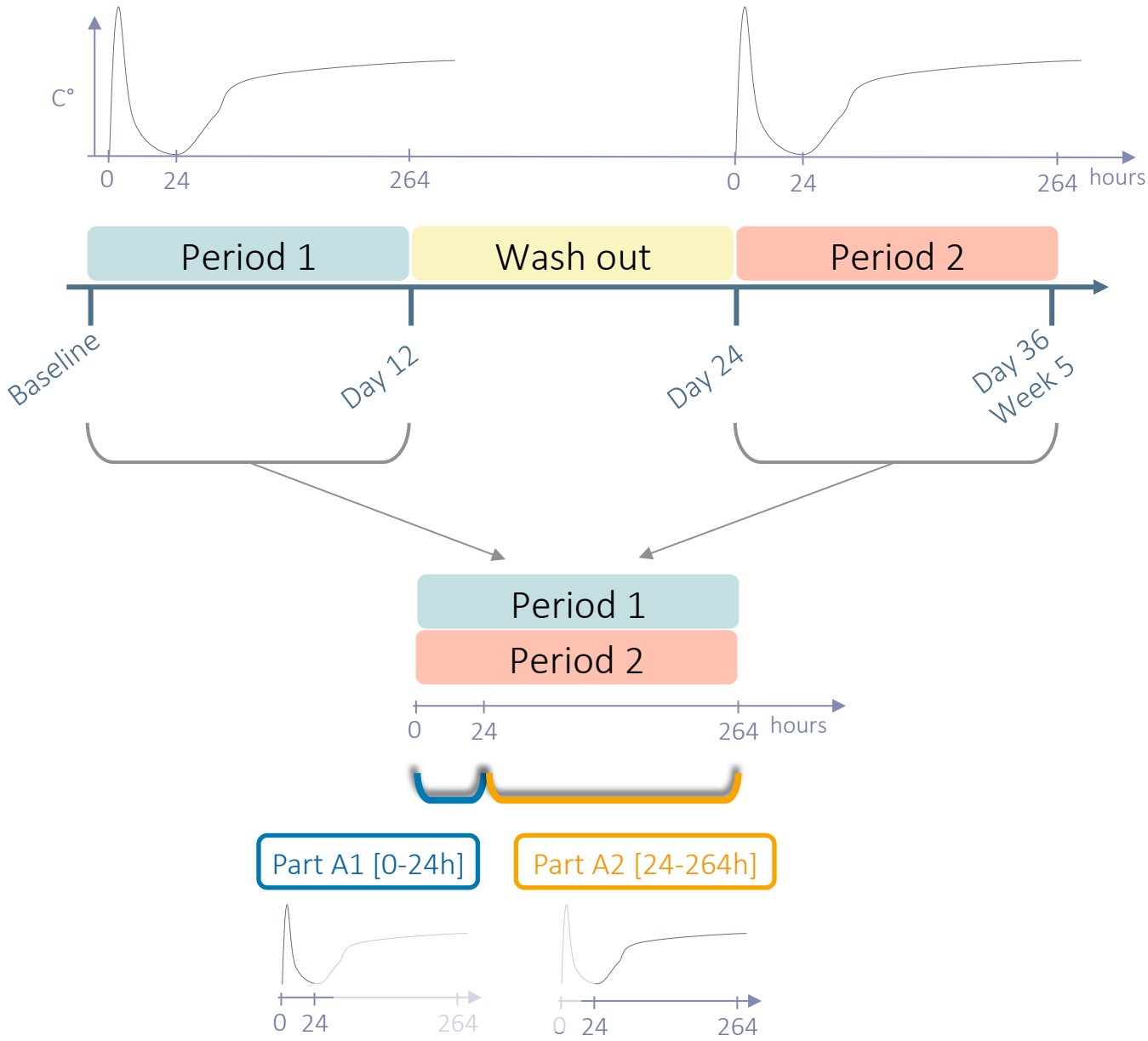
Design and Exploratory Endpoints of the Phase 2a



Pre-specified Stated PK Time Points of the Phase 2a



Part A: Analysis of Distinct Timeframes



Analysis of All Relevant Time Periods

Part A1 [0-24h]	Part A2 [24-264h]	Part B [52 weeks]

Immediate response

Short-term response

Long-term response

ANAVEX™ 2-73 Rational Clinical Trial Execution Plan

ANAVEX™2-73-001 Study:
- Phase 1 (oral)
- Single Ascending Dose (SAD)
- Healthy subjects

Completed

More "informative" trial

ANAVEX™2-73-002 Study#:
- Phase 2a (iv/oral)
- Mild-to-moderate AD patients
- Adaptive trial with Population PK
- Bioavailability, dose finding (PART A), and exploratory efficacy with 52 week open-label extension (PART B)

ANAVEX™2-73-003 Study##:
- 104-week extension study after PART B

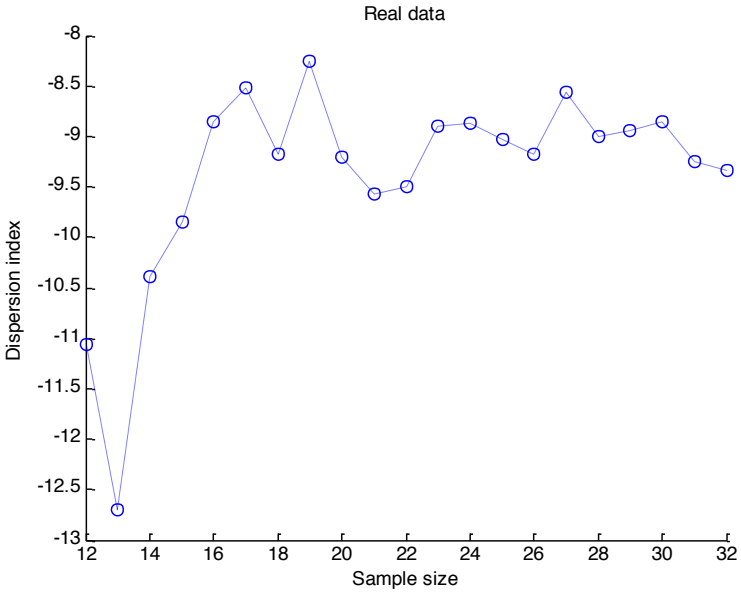
PART A: Completed
PART B: Completed
Full Data Population PK: November CTAD 2017

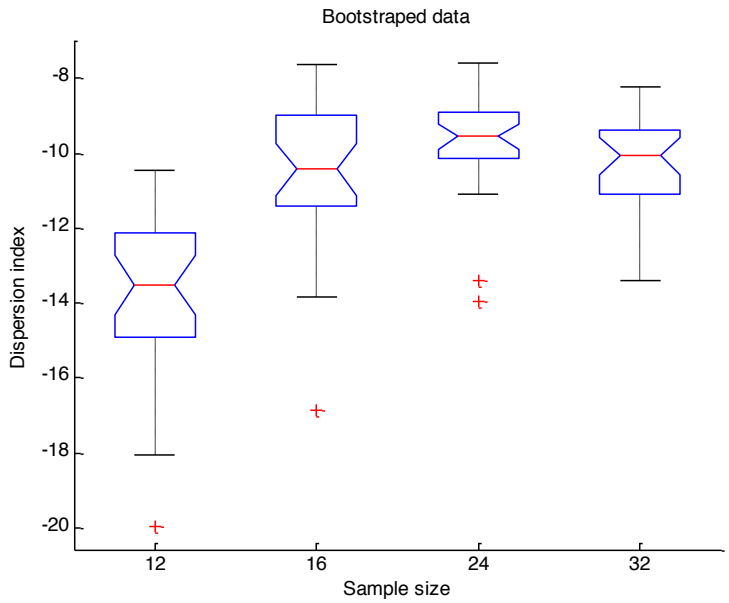
Initiation of subsequent randomized, double-blind, placebo-controlled ANAVEX™2-73 studies:
- Rett syndrome
- Parkinson's disease
- Alzheimer's disease

Preparation underway

ClinicalTrials.gov Identifier: #NCT02244541; ##NCT02756858

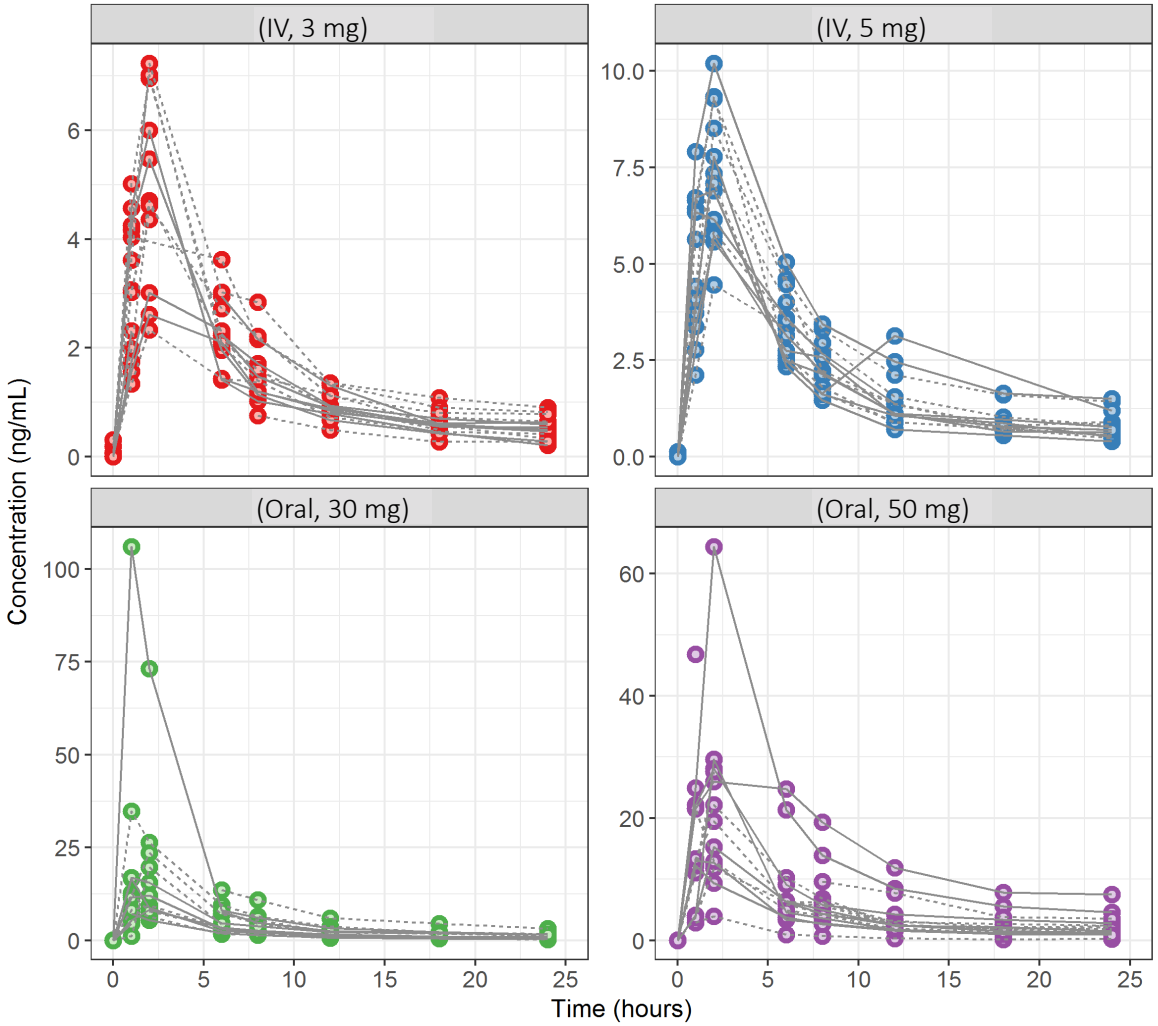
Confirmed Reliable Inter-Individual Variability (Dispersion) for the ANAVEX2-73 Phase 2a Study with 32 Patient Cohort





- Evaluation of the dispersion index of all the 32 patient of the Phase 2a reveals that above 16 patients, the dispersion index is maintained at a fixed level with the narrowest confidence intervals
- That is confirmation that the sample of 32 patients of the Phase 2a provides reliable information regarding dispersion and as such allows for meaningful predictions for larger populations

Relation Between ANAVEX2-73 Exposure and Dose (PK) are Consistent Across Administrations

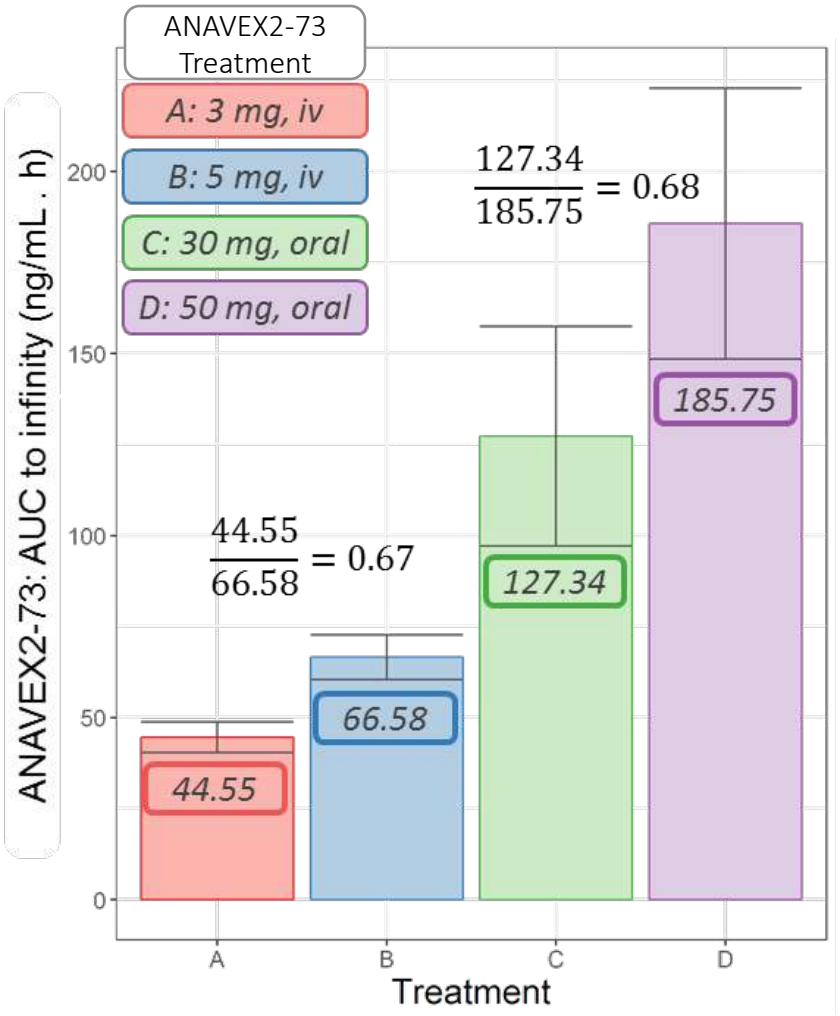


High Dose of ANAVEX2-73 Correlates with Exposure

Total average drug exposure over time

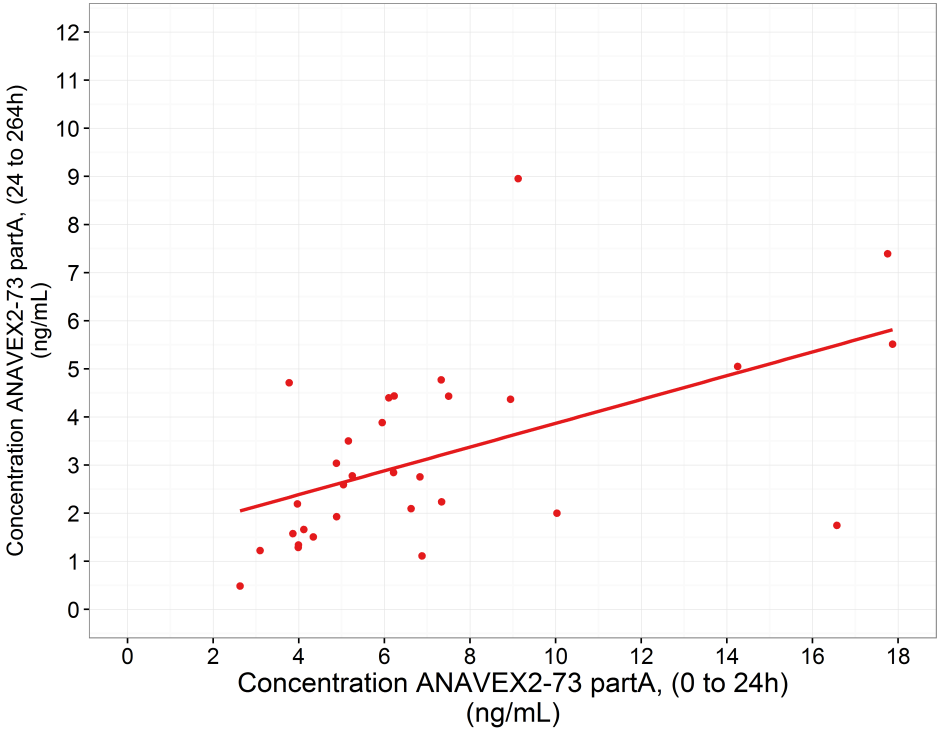
$AUC_{(0 \text{ to infinity})}$

Area Under the Curve, 0-24h



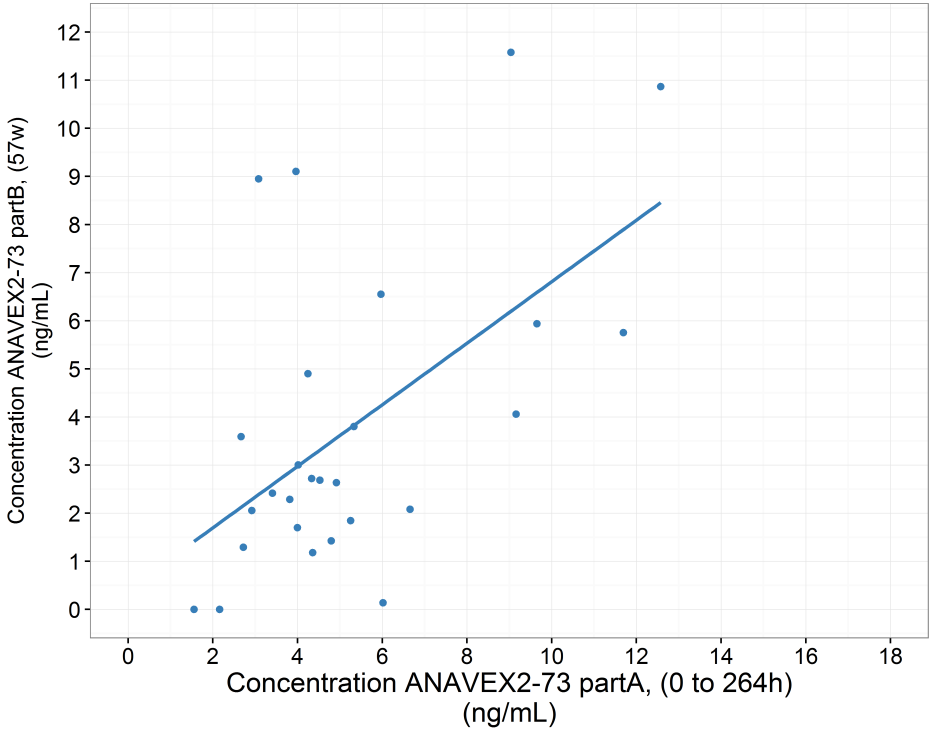
Measured Concentration of ANAVEX2-73 is Reproducible over Time

Part A1 [0-24h] vs Part A2 [24-264h]



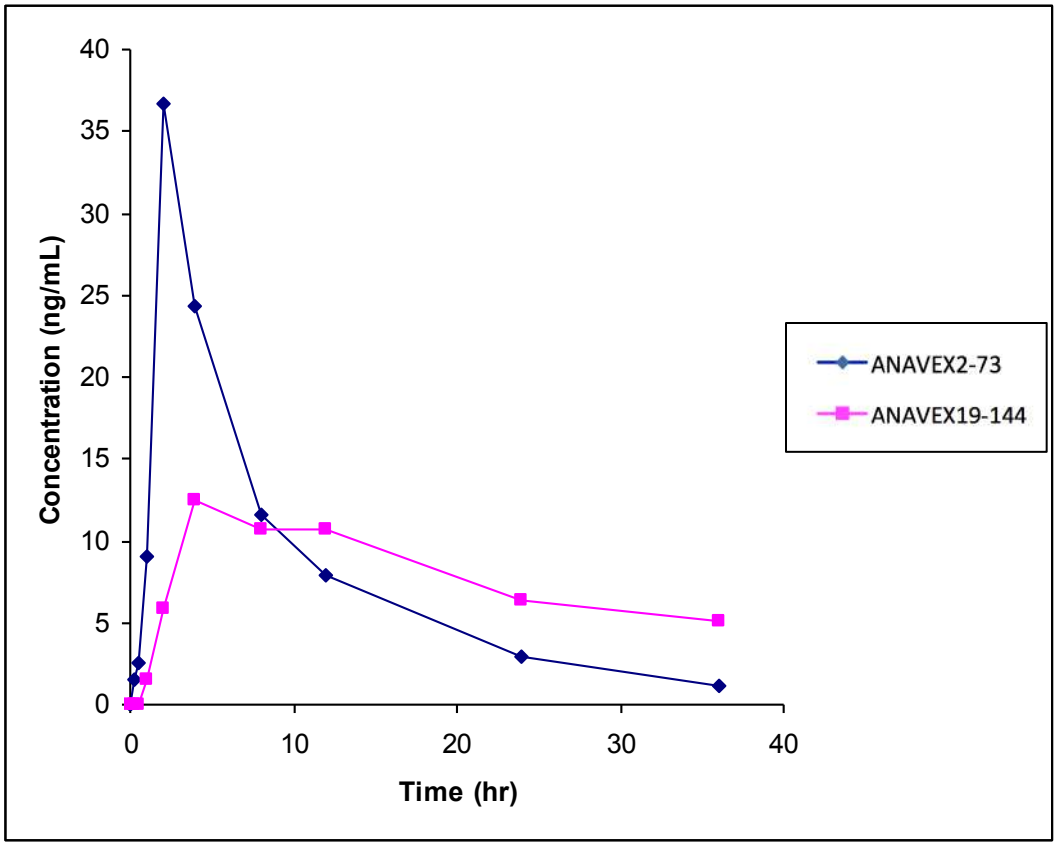
$R^2 = 0.285$
$p = 0.0019$

Part A vs Part B



$R^2 = 0.318$
$p = 0.0021$

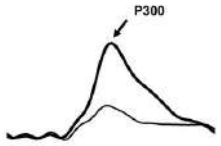
Metabolite of ANAVEX2-73 Extends Activation of Sigma-1 Receptor Activity

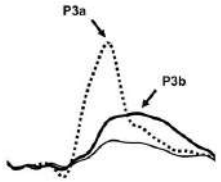


- A typical concentration-time for ANAVEX2-73 and metabolite for a subject administered orally 60 mg ANAVEX2-73
- ANAVEX2-73 is rapidly absorbed with an absorption half-life of 30 min and an apparent elimination half-life of 10.71 hr
- The active metabolite is slowly eliminated with an apparent elimination half-life that is approx. twice that of the parent (21.45 hr)

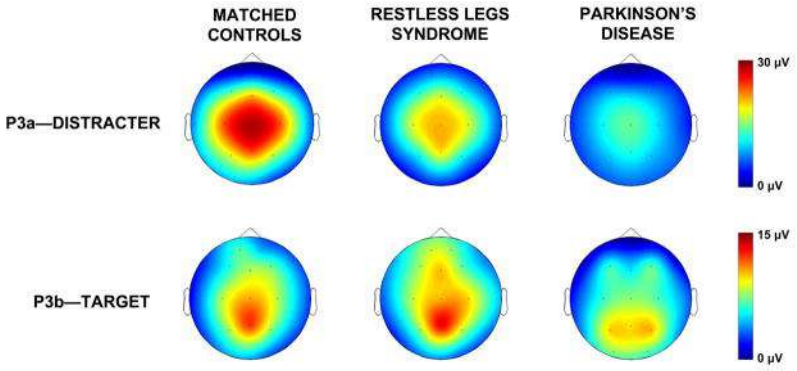
P300 ERP Biomarker Measuring Direct Brain Activity

P3a and P3b are Subcomponents of P300 ERP Biomarker





Polich and Criado, Int J Psychophysiol. 2006
doi:10.1016/j.ijpsycho.2005.12.012

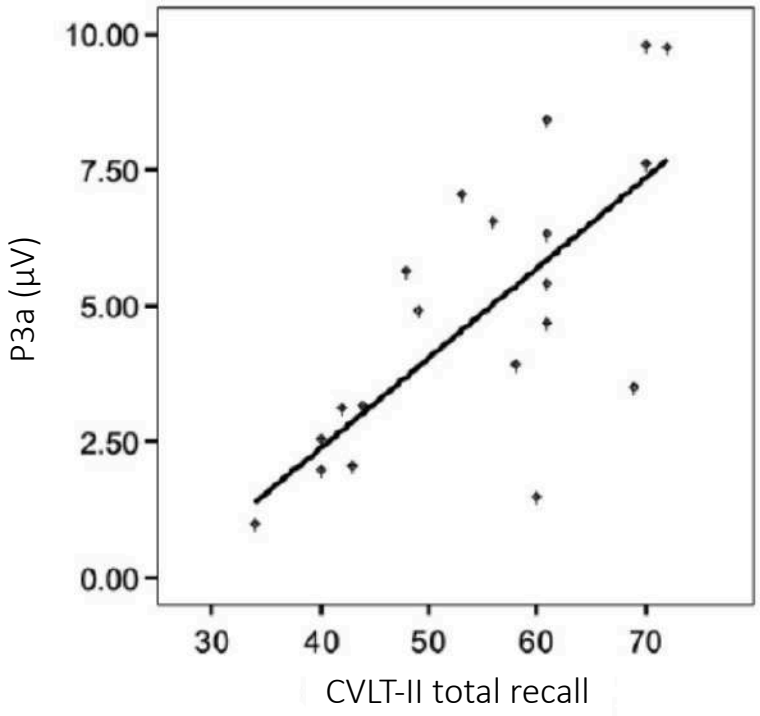


Polich, Detection of Change, Springer Science, 2003
doi:10.1007/978-1-4615-0294-4

- Non-invasive biomarker ERP[#] measures cortical network performance in the brain
- Demonstrated sensitivity to Alzheimer's disease and other neurological disorders
- Real-time physiological biomarker measure of cognitive processes
- More proximal to disease pathology and pharmacological intervention than psychometric measures

[#] ERP = Event-Related Potential

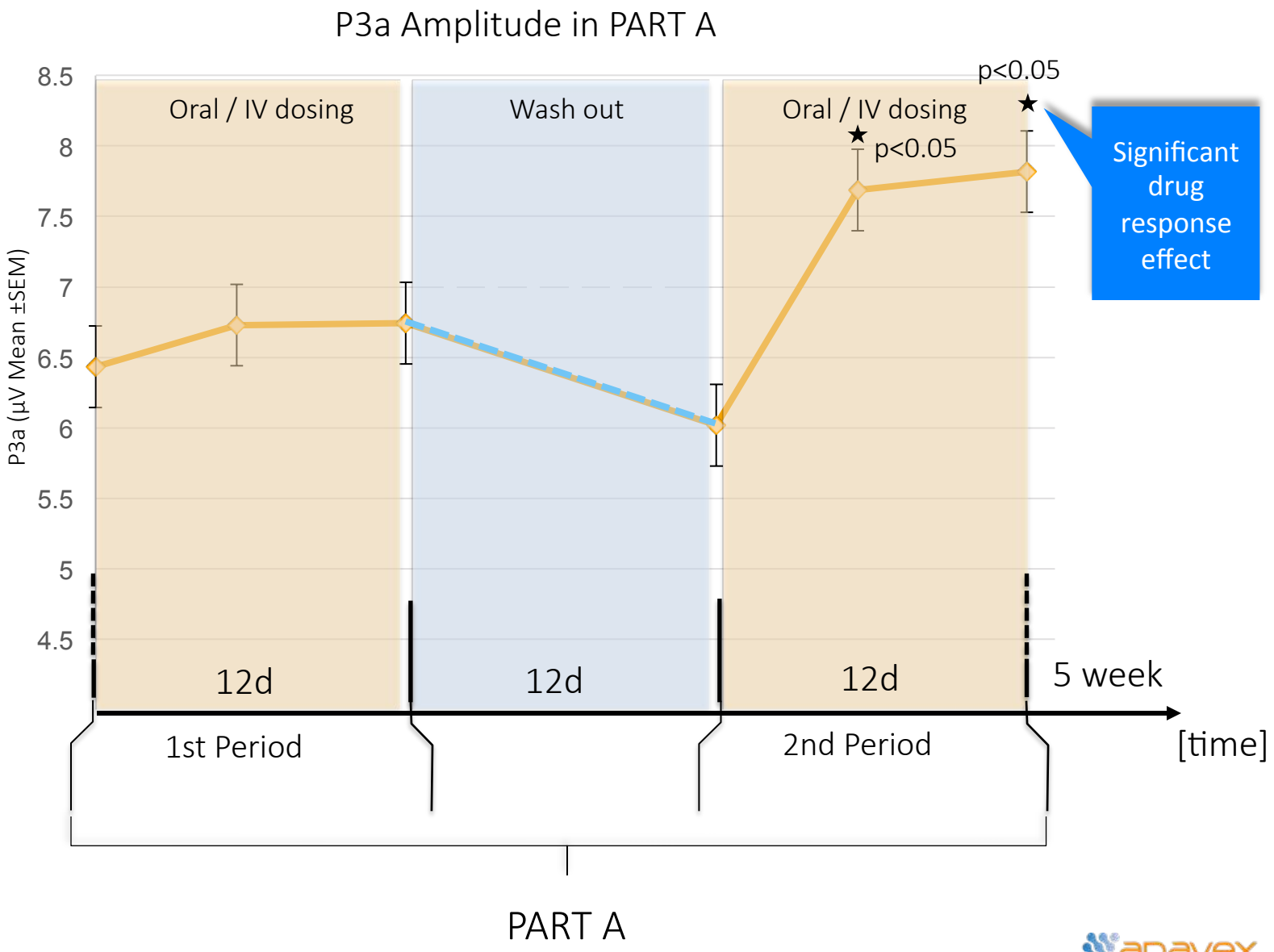
P3a Amplitude Correlates With Verbal Memory Performance



- 20 subjects: P3a amplitude is associated with verbal memory performance
- Scatterplot of P3a amplitude and CVLT-II total recall ($r = 0.72$, $p < 0.001$)
- Topography of the correlation plotted across electrode sites
- Red and black indicate significant correlations at fronto-central electrodes

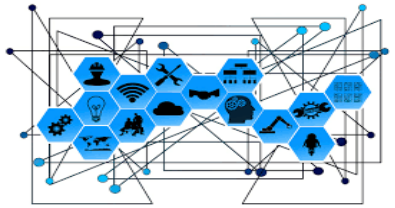
Source: Light G et al J Cogn Neurosci. 2007 October; 19(10): 1624–1632

ERP Biomarker Shows Significant Drug Response: P3a Amplitude Increases with ANAVEX2-73

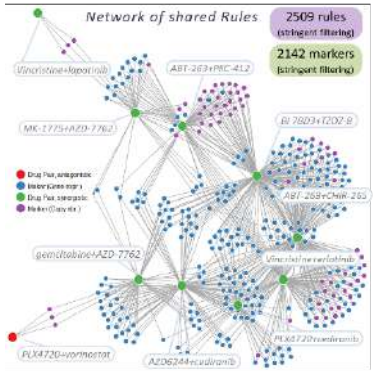


Ariana's KEM® Platform

Advanced Artificial Intelligence Platform Supporting Clinical Trial Design



- KEM®: a Formal Concept Analysis (FCA) Artificial Intelligence framework



- Comprehensively analyzes complex datasets by measuring all logical relations within a dataset, exploring all combinations of parameters and End-Points
- Identifies most relevant and powerful causal relations, revealing hidden relationships and deriving new hypothesis

- Validated by a large selection of clients and and partners including Sanofi, Ipsen, Pierre Fabre, Chemo, ValiRx, Harvard Medical School and the FDA (www.arianapharma.com/about/our-customers/)

Precision Medicine Paradigm in Oncology

Large number of biomarkers characterize patient tumors, dominated by genomic data from Next Generation Sequencing (NGS)

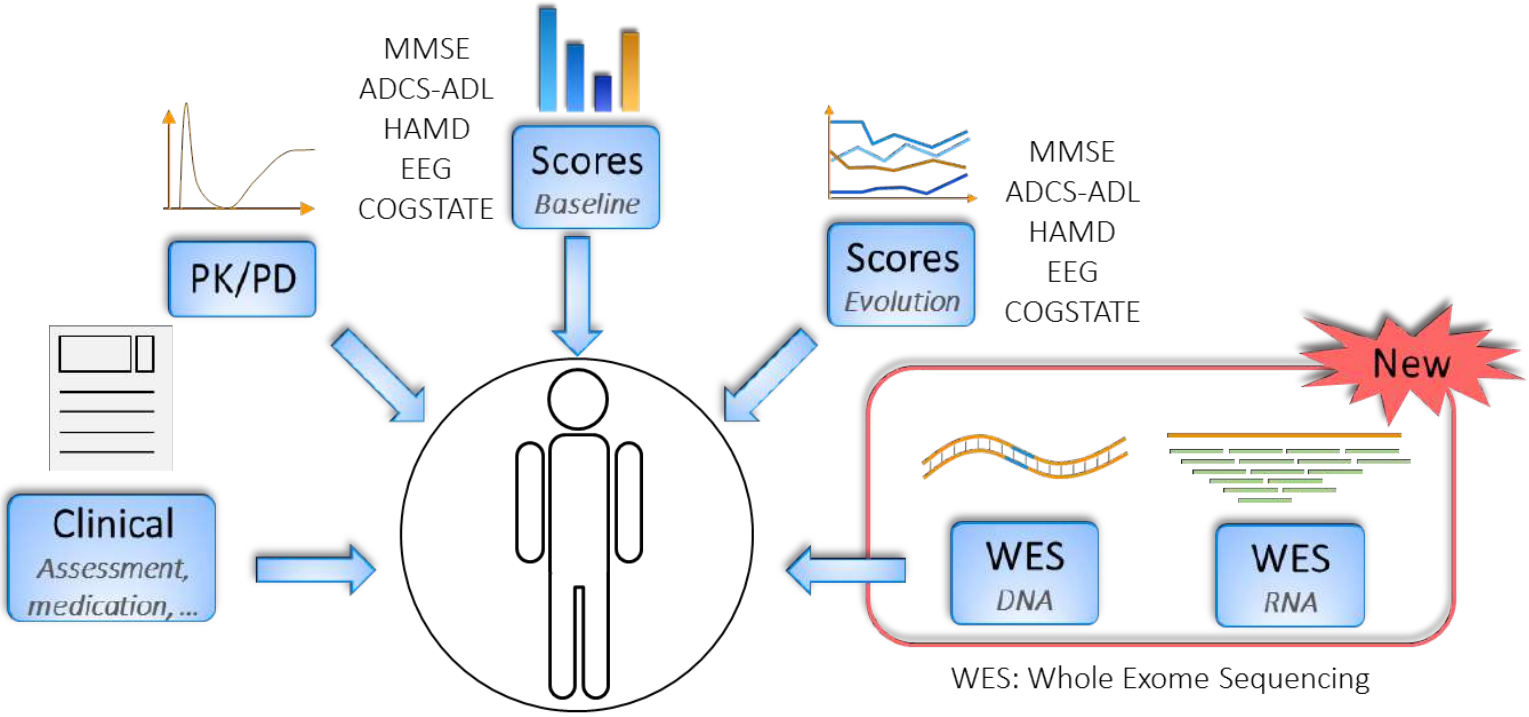
- Cancer seen as a collection of heterogeneous diseases
- Characterized by molecular features of the tumor
- Molecular test performed prior to treatment decision
- ~40% of new drugs have a companion marker

Precision Medicine in Alzheimer's Disease

- Current Alzheimer's disease drug development paradigms continue to fail in Phase 3 clinical trials
- Deconstructing Alzheimer's disease into multiple biological and genetic subsets within this heterogeneous target population
- Transposing the Oncology Precision Medicine Paradigm to the Neurological disease area requires:
  - Collecting the right data
  - Enabling effective Data Analytics Tools
  - Executing more rigorous clinical trials

➔ effective Precision Medicine strategy for treating individual patients with agents that are likely to work most effectively based on the specific individual's biological make-up

Comprehensive Phase 2a Patient Characterization to Identify Actionable Phase 2/3 Clinical Trial Parameters



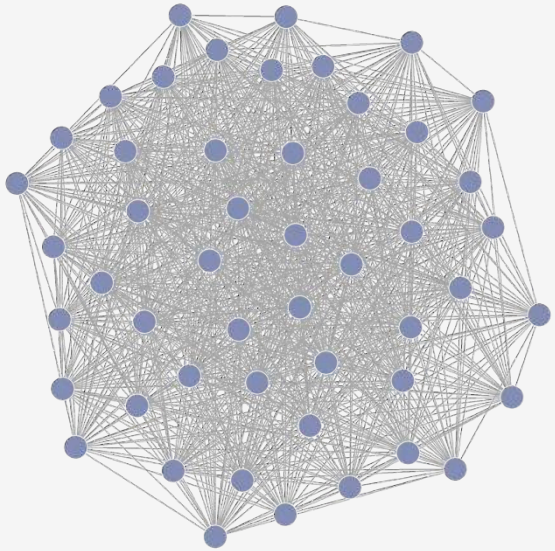
Ariana's KEM® data analytics:

- Systematic integrated analysis of all combined parameters
- Identification of actionable parameters
- Design of an optimized Phase 2/3 clinical trial

KEM® Systematic Analysis

Ariana's KEM® platform enables a systematic and exhaustive search of all possible relations across variables, endpoints, PK parameters and time

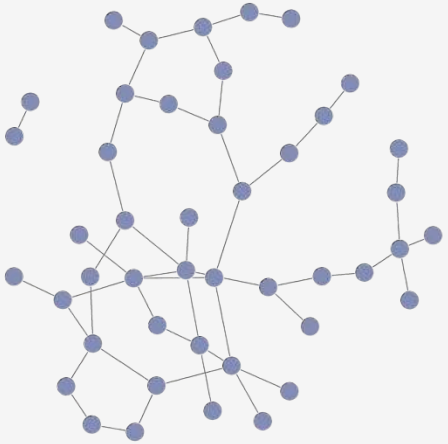
71,172 relations



3 Periods (A1, A2, B)
12 Endpoints and 3 molecules' PK
4 Transformations
80 Baseline variables
2 or 3 Categories per variables

Exploration & pruning

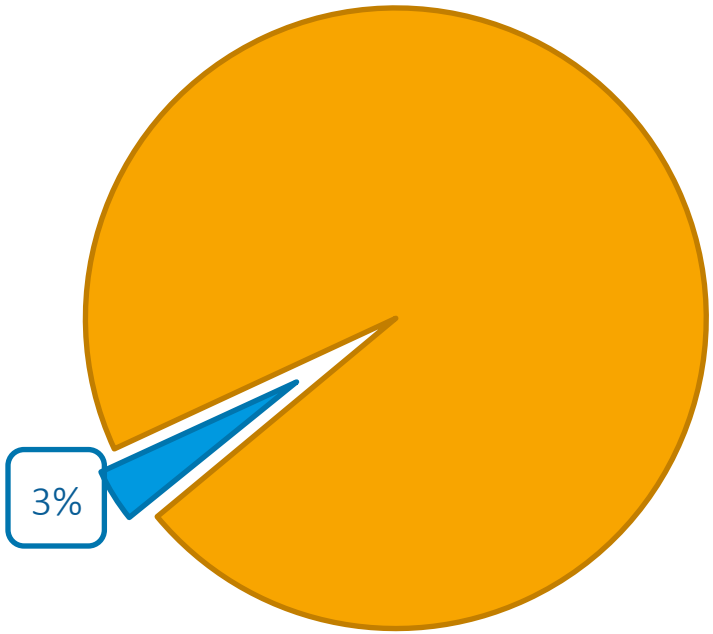
83 rules



97% of them showing coherent dose-response relation

Robust Dose (Concentration) / Response Effect of ANAVEX2-73

KEM® analysis: Consistency for 6 main exploratory endpoints cognition, function and biomarker (MMSE, ADCS-ADL & EEG/ERPs) demonstrated through systematic exploration of the full data matrix



54%
High dose -> Improved response

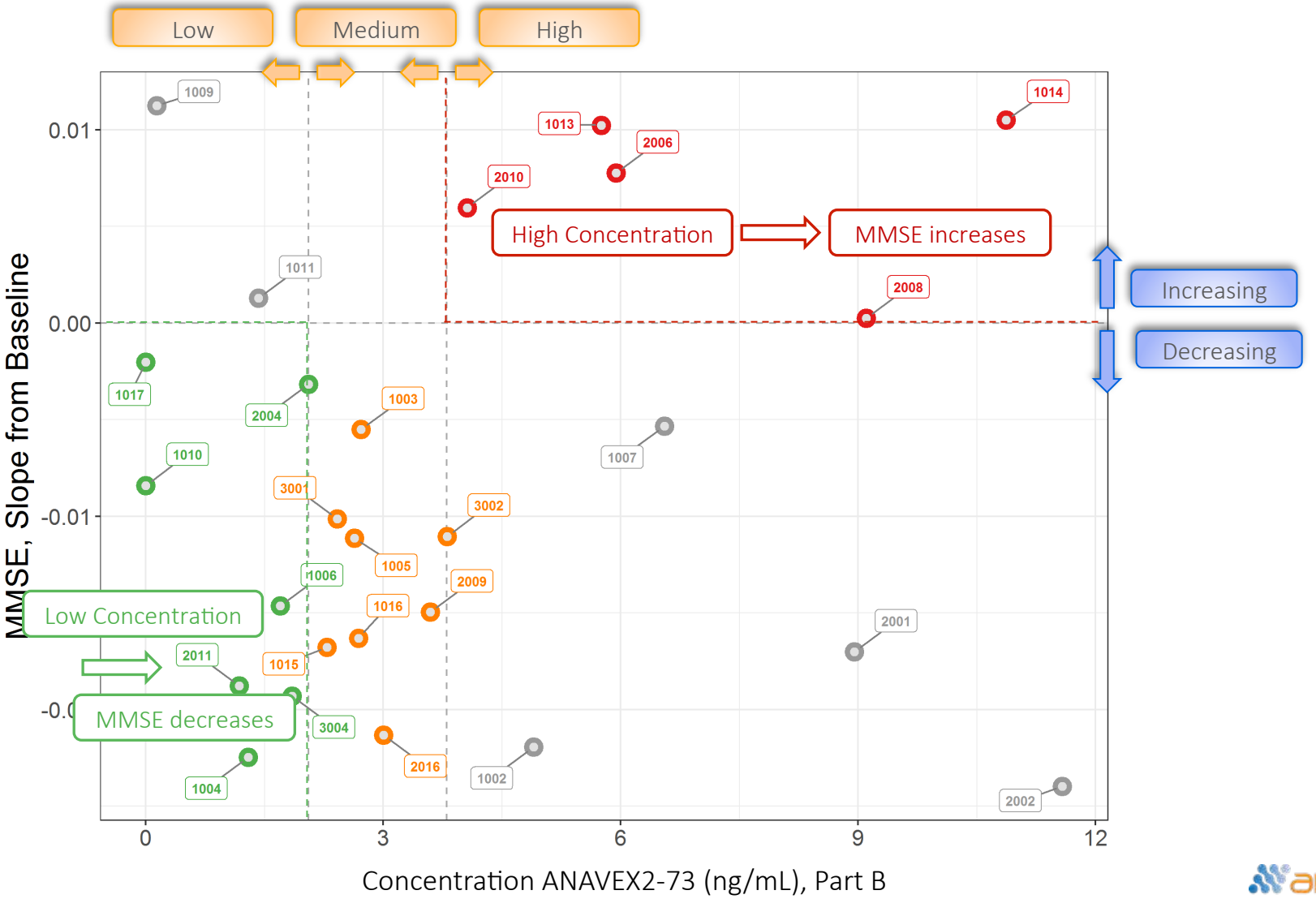
43%
Low dose -> Poor response

High dose -> Poor response or
Low dose -> Improved response

97% Consistency: MMSE, ADCS-ADL and EEG/ERPs: Identified relations show that high dose (concentration) is linked to improved response and low dose (concentration) to poor response

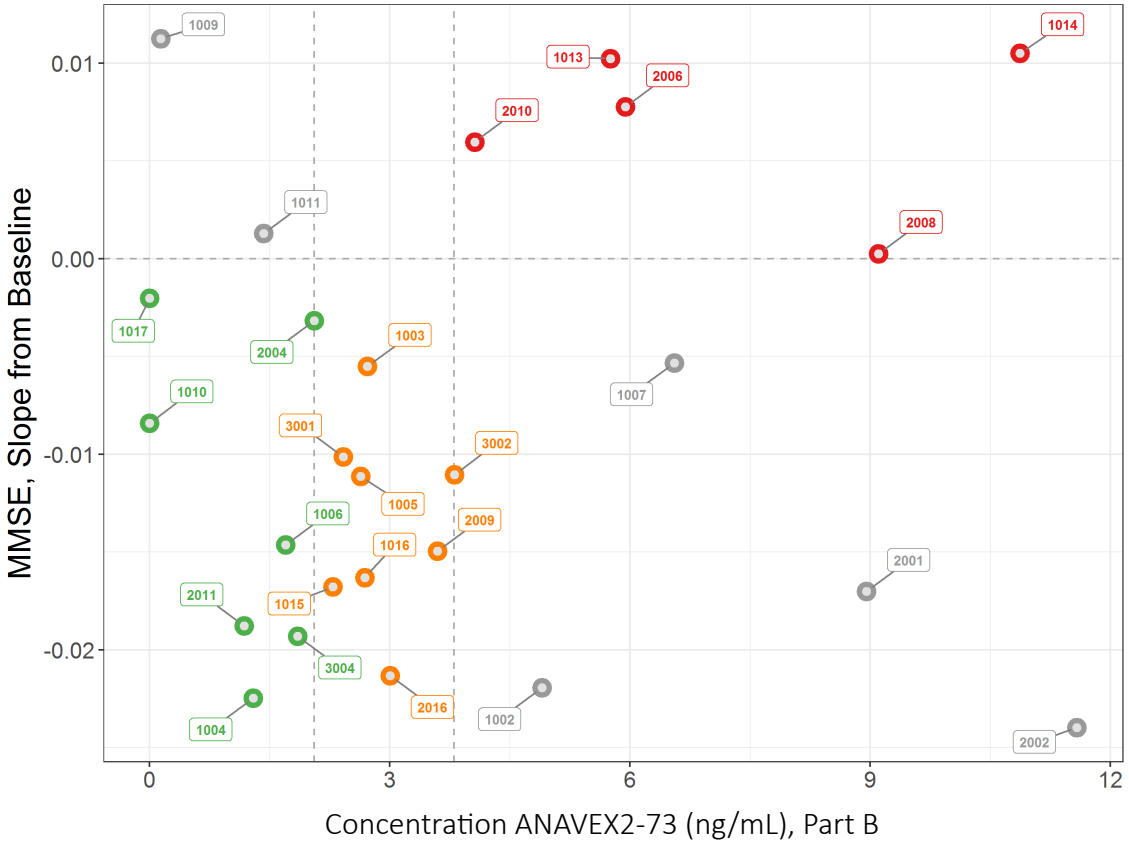
Relation between ANAVEX2-73 Concentration and MMSE

KEM® explores all possible relations



Relation between ANAVEX2-73 concentration and MMSE

KEM® characterizes all identified relations



How many patients?

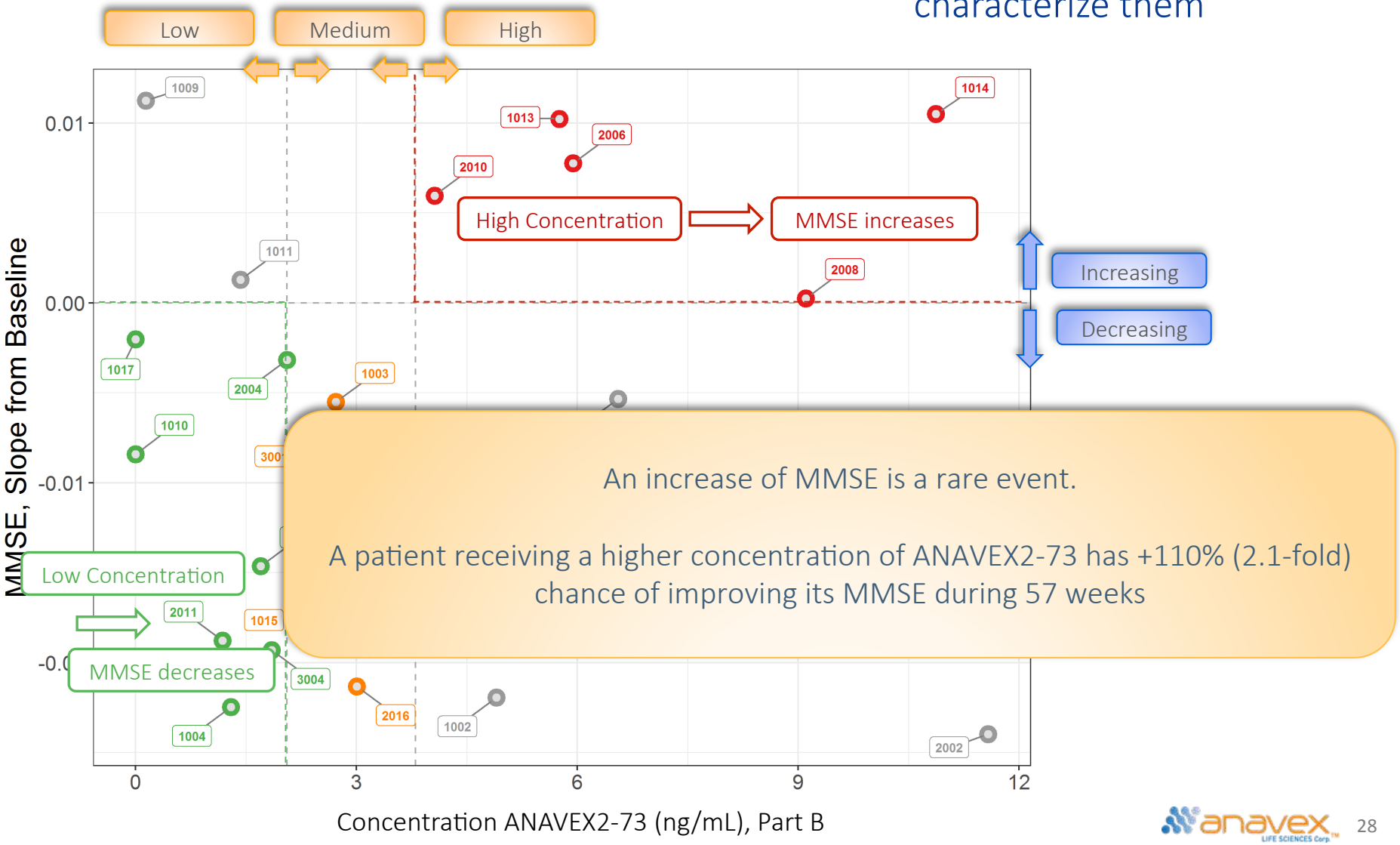
Probability of implication

Increased frequency

Left	Right	SupportRatio	Confidence	Lift
Concentration ANAVEX2-73_partB__Medium	MMSE.SlopeFromBL__Decreasing	33.3%	1.00	1.35
Concentration ANAVEX2-73_partB__Low	MMSE.SlopeFromBL__Decreasing	25.9%	0.78	1.05
Concentration ANAVEX2-73_partB__High	MMSE.SlopeFromBL__Increasing	28.5%	0.56	2.14

Relation between ANAVEX2-73 Concentration and MMSE

KEM® will explore all possible relations and characterize them



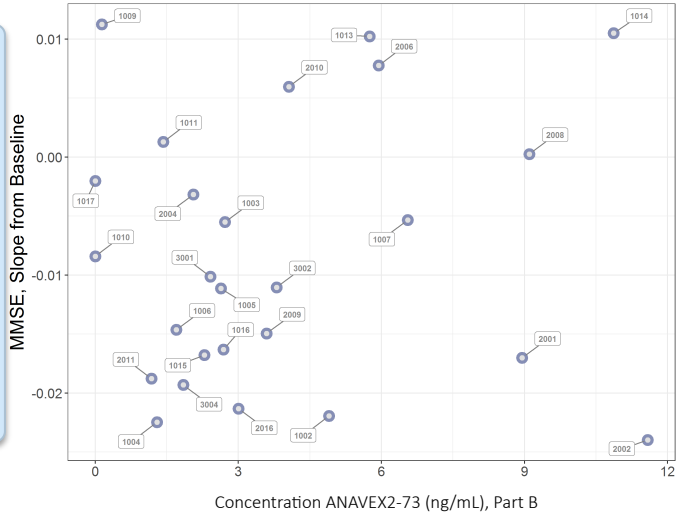
An increase of MMSE is a rare event.

A patient receiving a higher concentration of ANAVEX2-73 has +110% (2.1-fold) chance of improving its MMSE during 57 weeks

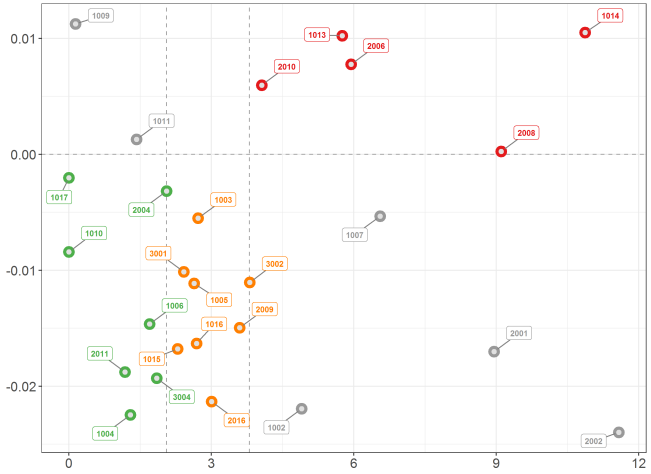
KEM® Identifies Strong non linear Relations Linking Concentration with Response for both MMSE and ADCS-ADL

MMSE

Dose	Response	SupportRatio	Confidence	Lift
Concentration ANAVEX2-73_partB__High	MMSE.SlopeFromBL__Increasing	18,50%	0,556	2,143

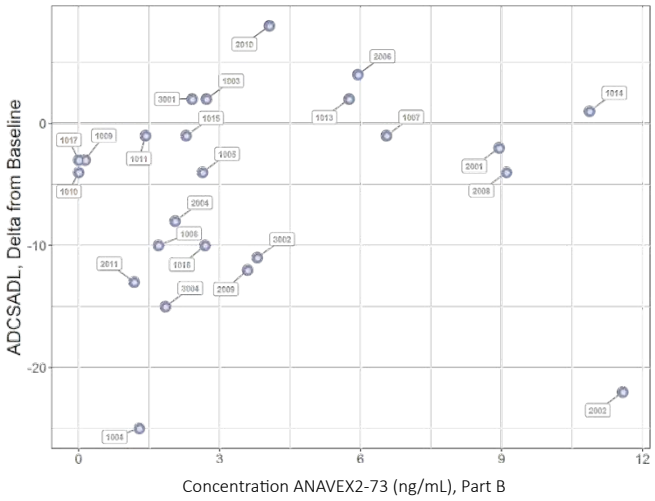


KEM®

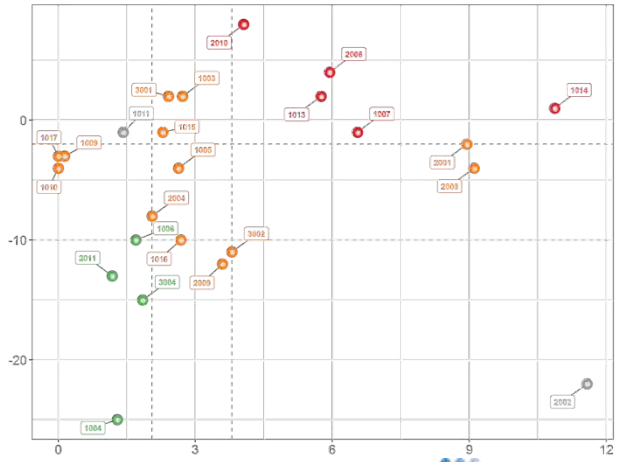


ADCS-ADL

Dose	Response	SupportRatio	Confidence	Lift
Concentration ANAVEX2-73_partB__High	ADCS-ADL.DeltaFromBL__High	18,50%	0,625	1,667



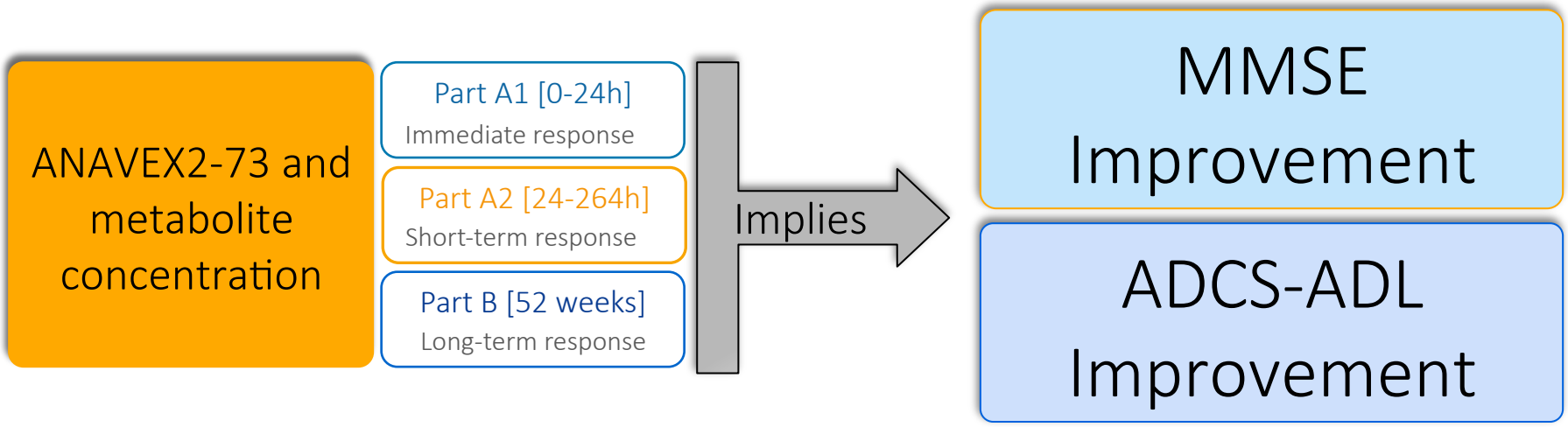
KEM®



High ANAVEX2-73 Concentration linked to Improved Response Consistently Across All Analytes and Periods

Both ANAVEX2-73 and metabolite show a consistent response across the 3 different times frames:

Part A1 [0-24h]	Part A2 [24-264h]	Part B [52 weeks]
Immediate response	Short-term response	Long-term response



Correlation of MMSE with ADAS-Cog

MMSE to ADAS-Cog

How do Scores on the ADAS-Cog, MMSE, and CDR-SOB Correspond? FREE

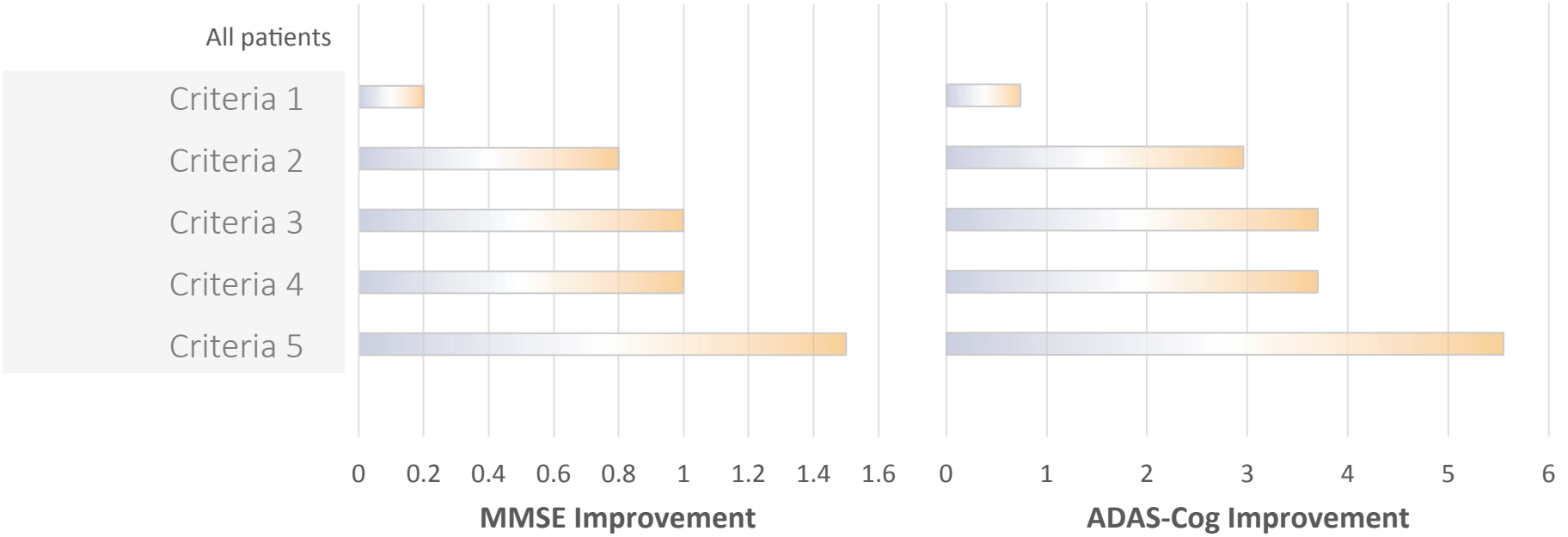
D Lowe, S Balsis, J Benge, L Geraci, L Toomey, A Gutierrez Ramirez

Archives of Clinical Neuropsychology, Volume 30, Issue 6, 1 September 2015, Pages 478,
https://doi.org/10.1093/arclin/acv046.09
Published: 25 August 2015

1 MMSE ≈ 3.7 ADAS-Cog
MMSE range for linear equivalence: 20 to 30

Identified Exclusion / Inclusion Criteria to Increase Signal in Planned ANAVEX2-73 Phase 2/3 Trial

KEM® analysis has identified exclusion / inclusion criteria. Each criteria has the potential to improve MMSE / ADAS-Cog for mild-to-moderate Alzheimer's patients treated with ANAVEX2-73



These criteria will be incorporated into the upcoming ANAVEX2-73 Phase 2/3 trial

Executive Summary

- ANAVEX2-73 focuses on a new target relevant to Alzheimer's disease and other neurological diseases
- Sophisticated design of ANAVEX 2-73-002 trial with multiple dosing and availability of longitudinal PK/PD data enables detailed responder analysis
- Initial study and in depth data analysis using ARIANA technology demonstrates
  - Relationship between ANAVEX2-73 measured exposure and dose (PK) are consistent across study periods
  - Strong drug concentration / response relationship revealed for key Alzheimer's disease trial endpoints cognition and function, MMSE and ADCS-ADL (PK/PD). This relationship is consistent across multiple time periods
  - Same applies for the brain activity biomarker ERP (PK/PD)
  - Systematic analysis using KEM® identifies actionable parameters enabling a precision medicine approach to include best responders in follow-up Phase 2/3 study
- Additional data to be incorporated
  - DNA, RNA and gut microbiota
  - Advanced data analytics will enable "targeted therapy" design for new trial

Anavex Highlights

FDA granted Orphan status to ANAVEX™ 2-73 for Rett syndrome; Clinical trial Q4 2017

- Orally available novel sigma-1 receptor (S1R) agonist with strong IP (COM to 2033)
- S1R linked to cellular homeostasis and plasticity relevant to CNS disorders

Safety with signals of efficacy established in Phase 2a Alzheimer's Disease trial

- 54 subjects treated with ANAVEX 2-73 (Phase 1 and Phase 2a)

Preclinical validation in other orphan and larger CNS diseases

- Portfolio of clinical and preclinical compounds varying in S1R and muscarinic binding kinetics

Partnerships with RettSyndrome.org, Michael J. Fox Foundation, FRAXA, and FAST

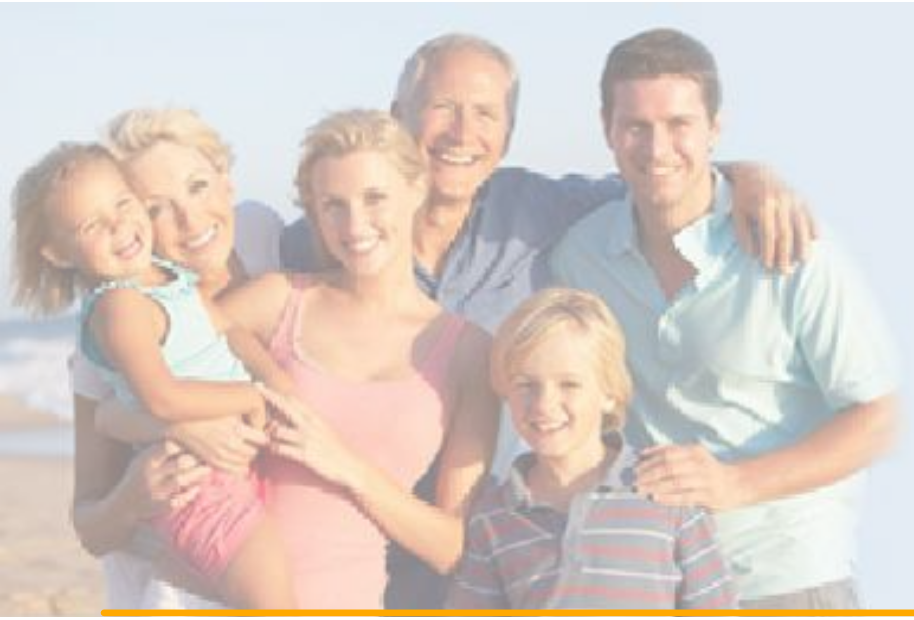
- Clinical studies focused on pursuing fastest path to market

Near term clinical advancements

- 4Q 2017 Phase 2a Alzheimer's disease – PK/PD data
- 4Q 2017 Phase 2 clinical trial in Rett syndrome
- 4Q 2017 Phase 2 clinical trial in Parkinson's disease
- 4Q 2017 Phase 2/3 clinical trial in Alzheimer's disease

Cash to fund operations over the next 2 years

Contact Us



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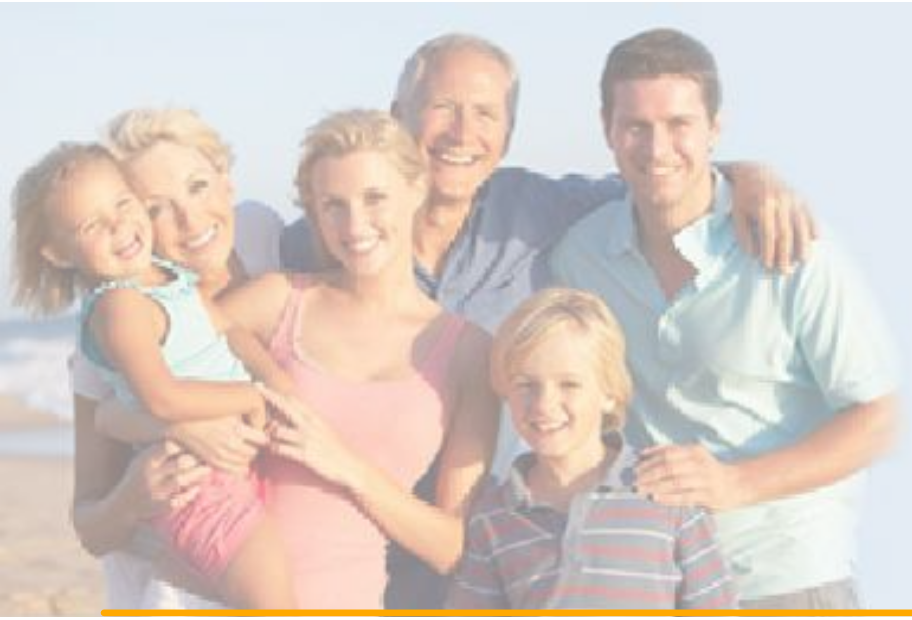
Back Up Slides

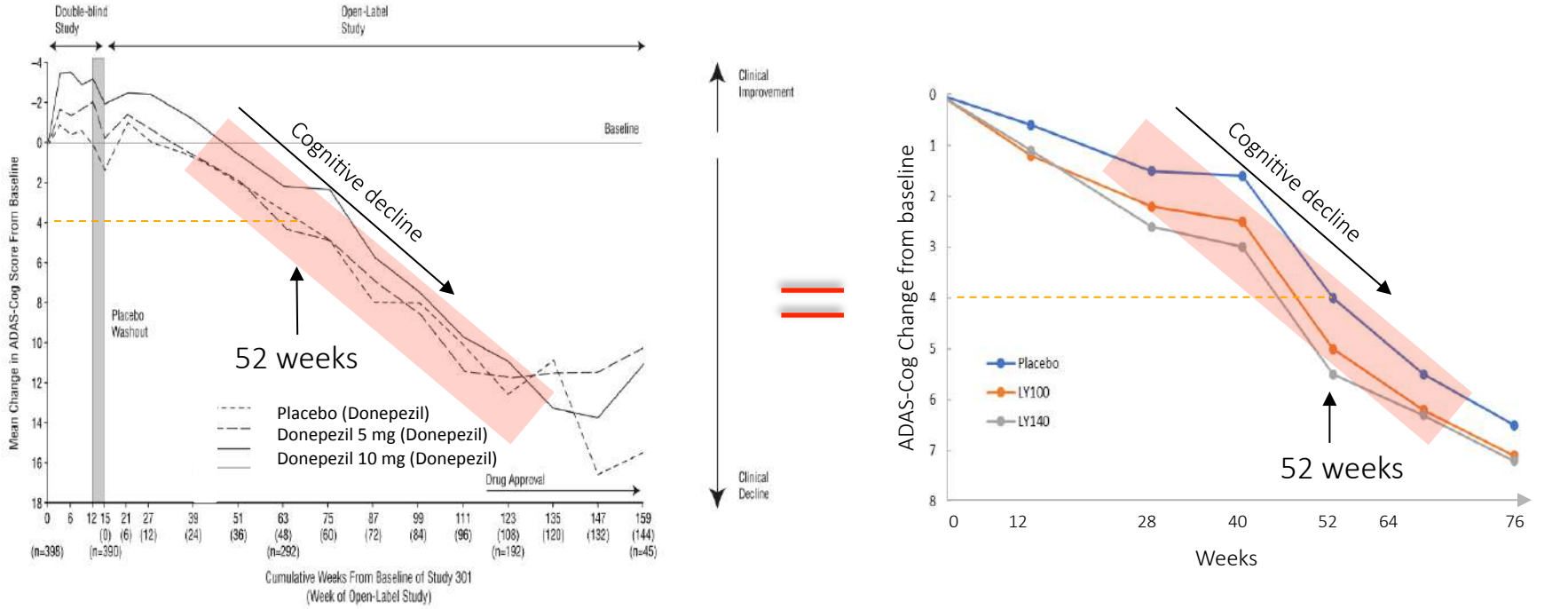


Alzheimer's Disease Progression:

Comparable cognitive decline in open-label studies as in placebo-controlled studies

Progressive decline in cognition: Open-label study with SoC#

Progressive decline in cognition: Double-blind placebo-controlled study with SoC##



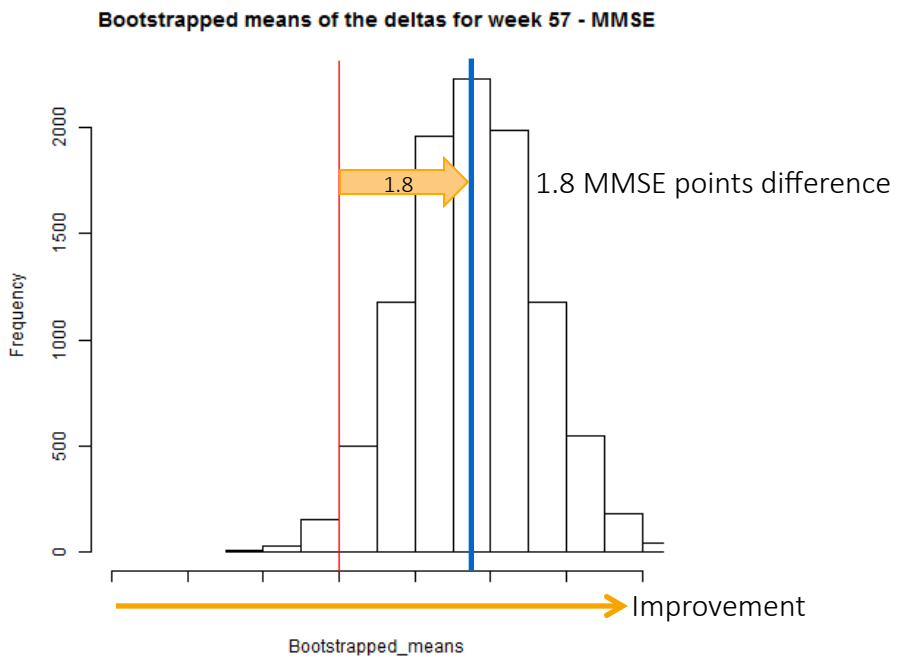
- Open-label and double-blind controlled studies equivalent for long-term cognition changes

 # Doody RS et al (2001) Arch Neurol. 58(3):427-433 (SoC = donepezil)

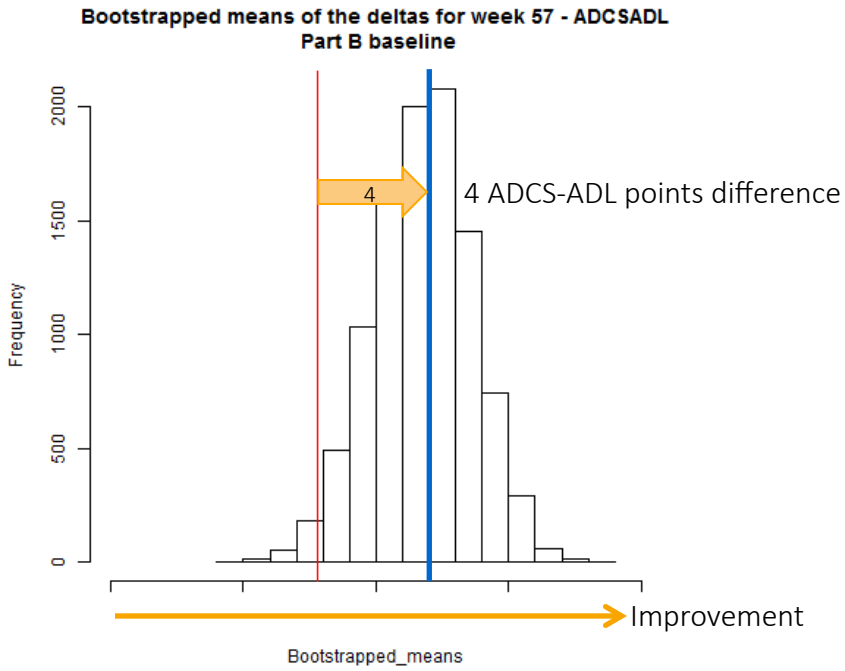
Figure adapted from Doody RS et al (2013) N Engl J Med; 369:341-350 (SoC = Ach inhibitors and/or memantine)

MMSE Δ and ADCS-ADL Δ Significantly Different to SoC AD

Bootstrap test for difference between ANAVEX 2-73 and SoC AD



1.8 MMSE points improvement to historical control (SoC)[#] at week 57 (p=0.0164)

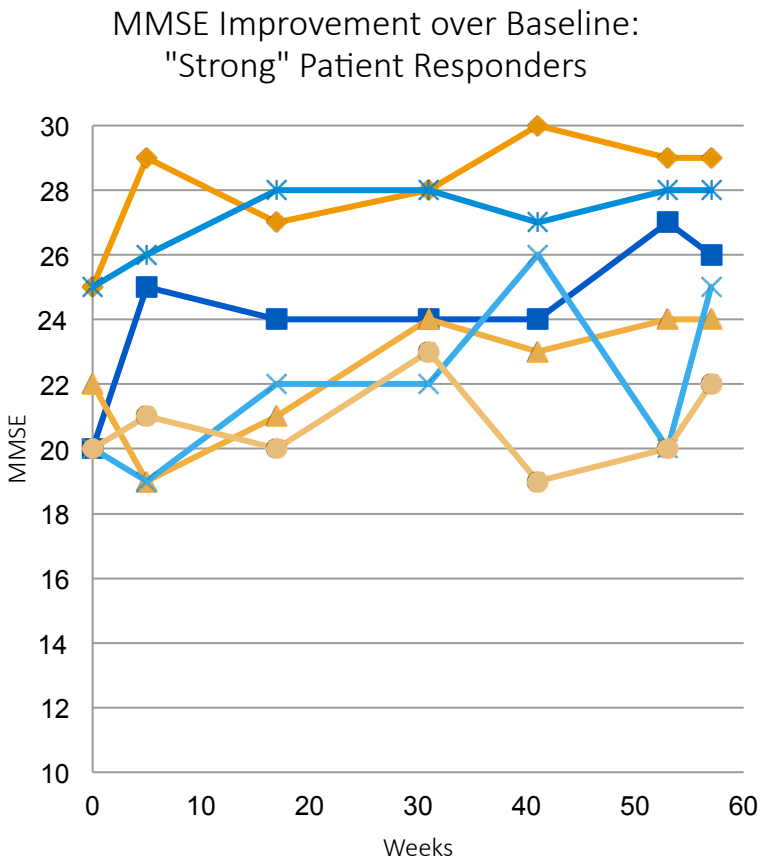


4 ADCS-ADL points improvement to historical control (SoC)[#] at week 57 (p=0.0186)

- SoC (Standard of Care AD): Comparison to historical control subjects with mild-to-moderate AD with comparable MMSE baseline, assigned to the placebo arm from pooled cohort study conducted by the Alzheimer Disease Cooperative Study Group, age adjusted[#]

[#] Source: C Bernick, J Cummings, R Raman, X Sun, P Aisen, Arch Neurol. 2012;69(7):901-905. doi:10.1001/archneurol. 2011.3758. RG Thomas, M Albert, RC Petersen, PS Aisen, Alzheimers Dement. 2016 May;12(5):598-603

Examples of Continued Improvements and Reported Events ‘Therapeutic Response’ during 57 Weeks



PATIENT	EVENTS: THERAPEUTIC RESPONSE UNEXPECTED
101001	MORE ALERT REGARDING SURROUNDINGS
101002	FEELS MUCH HAPPIER MAKING JOKES
101003	MUCH HAPPIER WHEN ATTENDING CLINIC APPTS AND ENJOYS MAKING JOKES AND ENGAGES WELL IN CONVERSATION
101004	BETTER HAND COORDINATION. CALMER AND MORE COMMUNICATIVE
101006	IMPROVING MOODS. READING MORE BOOKS
101007	ABILITY TO PLAY THE PIANO AND READ MUSIC NOTES AT ABOUT 9 MONTHS INTO TRIAL. SHE USED TO PLAY THE PIANO AT AGE 5 AND LOST HER ABILITY PRE-ALZHEIMER TRIAL
101010	ABLE TO FOLLOW PLOT WHEN WATCHING MOVIES WHEREAS PREVIOUSLY COULD NOT
101010	MORE COMPASSION FOR CHILDREN
101011	WIFE THINKS PATIENT IS A BIT MORE CHEERFUL
101013	ABLE TO DO MUCH MORE HOUSEWORK THAN BEFORE
101013	MORE DRIVEN AND UPBEAT LESS ANXIOUS ACCORDING TO CARER
101014	AN INTERNATIONAL ARTIST WHO RESUMED HER PAINTING ABILITIES AND NOW HAVING AN EXHIBITION IN NOV 2016. WRITTEN A 3 PAGE LETTER TO LONG LOST BROTHER
101015	PLAYING MORE GOLF NOW BY HIMSELF. MORE CONFIDENT AT GOING OUT BY HIMSELF
101017	ENJOYED HER TRIP TO BELGIUM - TALKS ABOUT SOME BITS OF HER TRIP
102001	IMPROVED ENGAGEMENT WITH FAMILY/FRIENDS/OUTSIDE WORLD
102008	IMPROVEMENT IN MOOD
102010	FEELING GREAT - IMPROVEMENT IN COGNITION AND MOOD, BALANCE AND GAIT HAS IMPROVED
103001	PATIENT REMEMBERING SOMETHING HE WOULDN'T HAVE PREVIOUSLY

ANAVEX™ 2-73 Shown to be Safe in Phase 2a Clinical Trial of Mild-to-Moderate Alzheimer's Patients

- Phase 2a results demonstrate a favorable safety, bioavailability, dose-response curve and tolerability/risk profile at doses between 10mg and 50mg of oral daily ANAVEX 2-73

- Primary endpoints met with favorable safety and tolerability

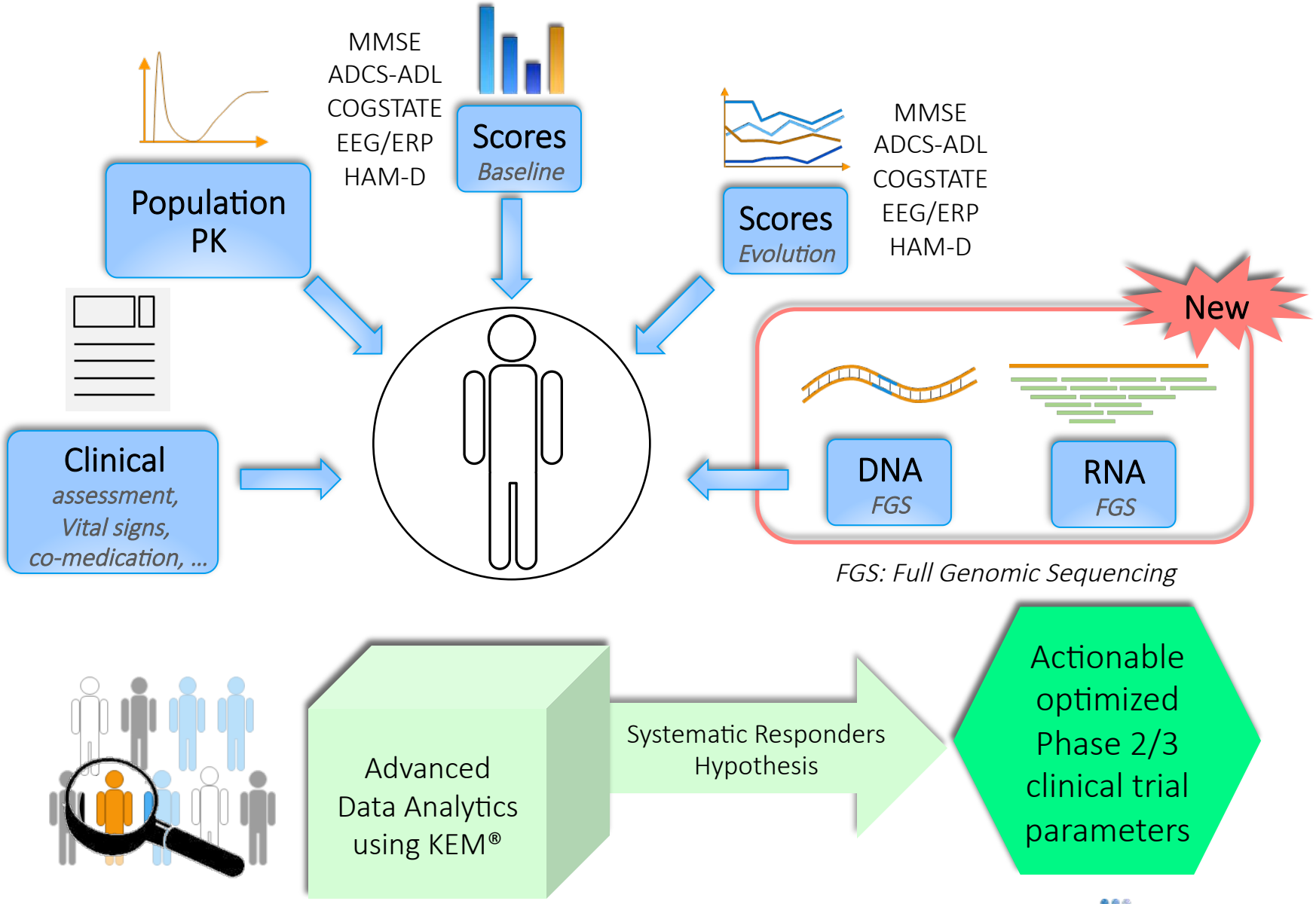
- Secondary endpoints met with supportive exploratory biomarker, cognition and functional measures correlating
  - Low-High dose was statistically significant to affect MMSE-Δ and EEG/ERP-Δ scores with **MMSE-Δ (p=0.0285) and EEG/ERP-Δ (p=0.0168)**, respectively

Stepwise Strategy to Address Major Unmet CNS Indications

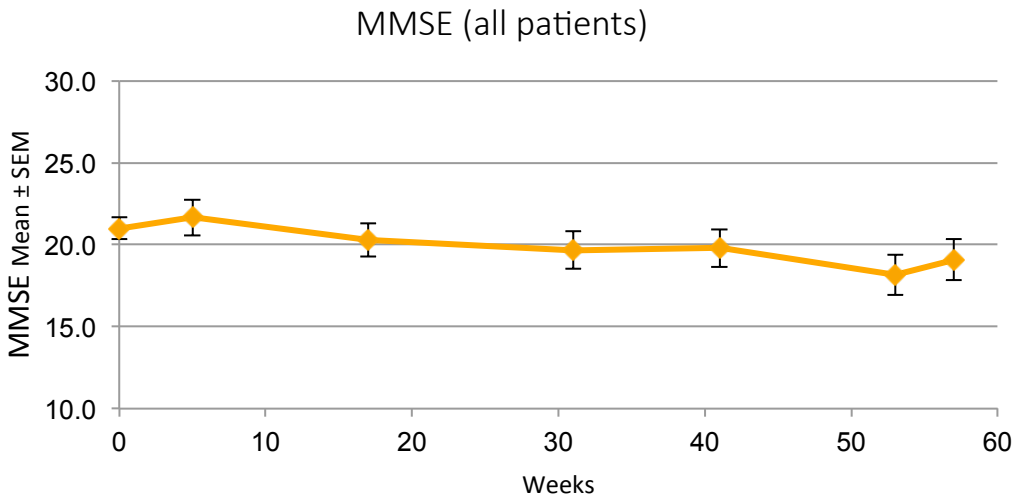
- ✓ Valuable feature of Sigma-1R agonists are their favorable safety profiles, particularly in humans due to the modulatory action of Sigma-1R
- ✓ Selectively only under pathological conditions while sparing normal physiological activity, thus limiting adverse side effects[#]
- ✓ Rational clinical strategy targeting first shorter-term endpoints. Goal: Reduction of clinical development risk
- ✓ Later expansion of indication scope with disease modification or prevention trial – ANAVEX 2-73 has already demonstrated preclinically to prevent symptoms of Alzheimer's[##]

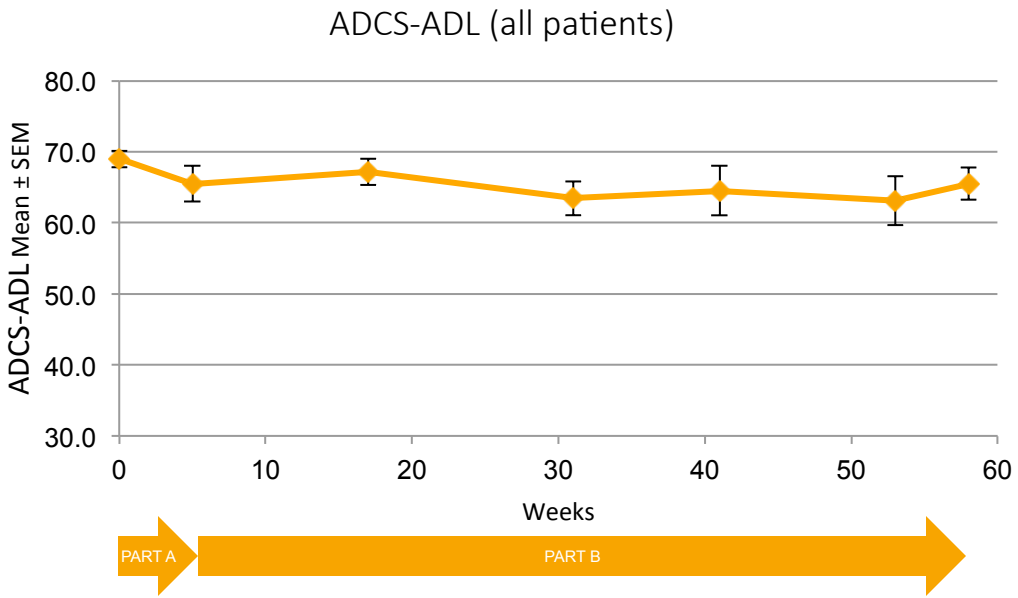
Source: [#]Nguyen et al J of Pharmacological Sciences 127 (2015) 17-29. [##]Lahmy et al Front Cell Neurosci. 2015 Jan 20;8:463, Presented at AAIC 2012

Comprehensive Phase 2a Patient Characterization to Identify Actionable Phase 2/3 Clinical Trial Parameters



57 Week Longitudinal Cognition MMSE and Function ADCS-ADL





- 57 week longitudinal MMSE and ADCS-ADL *without* dose optimization
- Cognition MMSE and Quality of life score ADCS-ADL (Activities of Daily Living) maintained close to baseline through week 57