

From: Santosh Naik (External) <Santosh@herspiegel.com>
To: Matthew Day
CC: Tyler Sagardoy; Jeffrey Dierks
Sent: 10/14/2014 5:42:57 PM
Subject: VANTRELA Draft Summit template
Attachments: VANTRELA ER Oct Launch Summit 2014 10 14.pptx



Hi Matt,

Please see attached the consolidated VANTRELA ER Summit slides for our meeting at 2 PM. We can review via GlobalMeet during the meeting. Thanks!

Regards,

Santosh Naik



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LAUNCH SUMMIT

Section	Presenter	Time
Welcome and Introduction	Jeffrey Dierks	1:00-1:0pm
VANTRELA AOP Review	Jeffrey Dierks	1:10-1:25pm
Regulatory Timeline Update	Douglas Harnish	1:25-1:35pm
Medical/Clinical Overview	Matt Wieman	1:35-2:00pm
REMS	Robin DeChristopher	2:00-2:15pm
Sales Overview	Jim Reilly	2:15-2:35pm
<i>Break</i>		<i>2:35-2:55pm</i>
Market Access	Deb Bearer	2:55-3:15pm
Govt. Affairs/Advocacy Overview	Karen Hill/Rob Falb	3:15-3:35pm
Operations/Trade	Derek Moe/Jason Jones	3:35-3:55pm
Marketing Overview	Matt Day	3:55-4:30pm
Conclusion	Matt Day	4:30-4:40pm

- **Highlight Goals and Objectives for each team**
- **Review Recent Accomplishments**
 - Highlight work that has been completed
- **Identify immediate priorities for each subteam**
 - Identify interdependencies, gaps, and ensure alignment on priorities
- **Review Launch Timelines**
- **Review Subteam Key Performance Indicators**





Jeffrey Dierks

VANTRELA ER AOP

**Large market
opportunity
with actionable
target segments**

- Significant chronic patient population, societal impact, advocacy pressure, limited LAO Abuse Deterrent options

**Abuse Deterrent
Education for
HCPs**

- Empower prescribers with understanding on technology, tiering and FDA guidelines to establish relevance, value of VANTRELA™ ER

**Establish equity
for TEVA AD
technology**

- CIMA® AD technology platform expected to deliver differentiated label tiering (Tier III – Oral/Nasal)
 - Foundation for entire ADT Opioid franchise

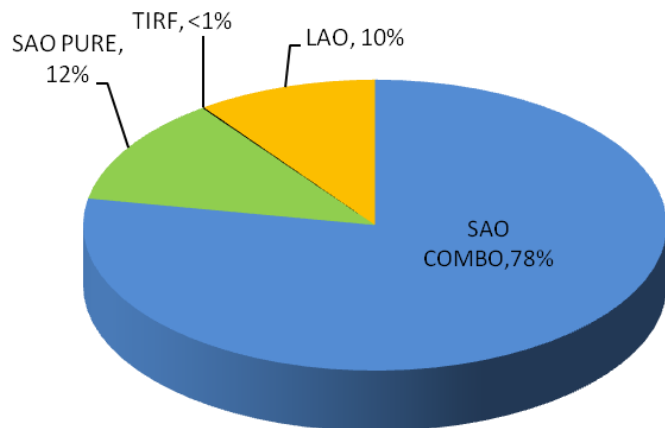
**Develop
Differentiated
Brand**

- ‘Intelligent Design’ positioning - broadest dosing range, differentiated ADT tiering, no alcohol dose dumping

**Optimized
Resourcing**

- Industry benchmarks, research inform go to market strategy to maximize return to organization over product life cycle

SAO/LAO Market:
Sales: \$8.1B
Volume: 221MM TRx
Graph Depicts Volume Share



Hydrocodone = 127MM TRx

~900K HCPs Rx IR Hydro
~46K D 3-10 HCPs Rx LAO and IR Hydro
Current PCSF Covers 11% of 46K

Key Insights & Market Opportunity

- 100M Americans affected by chronic pain (IOM 2011 Report)
- Opioids make up ~1/3 of U.S. chronic pain market sales
- Opioid abuse & misuse epidemic putting pressure on society, presents opportunity
 - IR Hydrocodone reclassified from CIII to CII – Oct 2014
- VANTRELA™ ER uniquely positioned with (AD) technology

Key Competitors

- | | |
|--|---------|
| • Zohydro non AD BID ER Hydrocodone | Q1 2014 |
| • Purdue (Hysingla ER) AD QD ER Hydrocodone | Q4 2014 |
| • Zohydro BID reformulation w limited AD claims | Q1 2015 |
| • Mallinckrodt AD ER Low Dose HC with APAP | Q1 2015 |

Access Landscape

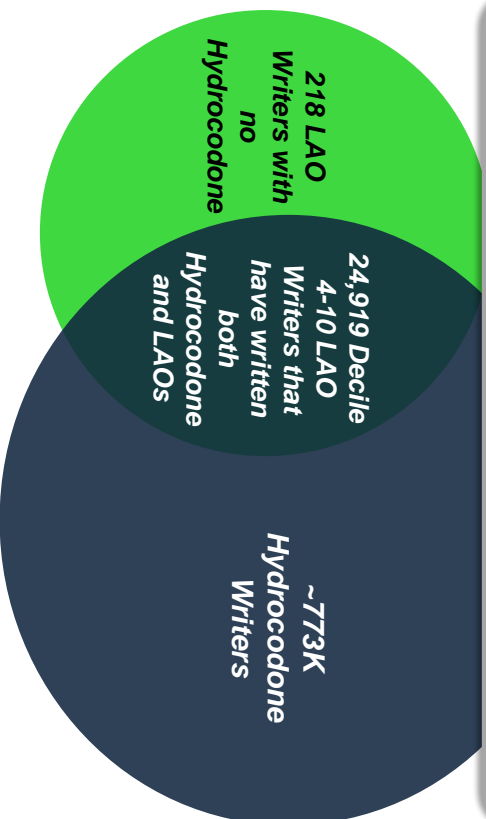
- IR Hydrocodone is highly genericized
- Payers do not actively manage LAOs
- HEOR data needed for AD LAOs

Sources: IMS National Sales Perspectives and IMS National Prescription Audit (MAT May 2014); Institute of Medicine (2011); Decision Resources Chronic Pain Report (2013)

VANTRELA™ ER Target Audience

HCP TARGET AUDIENCE

- Opioid Experienced Pain Specialists treating pain severe enough to require around-the-clock opioid treatment
- ~25K HCPs make up 60% of market opportunity



ADVOCACY AUDIENCE



PRIORITY

ENGAGEMENT

AWARENESS



VANTRELA™ ER PATIENT

- Current SAO hydrocodone patients who are transitioning from SAO to LAO for improved pain relief/control
- 1.8MM patients



Product	PDUFA Date	Dosing	Total Daily Dose	Food Restriction	Effect of Alcohol PK	Anticipated AD Label Tiering
Hysingla™ ER	Q4 2014	QD	20-120mg	No food restriction	Decreased release with higher alcohol	Tier I, III (Nasal)
Zogenix	Q1 2015	Q12hrs	20-100mg	No food restriction	Increased release in presence of alcohol	No AD claims at launch
VANTRELA™ ER	Q2 2015	Q12hrs	30-180mg	Must take on empty stomach	No dose dumping	Tier I, III (Oral & Nasal)

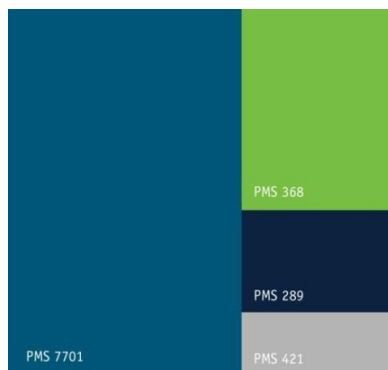
Abuse Deterrent Tiering

Tiers	Study type	Claim
1	Laboratory extraction and manipulation studies	The product is formulated with physiochemical barriers to abuse
2	Pharmacokinetic studies	The product is expected to reduce or block effect of the opioid when the product is manipulated
3	Clinical abuse potential studies	The product is expected to result in a meaningful reduction in abuse
4	Post marketing studies	The product has demonstrated reduced abuse in the community

VANTRELA™ ER Positioning – ‘Intelligent Design’*

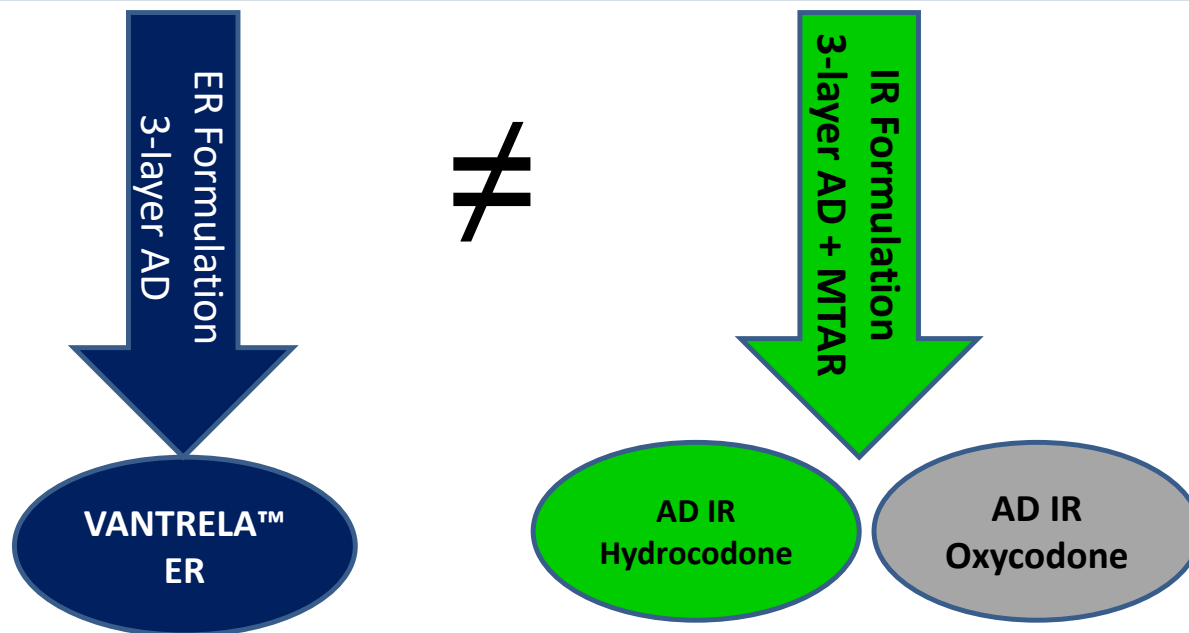
- Built with the trusted and most widely prescribed molecule, hydrocodone,
- Delivered as polymer granules in a tablet matrix to provide consistent 12-hour pain relief
- Advanced technology designed to deter abuse in 3-ways: crushing, snorting & alcohol dose dumping
- Q12hr. dosing with broadest range of dosing (30mg - 180mg per 24 hours)
- Available in 5-dosage strengths to address individual patient pain relief needs, APAP-Free

SAO ➡ **VANTRELA™ ER** ➡ **LAO**



* Positioning Statements are not marketing messages. They are aspirational in nature and not approved for use in promotion

CIMA® ADT Technology Platform



- Comprehensive clinical program expected to deliver differentiated label tiering (Tier III – Oral/Nasal) builds equity in CIMA® ADT technology platform
- Platform branding allows for use prior to launch, building equity in technology prior to approval
- Platform not formulation is foundation for entire ADT Opioid franchise

Strategies

Objectives

KPIs

1

Educate on Appropriate Use,
Abuse Potential and
Deterrence technology

- Educate marketplace about appropriate opioid prescribing, abuse potential, technology and FDA guidelines
- Help to shape, establish AD industry & market standards

- Reach 60% of target HCPs with '**Pain Matters**' educational program touchpoint
- Drive aided AD awareness among target physicians \geq 30%
 - D 9-10 > 50%
 - D 5- 8 > 25%

2

Develop a differentiated
brand

- Differentiate and integrate Teva AD technology into VANTRELA™ ER profile
- Build differentiated, ownable and unique positioning, message platform for defined appropriate patient
- Collaborate with clinical team to optimize data to align with unmet market needs

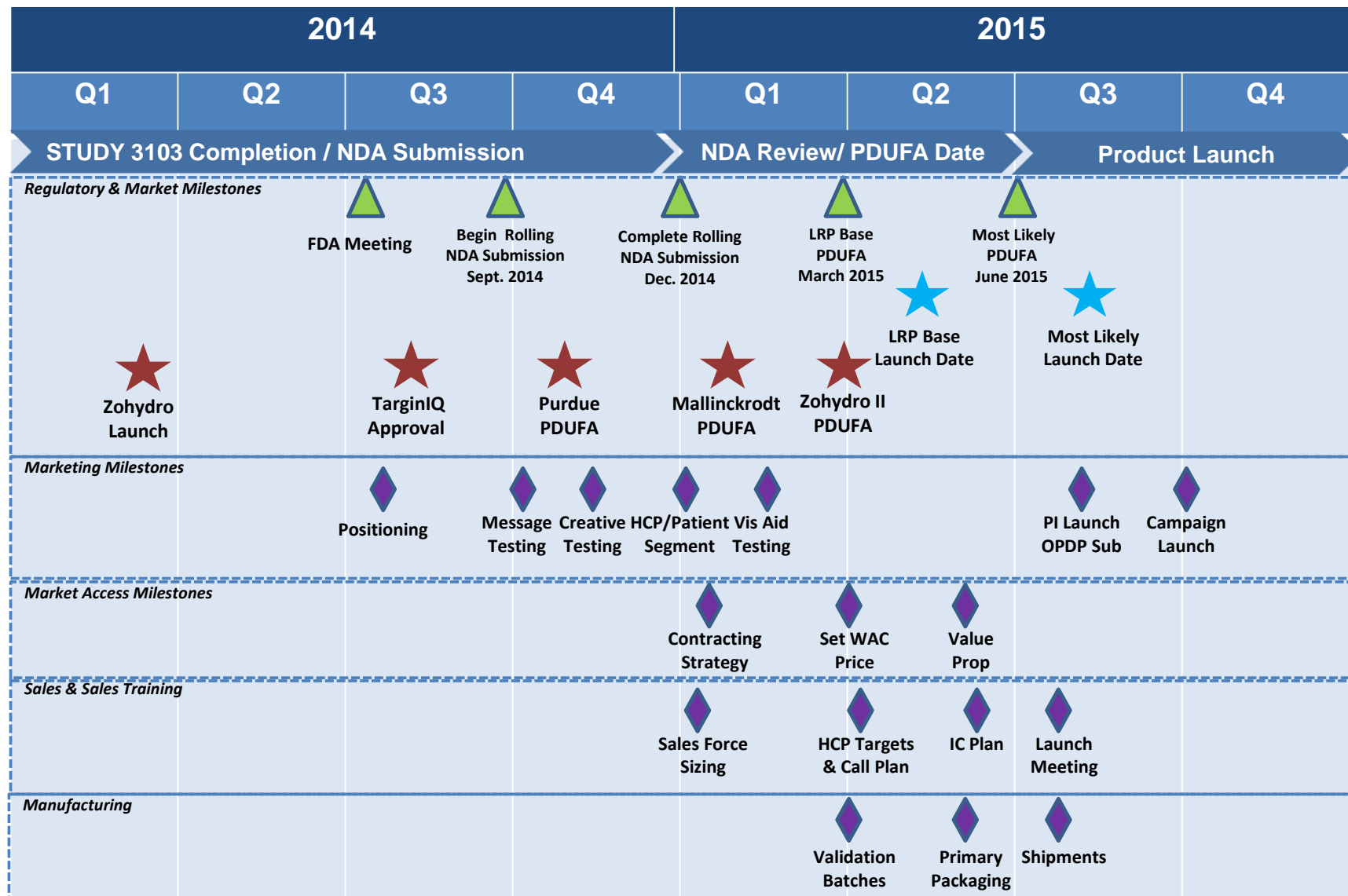
- Quantitative verification of differentiated profile, patient type
- Exceed industry benchmarks to measure message relevance, believability & credibility
- Initiation of conversion study by Q1, completion by Q4 2015

3

Ensure reimbursement
access for HCPs and
appropriate patients

- Differentiate brand through clinical profile, compelling value proposition, optimal pricing and contracting platform
- Partner with key constituents to strengthen access landscape

- Ensure 75% Commercial live access
- Ensure launch stocking at 15K pharmacies
- Optimize sales force alignment to deliver maximum impact among ~20K targets
- Develop partnerships with top 4 advocacy groups

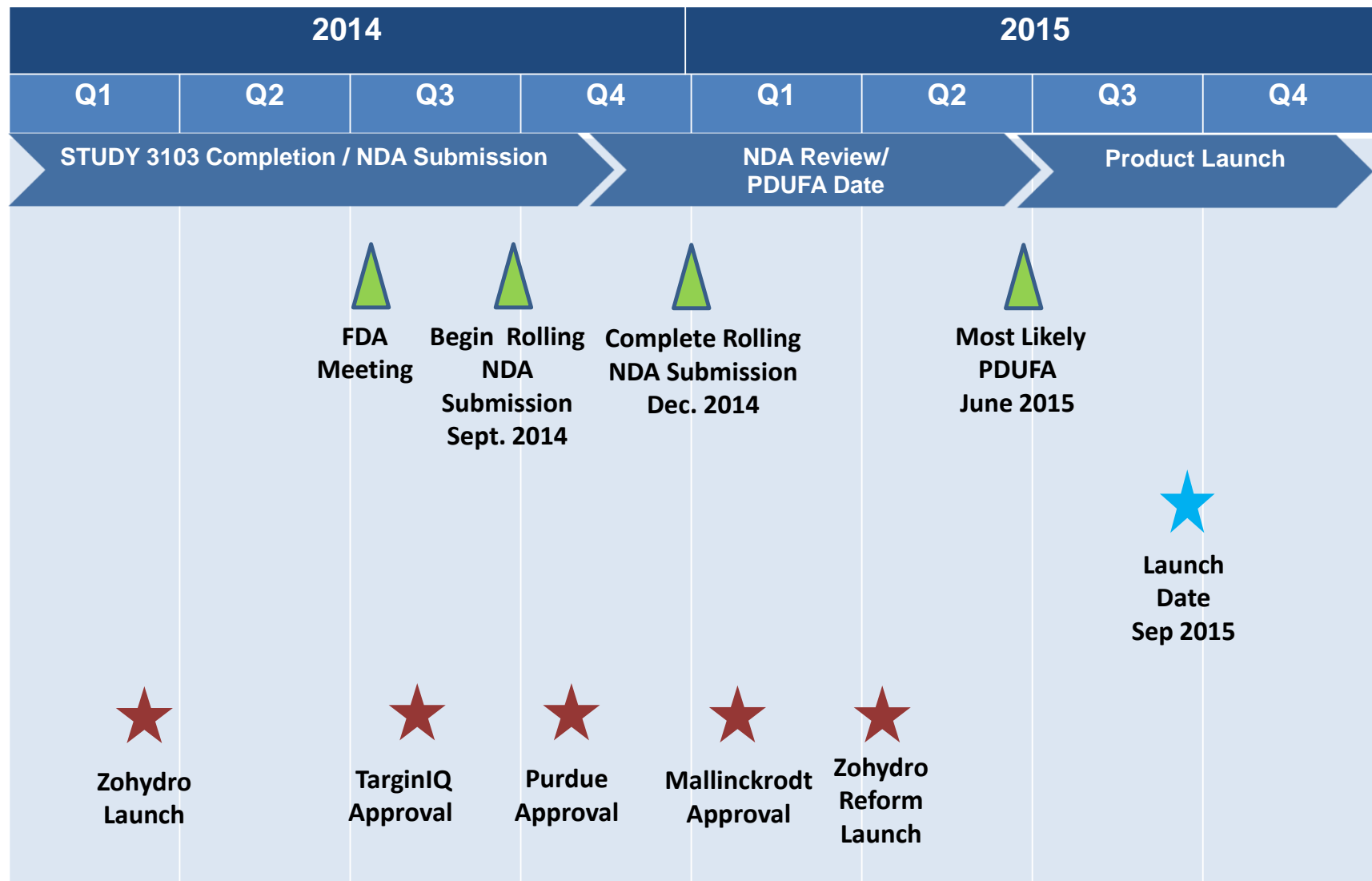




Douglas Harnish

REGULATORY UPDATE

VANTRELA™ ER Regulatory Timeline



Immediate Priorities (Next 3 Months)

- *Submit final NDA documents to FDA by end of December*
- *Address FDA comments on Carcinogenic Special Protocol Assessment and NDA*





Matt Wieman

MEDICAL / CLINICAL

Goals and Objectives

1. Support the VANTRELA™ ER launch for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate
2. Educate healthcare providers regarding appropriate use of abuse deterrent technologies for opioids
3. Support educational programs, and respond to Medical Information requests regarding abuse deterrent technology and VANTRELA™ ER
4. Support key Health Economics and Outcomes research to communicate the value of VANTRELA ER
5. Develop Scientific Communications (abstracts/presentations) for a wide-ranging number of US Scientific Conferences
6. Increase knowledge of the role of VANTRELA ER on active day-to-day chronic pain management through the design and execution of Phase IV trials
7. Educate healthcare providers regarding VANTRELA™ ER and inclusion in LAO REMS program

Recent Accomplishments

- *Finalized 2015 medical educational grants budget*
- *Completed and reviewed Phase IIIb/IV study synopsis with external experts*
- *Presented Human Abuse Liability Study 10032 to PAC and began CSR development*
- *Developed budget impact model framework*
- *Drafted primary manuscript on open label study 3080 on long-term safety and abuse divergence*
- *Presented 3103 data at IASP*

Activity 1: Medical Affairs Data Gaps: NIS/ Ph IV/ISS

Key Data Gaps by Strategic Imperative
Key Data Generation:
Ongoing NIS / Ph IV/ ISS
Planned NIS/ Ph IV
ISS Strategy
Budget

Activity 2: Scientific Communications

Information Gap by Strategic Imperative
Planned Scientific Message
Journal
Functional lead
Publication Plan
Budget

Activity 3: Medical Affairs: Customer Engagement

Define the key customers to be involved in Medical Affairs Activities (number and type)
Define key Medical Affairs engagement plan, CSF, timelines and Budget

Activity 4: GHEOR

GHEOR Value Gaps
GHEOR Strategy and Objectives
GHEOR
Projects/Purpose/Component/
Timelines
Budget

Activity 5: Medical Affairs – MSL and Medical-to-Medical Communication

Medical-to-Medical Engagement Plan:
Strategic Imperative and MSL Tactics:
Contact Targets
Key messages
MSL materials and projects
Budget

Activity 6: Medical Information and Training

Medical Information needs
Training and Education needs
Medical Information and Training Plan
Budget

Description	An 8-Week, Open-Label, Observational Study to Evaluate the Efficacy and Safety of Hydrocodone Bitartrate Extended-Release Tablets (CEP-33237) at an Individually Optimized Treatment Regimen (15, 30, 45, 60, or 90 mg Every 12 Hours) for Relief of Moderate to Severe Pain in Patients with Chronic Low Back Pain Who Require Opioid Treatment for an Extended Period of Time After Opioid Rotation from Immediate Release Hydrocodone/Acetaminophen
Type/Design	Phase 4 study
Region/Countries	United States
Primary Endpoints	The primary objective of this study is to determine the successful dose of hydrocodone extended-release tablets for individual subjects that produced stable pain relief without unacceptable adverse events.
Population	150 patients with chronic low back pain who require opioid treatment for an extended period of time
Timelines	1Q 2015 – 4Q 2015
Total Budget	\$3,500,000
Status	Planning

Draft Areas of Interest for Future ISS

Rotation from short-acting opioids (other than hydrocodone) and long-acting opioids to VANTRELA™ ER

VANTRELA™ ER in Patient Populations:

- **Opioid-naïve patients**
- **Patients with acute pain**
- **Patients with chronic pain**
- **Patients with breakthrough pain**

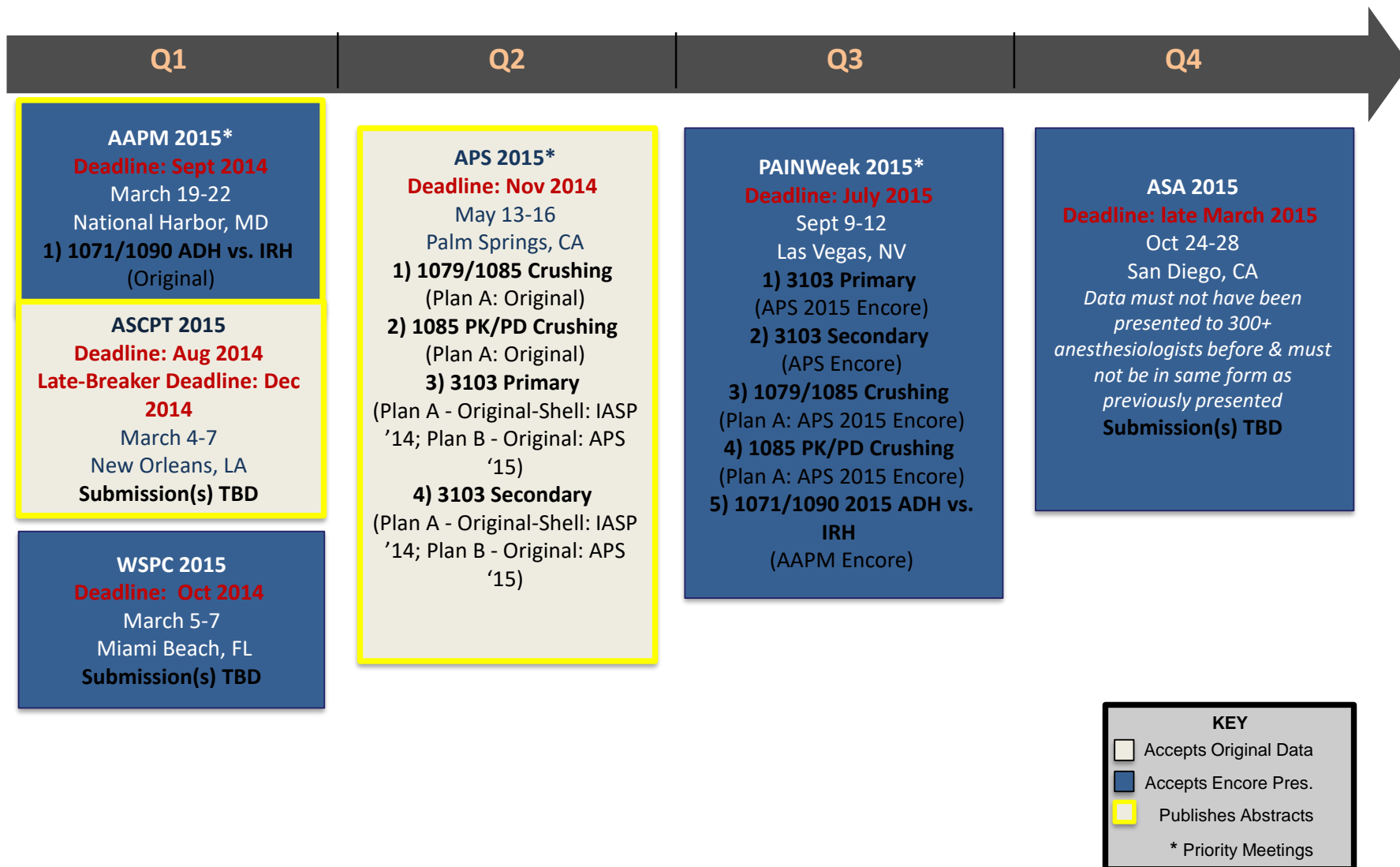
HEOR Outcomes:

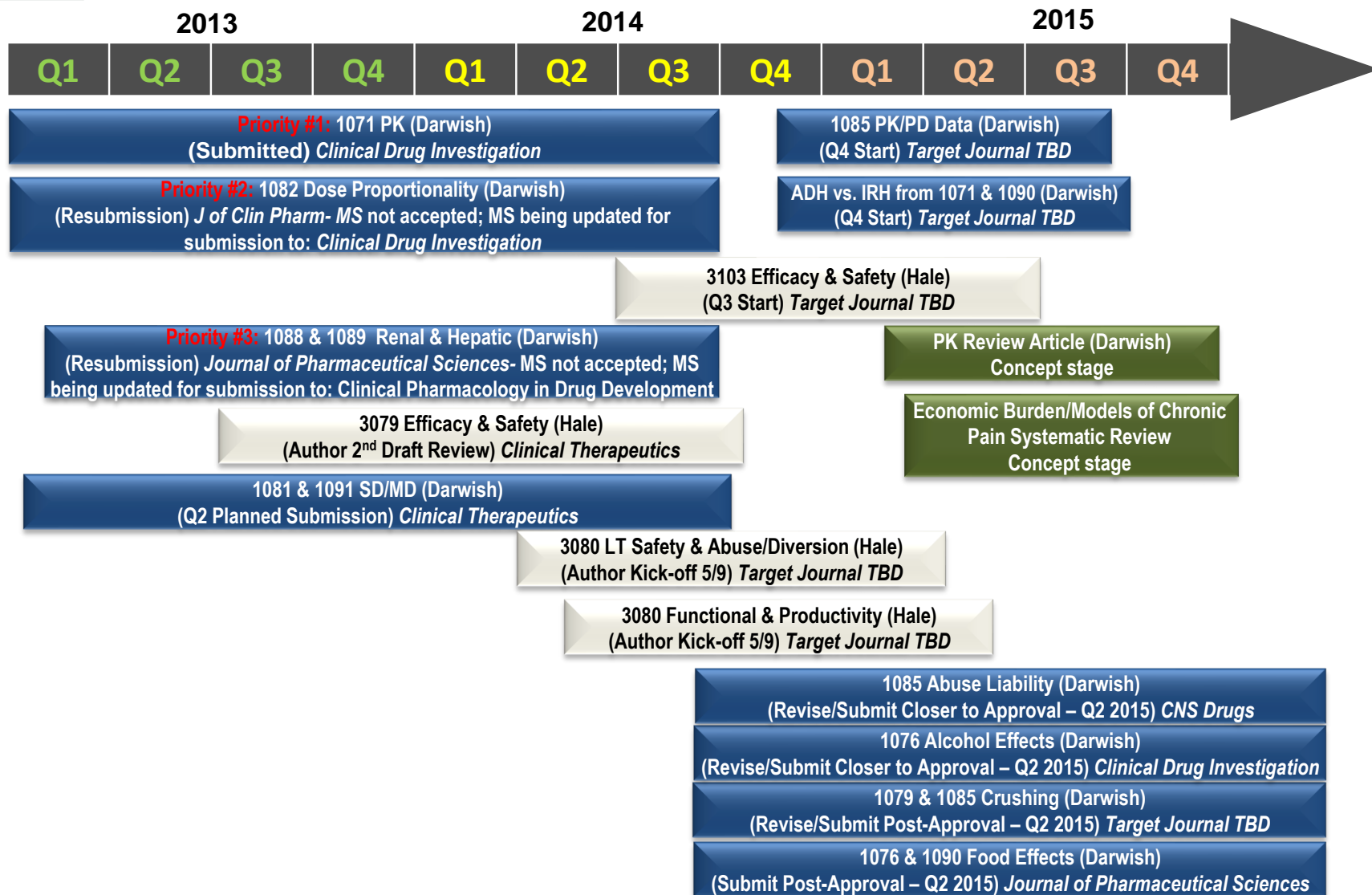
- **Quality of life**
- **Global functioning measures**

Impact of acetaminophen-combination products on safety and efficacy in patients with chronic pain

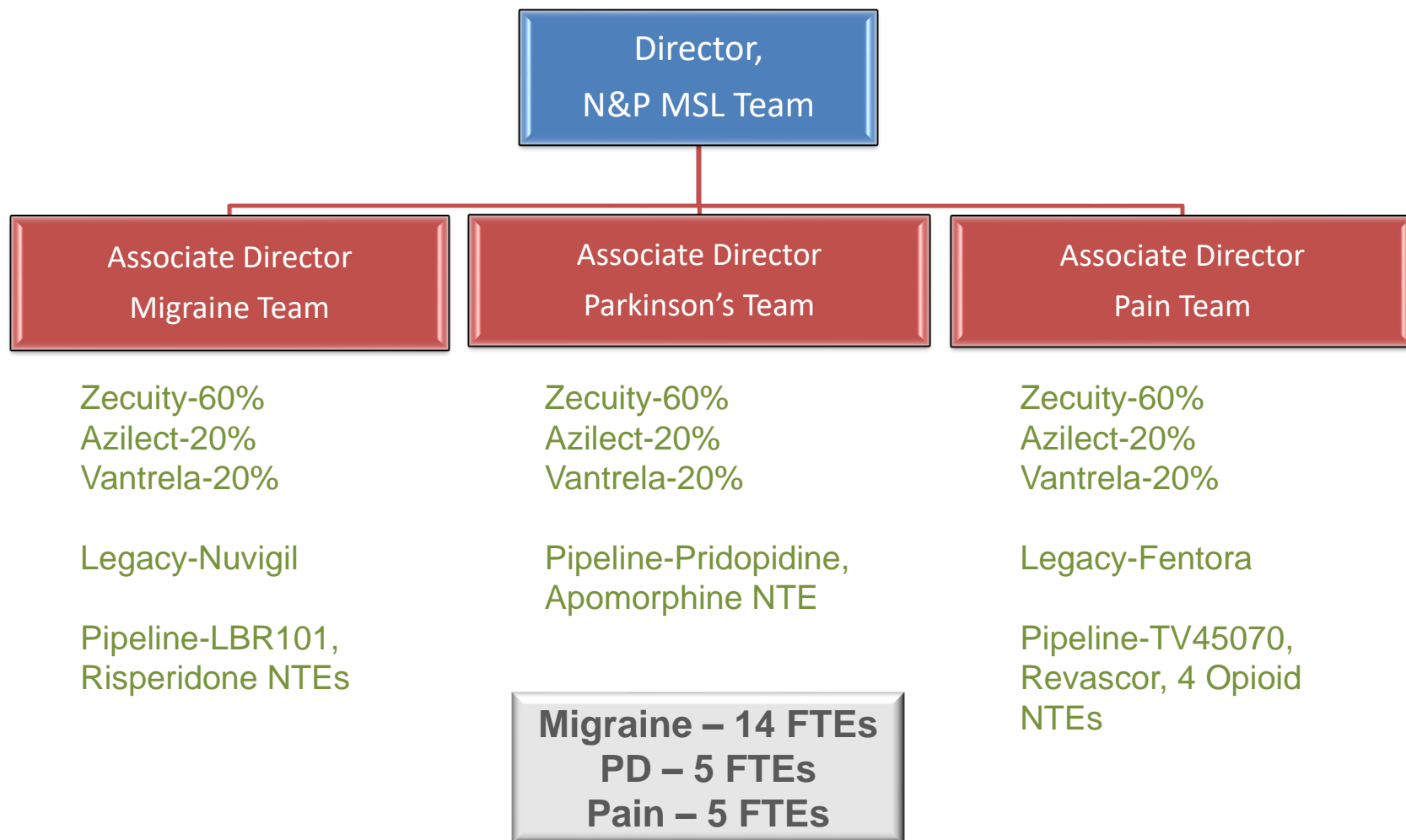
Options for rescue medications

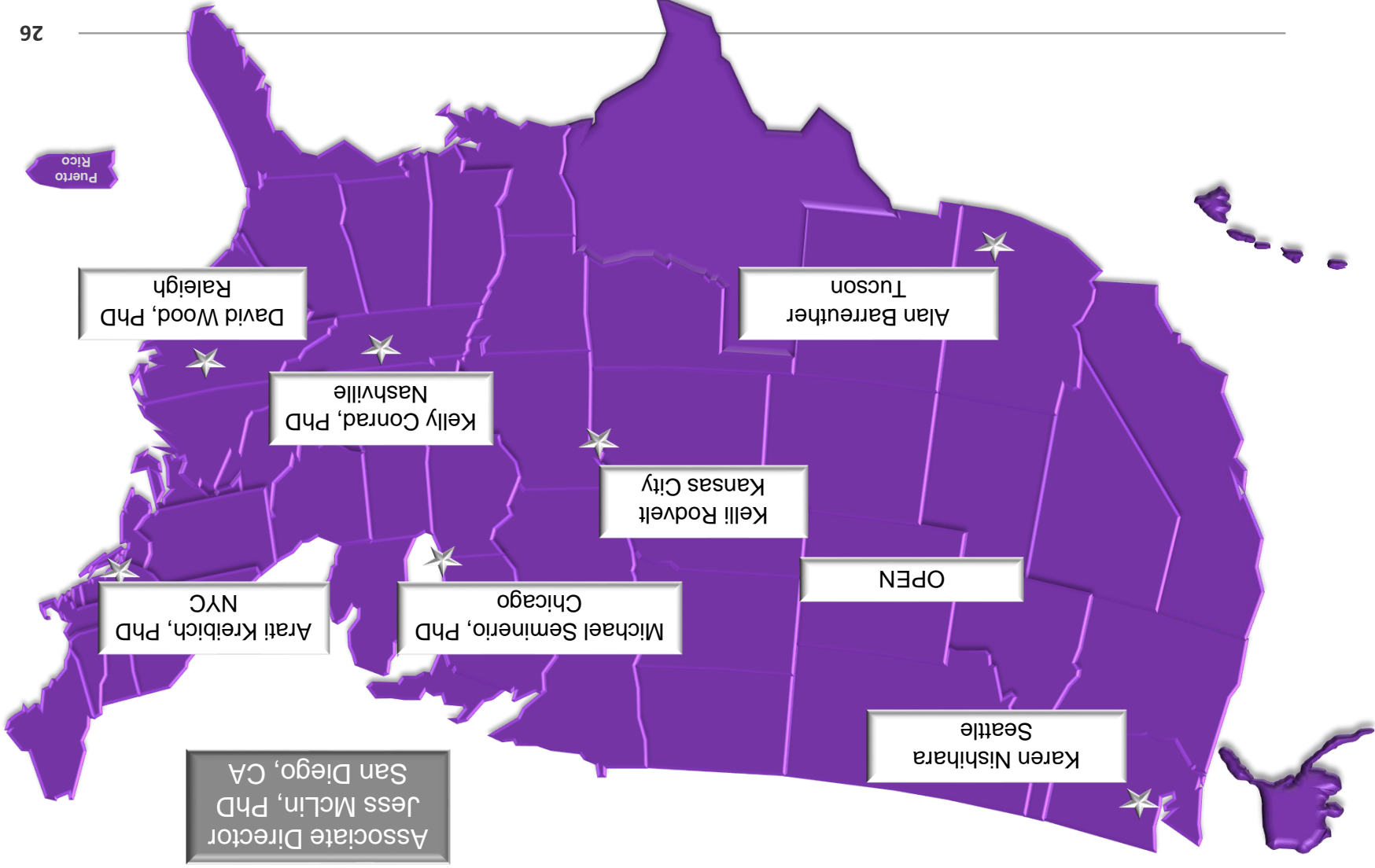
Total Budget: \$198,000





Objective	Study/Tactic	Status/ Timeline
Differentiate brand through clinical profile, compelling value proposition, optimal pricing and contracting platform	Demonstrate the economic benefits of LAO use versus SAO use in management of chronic pain	Analysis completed. Publication planning in process
	Demonstrate increased economic burden in terms of cost of care in LAO patients who are casual users of alcohol	Proposal Received Study completion- Q1 2015
	Budget Impact Model for VANTRELA™ ER	Started, completed Q2/3 2015 (for availability at time of launch)
	AMCP Dossier for VANTRELA™ ER	Anticipated completion Q3 2015





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Immediate Priorities (Next 3 Months)

- *Complete Human Abuse Liability Study 10032 CSR*
- *Conduct Medical Ad Board in December*
- *Finalize draft protocol for Phase IIIb/IV studies*
- *Develop draft ISS plan*
- *Finalize Budget impact model*
- *ePublish manuscript for Safety & Efficacy Study 3079*
- *Conduct MSL Datacrunch meeting*



Launch Key Performance Indicators

KPI 1: Execute 100% Scientific Publications plan by Launch

KPI 2: Educate and Train Medical Science Liaisons to complete 100% of scientific exchange objectives

KPI 3: Finalize all Standard Response Letters and train call center staff by launch







Robin DeChristopher

REMS



Jim Reilly

SALES

Goals and Objectives

Sales Operations

- *Analyze and update sales force structure and alignment*
- *Develop HCP targeting lists/call plans for sales force*
- *Gather and integrate sales data*
- *Develop and implement incentive compensation plans*

Training

- *Develop educational materials and programs for sales force*
- *Facilitate RSM training and sales force trainings at launch meeting and educational workshops*
- *Provide post-launch reinforcement training*

Launch Meeting Preparation

- *Plan and execute launch meeting*

Recent Accomplishments

- ✓ Developed 'Optimized Resource' Sales Structure Model to support Vantrela Launch and existing in-line product promotion:
 - ☐ completed analysis in coordination w/ 2015 AOP
 - ☐ reviewed recommendation w/ key stakeholders and Senior Leadership
 - ☐ pending final approval 2015 AOP (Executive Leadership)
- ✓ Selected Sales Training Vendor
- ✓ Kicked off HCP Segmentation project



	Q1 2015	Q2 2015	Q3 – Q4 2015	2016
TNS	199 <div>Copaxone</div> <div>Azilect</div>	87 87 25 <div>Copaxone</div> <div>Copaxone</div> <div>Copaxone</div> <div>Zecuity</div> <div>Azilect</div> <div>Zecuity</div> <div>Azilect</div>	87 87 25 <div>Copaxone</div> <div>Copaxone</div> <div>Copaxone</div> <div>Zecuity</div> <div>Azilect</div> <div>Zecuity</div> <div>Azilect</div>	87 87 25 <div>Copaxone</div> <div>Copaxone</div> <div>Copaxone</div> <div>Zecuity</div> <div>Azilect</div> <div>Zecuity</div> <div>Azilect</div>
TPC1 (TNP)	254 <div>Nuvigil</div> <div>Amrix</div> <div>Azilect</div>	254 <div>Nuvigil</div> <div>Azilect</div> <div>Zecuity</div>		
TPC2 (TPC)	70 <div>Fentora</div> <div>Amrix</div>	70 <div>Fentora</div> <div>Amrix</div>	# Reps *	# Reps*
TPC			 <div>Nuvigil</div> <div>Nuvigil</div> <div>Zecuity</div> <div>Vantrela</div> <div>Azilect</div> <div>Fentora</div> <div>Zecuity</div> <div>Vantrela</div> <div>Amrix</div> <div>Amrix</div> <div>Azilect</div> <div>Fentora</div>	 <div>Vantrela</div> <div>Vantrela</div> <div>Amrix</div> <div>Zecuity</div> <div>Fentora</div> <div>Azilect</div> <div>Vantrela</div> <div>Zecuity</div> <div>Amrix</div> <div>Amrix</div> <div>Zecuity</div> <div>Azilect</div>

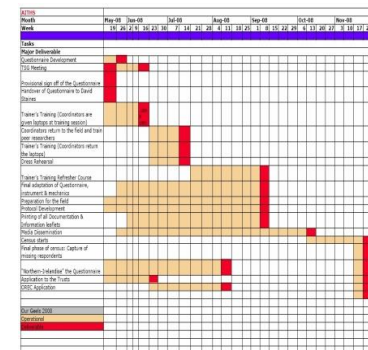
* Proposed Headcount = Assumes additional sales representatives to support Launch of Vantrela

- ✓ Launch plan draft complete
 - Final copy complete Nov 2014
- ✓ Vendor partner (Illuminate) selected for home study modules

- SOW with Legal for stamp & approval
- Module 1: Anatomy and Physiology of Pain
- Module 2: Classification & Epidemiology
- Module 3: Pain Management
- Module 4: Issues in Chronic Pain Management



- ✓ Vendor partner selected for building of launch workshops in 2015
 - Story flow in development
- ✓ Scale-up training matrix/grid in development
 - Completion Nov 2014



- *Optimize Sales force*
 - *Status: Optimized alignment work underway for completion in Q2 2015*
- *Incentive Comp design*
 - *Status: Design process has begun for completion by Q2 2015*
- *HCP Segmentation Project*
 - *Status: All data files delivered to ZS on Friday, October 3rd*
 - *Robust segmentation work underway for completion in January 2015*



Immediate Priorities (Next 3 Months)

- *Create hiring process for expansion of CNS BU Sales Force*
- *Complete Incentive Compensation design for 2015*
- *Build internal Sales Operations infrastructure to support Optimized Resource Sales structure*
- *Begin development of e-modules for Sales Training*
- *Complete HCP segmentation project*



Launch Key Performance Indicators

KPI 1: Complete Sales Force expansion w/ hiring dates for 2015:

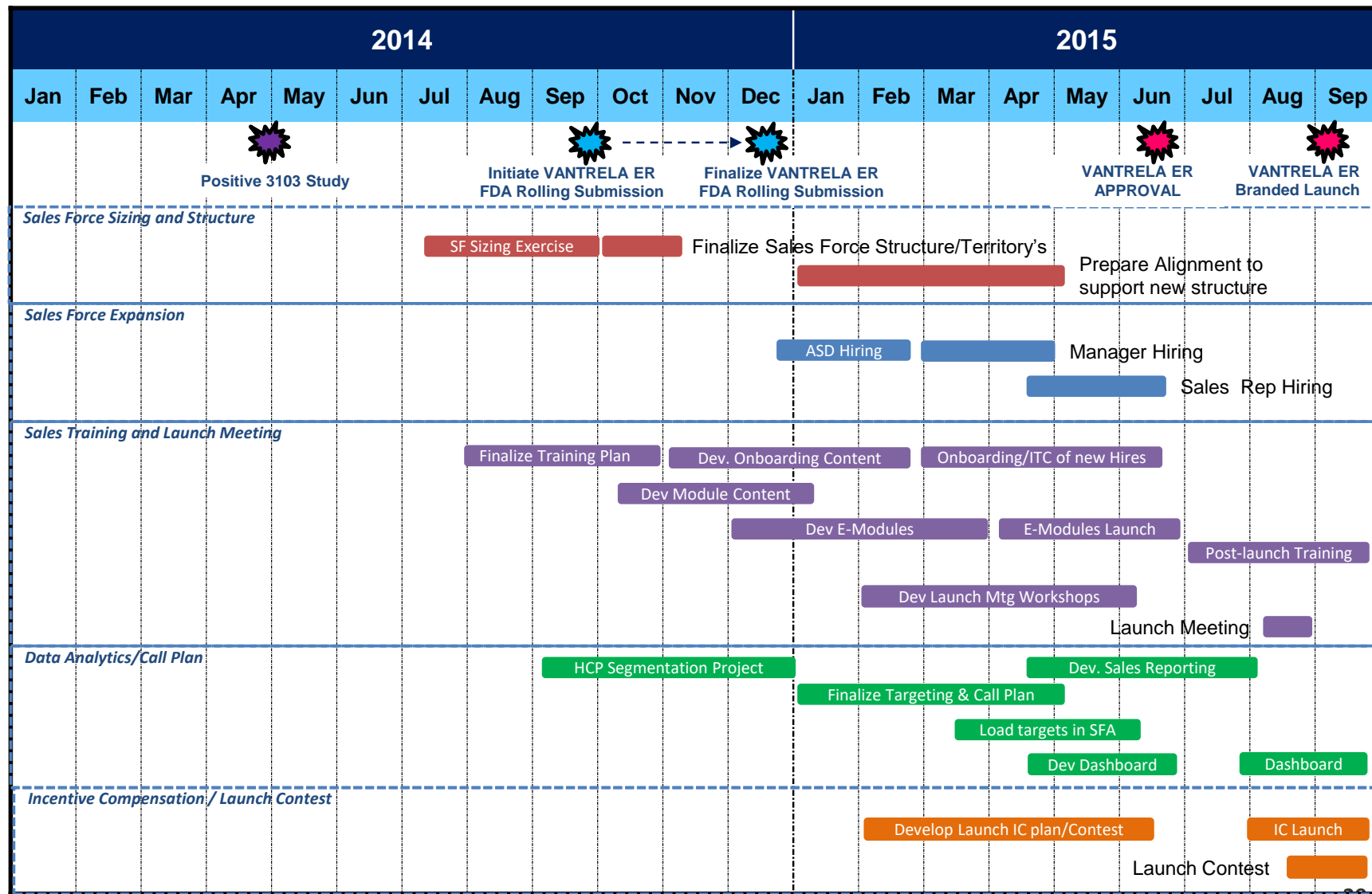
Directors - January; RSMs - Feb/Mar; Sales Reps by June/July

KPI 2: VANTRELA ER Incentive Compensation plan/launch contest in place by Q2 2015

KPI 3: Sales Representatives trained and certified by Launch in September 2015

KPI 4: Final target list/call plan finalized by Q2 2015







Deb Bearer

MARKET ACCESS

Goals and Objectives

1. Develop and communicate an effective value proposition for payers and policymakers
2. Develop contracting strategy and appropriate tools to support engagement with payers to ensure favorable reimbursement access
3. Maximize contribution through an effective pricing strategy



Recent Accomplishments

- *Kicked off Value Proposition Testing*
 - *Reviewed discussion guide development; screener development and recruitment for refined value proposition*
- *Conducted initial market access landscape assessment*
- *Developed initial access projections assessment*
- *Conducted access scenario working session for pricing sensitivity assessment*
- *Collaborated with Government Affairs and kicked-off planning Summit to define and establish Gov't Affairs strategies and messaging*

Objective*Develop a Payer Value Proposition (value deck) for VANTRELA™ ER***What has already been completed?**

- **Conducted two (2) payer ad-board** to understand payer management and value perception of long acting opioids and abuse deterrent formulations (July & Oct. 2013)
- **Conducted payer landscape/value driver assessment (primary research)** to understand current payer management of opioids and drivers that influence payer access decisions (Jan. 2014)
- **Developed and align on value proposition statement** (internal working session) based on value driver research (Mar. 2014)

What is planned/already in progress?

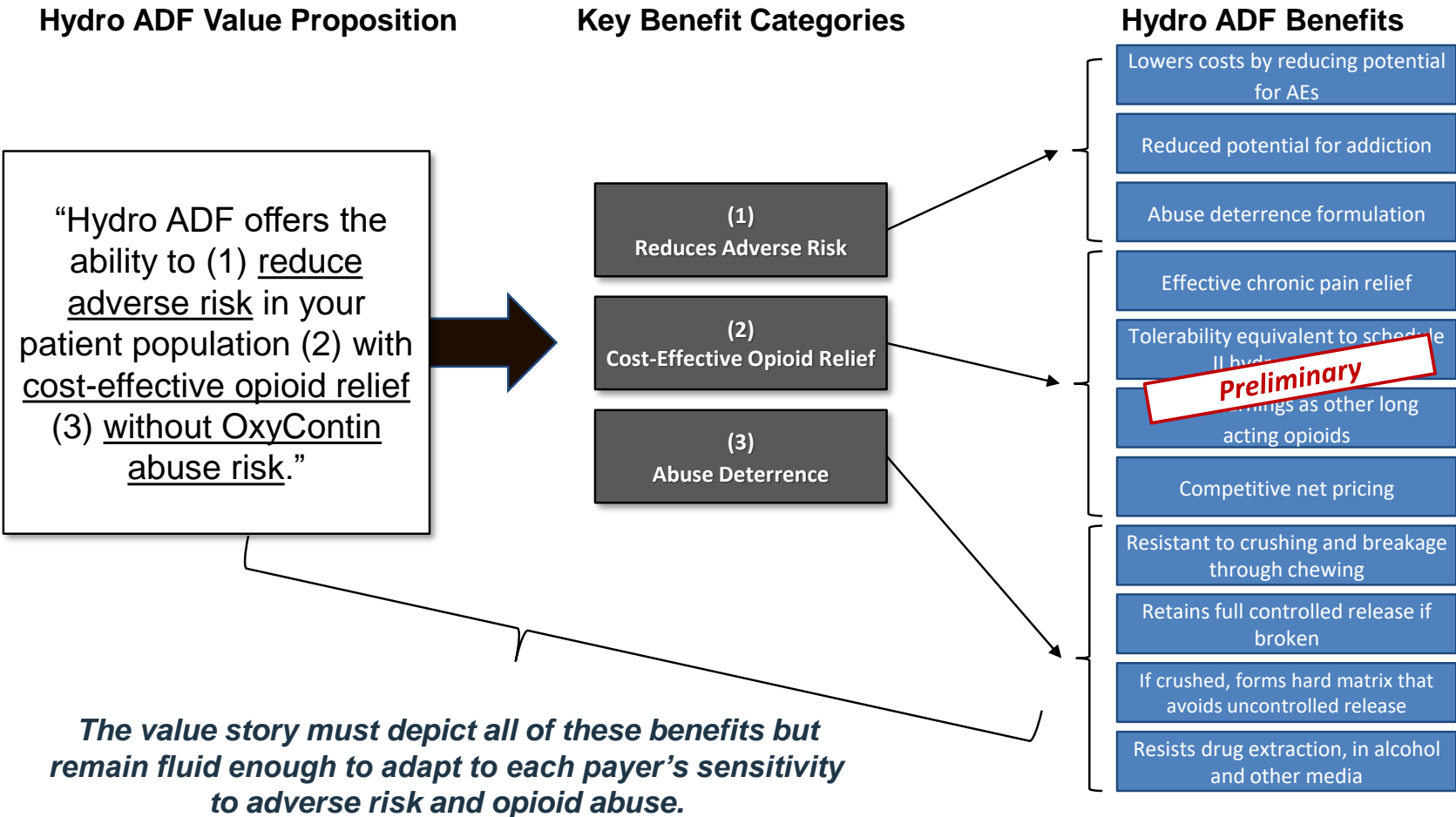
- **Conduct claims database analysis** to understand HRU* associated with high-risk opioid users to support value message development
(**Deliverable:** Budget Impact Model)
- **Develop initial value messages** based on the aligned value proposition and additional evidence generated through claims analysis
(**Deliverable:** initial value messages as input for Agency finalization)
- **Coordinate with the Agency to transition value message finalization** based on initial draft messages (**Agency Deliverable:** finalized value messages for payer testing)

When will results be available?

- **Begin value message/initial value story testing** by end of year 2014
- **Begin initial draft of value story** as input for Agency finalization by end of year 2014

*Health Resource Utilization

Hydro ADF’s value proposition includes three key benefit categories that should remain fluid to adapt to payer sensitivity.



Objective

Develop the aligned VANTRELA™ ER Contract Strategy that results in meeting Access Objectives for the appropriate level of investment via payer rebates

What has already been completed?

- **Initial research to begin by the end of September**, however, prior research from payer landscape assessment, pricing/forecasting support, and government affairs strategy has laid initial groundwork for key contracting considerations.

Learnings:

- LAO not highly managed
- Commercial > 60% of TRx
- Contracting needed for Preferred Access
- All products have Co-pay programs
- Legislative opportunity based on level of activity/support for AD products

What is planned/already in progress?

- **Conduct an Access Scenario Work Session** (internal) to align on hypothesized access and channel strategies based on hypothesized market scenarios for VANTRELA™ ER (**Deliverable: summary of internally aligned access/channel strategies**)
- **Conduct payer contracting research** (primary – qualitative & secondary data analytics) to develop a Contracting Strategy for VANTRELA™ ER that takes into account state by state differences in opioid policy (**Deliverable: Contracting Strategy for VANTRELA™ ER***)

When will results be available?

- **Provide preliminary Access Projections** by mid-November 2014
- **Provide a finalized Contracting Strategy & executive summary** by mid-January 2015
- **Provide a Contingency Planning Tool & Account-specific Dashboards** by late-January 2015

*The finalized Contracting Strategy will include (not exhaustive): Access Projection, high level Payer Segmentation, Contingency Planning Tool, Geographic Heatmap, Account-Specific Dashboards, and a Contracting Strategy executive summary.

Objective	Develop a multi-layer strategy fro Teva to support key stakeholders in addressing opioid abuse		
What has already been completed?	What is planned/already in progress?	When will results be available?	
<ul style="list-style-type: none">▪ Conducted primary and secondary opioid policy research (policy KOLs, PDMP experts, and payers) to understand the current opioid policy landscape and state segmentation based on management of opioid abuse (Jun. 2014)▪ Prioritized states for targeted pull through based on tiers and developed strategic approach for each tier* (Jun. 2014)	<ul style="list-style-type: none">▪ Conduct due diligence with internal Teva stakeholders (e.g., Federal/State Govt Affairs, Advocacy) to align on current government affairs initiatives and gaps to inform the government affairs summit work session (Deliverable: summary of current government affairs initiatives)▪ Conduct a government affairs joint planning work session to align on strategic/tactical priorities and implementation logistics for Teva’s government affairs strategy (Deliverable: summary of internally aligned government affairs strategy priorities and next steps for implementation)	<ul style="list-style-type: none">▪ Provide summary of internal alignment on government affairs strategy priorities by mid-October 2014	

*States were segmented into 3 tiers based on the current opioid abuse management policy. Strategic recommendations and preliminary tactics were developed for each tier.

Objective

Evaluate payer price sensitivity, provider willingness to prescribe, and patient willingness to pay for VANTRELA™ ER to ensure appropriate “access”

What has already been completed?

- **Conducted analog payer research** based on a Zohydro ER and a hypothetical Zohydro ADF profile to gauge initial payer price sensitivity and evaluated account-specific share shift projections to inform VANTRELA™ ER forecasting (Jun. 2013)
 - Equal analgesic
 - \$511/TRx WAC pricing (10% premium to Oxy)

What is planned/already in progress?

- **Conduct payer pricing sensitivity research** (primary – qualitative) to understand the impact of price on payer access given the market landscape* (**Deliverable:** payer price sensitivity for VANTRELA™ ER)
- **Conduct provider research** (primary – qualitative & quantitative) to characterize provider willingness to prescribe given the market landscape* (**Deliverable:** provider willingness to prescribe VANTRELA™ ER)
- **Conduct patient research** (primary – quantitative) to characterize patient out of pocket sensitivity given the market landscape* (**Deliverable:** patient out of pocket sensitivity for VANTRELA™ ER)

When will results be available?

- **Provide recommendation for VANTRELA™ ER launch price** and pricing strategy by end of year 2014
- **Provide a Pricing Decision Support Tool** that considers possible profitability (e.g., payer mix, coverage, contracting, best price implications) and market access objectives by end of year 2014

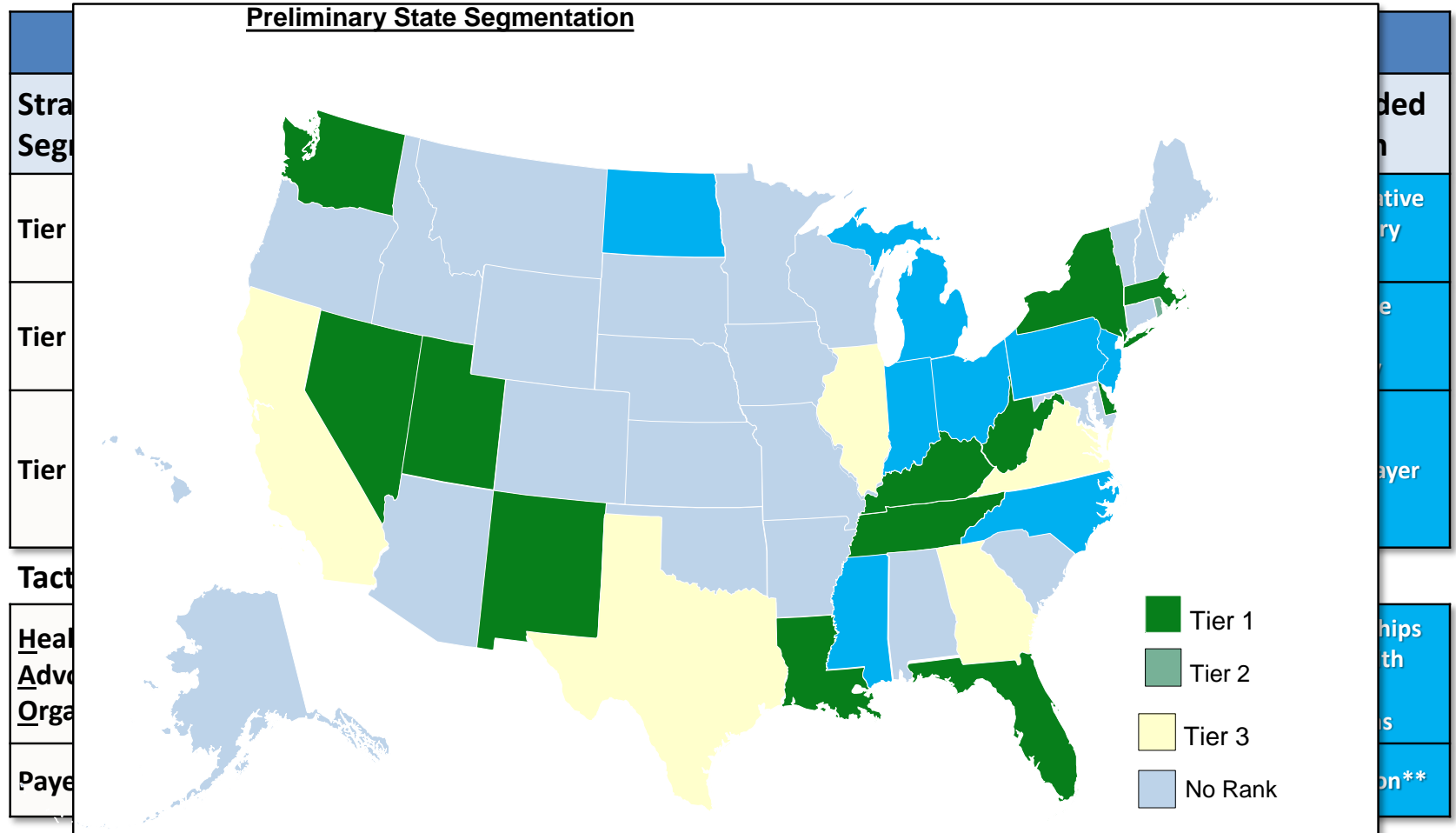
Company	Product	WAC Pricing
Purdue	OxyContin	\$464.71/TRx
Purdue	Targeniq	N/A
Zogenix	Zohydro	\$411/TRx

*An internal working session will be conducted in September 2014 to align on different market landscape scenarios that may impact pricing.

ISA recommends a holistic approach focused on education, financial support, and advocacy to help Teva become a trusted partner in the battle against opioid abuse.

Education	Provide access to education how key stakeholders want to receive it (one size doesn't fit all)
Funding for Infrastructure	Demonstrate investment in progressive states by providing grants to enhance PDMP capabilities
Help Connecting the Dots	Provide resources to help bring stakeholders together
Legislative Focused	Provide support for legislative advocacy initiatives that are aligned with state stakeholder needs
Payer Focused	Strengthen Teva's pull-through capability with payers in select states

VANTRELA™ ER Market Access Strategy = Integrated Approach of Contracting and Government Affairs



Immediate Priorities (Next 3 Months)

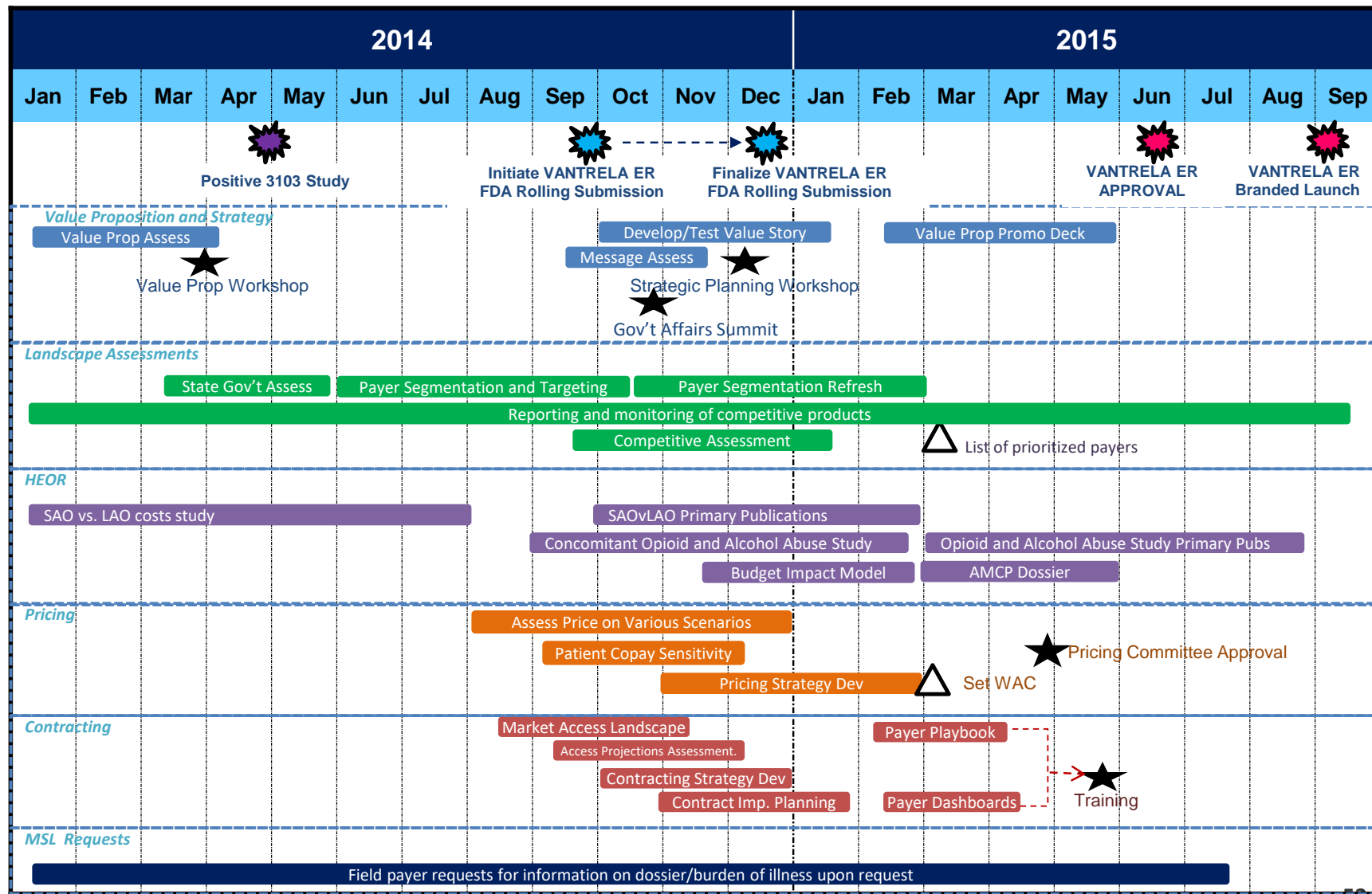
- *Kickoff payer segmentation*
- *Finalize and approve value proposition*
- *Finalize reports for market access landscape & access projections*
- *Finalize pricing & contracting strategy recommendations for leadership approval*
- *Update payer presentations to include HEOR findings*



Launch Key Performance Indicators

- KPI 1:** Finalize Payer Strategic Planning tools prior to launch
- KPI 2:** Achieve projected monthly target access goals as defined within the payer access strategy
- KPI 3:** Limit non-coverage to yet-defined percentage of covered lives







Karen Hill

FRANCHISE DEVELOPMENT/ADVOCACY

Goals and Objectives

1. To establish Teva as a strategic, ethical, and reliable partner with key pain organizations in order to optimize brand and franchise objectives.
2. Support initiatives, partnerships, and conferences in the pain market that bring awareness to:
 - Abuse deterrence and responsible care
 - Need for patient access to medication
 - Teva CNS's position as a committed, responsible pain care company
 - Policy issues affecting access to medication



Recent Accomplishments

- *Met with CLAAD and Alliance for Patient Access in DC*
 - *Policy focused groups*
- *2014 Advocacy Advisory Board Meeting planning*
- *Nov. 11 meeting in KC with PAINS and SPPAN*



Tier 1 Priority Group









- American Pain Society
- American Academy of Pain Medicine
- American Academy of Pain Management
- PAIN Week
- State Pain Policy Advocacy Network
- Pain Action Alliance
- Center for Lawful Access and Abuse Deterrence

Tier 2 Engagement

- American Academy of Family Physicians
- American Chronic Pain Association
- US Pain Foundation

Tier 3 Awareness

- American Society for Pain Management Nursing
- American Academy of Nurse Practitioners
- American Academy of Hospice and Palliative Medicine

2015											
J	F	M	A	M	J	J	A	S	O	N	D
		 American Academy of Pain Medicine March 19 – 22 National Harbor, MD				 APS: PCPC Joint Meeting July 2015 Orlando, FL		 PainWeek September 9 – 12 Las Vegas, NV			
				 American Pain Society Annual Meeting May 13 – 16 Palm Springs, CA				 American Academy of Pain Management September 2015 Phoenix, AZ			
								 AAFP September 29 – October 3 Denver, CO			
<div>  <i>Tier 1 Conference: Priority conference for brand and/or franchise</i>  <i>Tier 2 Conference: Brand and/or franchise may yield potential benefits</i> </div>											



American Pain Society

Approved: Annual Membership
Platinum Sponsorship

Under Review: Corporate Showcases



American Academy of
Pain Medicine

Under Review: Platinum Level Support



Pain Week

Anticipated Platinum Level Support,
aligning on any additional support



American Pain Society
PCPC

Prospectus expected early December



American Academy of
Pain Management

Anticipated booth and corporate
symposium only



Memberships

- APS, approved
- AAPManagement
- US Pain Foundation

Immediate Priorities (Next 3 Months)

- *Continue to secure sponsorships for 2015 conventions and 2015 memberships*
- *Continue to meet with advocacy groups*
- *Approval of communication templates*
- *Planning of Dec. Advocacy Ad Board*
- *“Pain Matters” screening program events for Q1 2015*



Launch Key Performance Indicators

KPI 1: Raise the profile of the opioid abuse epidemic among advocacy groups and policymakers as measured by an ATU

KPI 2: Conduct up to 3 screenings of “Pain Matters” video in Q1 2015 at state legislatures

KPI 3: Execution of Dec. Advocacy Advisory Board and resulting action items





Rob Falb

GOVERNMENT AFFAIRS

- It's The Public Policy Position Not The Product
- Keep Your Friends Close And Your Enemies Closer
- It's A Marathon Not A Sprint
- Establish Teva As The Trusted, Go-To Resource for Policymakers



What Have We Done For You Lately?

■ **State**

- DAW model legislation
- Working with Purdue, Pfizer, Endo etc.
- State Legislative Briefings
 - CA, PA, WA
- NCSL Briefing
- Meeting, Monitoring and Acting

■ **Federal**

- Federal Legislative Initiatives
- Senate Rx Abuse Working Group Meeting
- Alliance to Prevent the Abuse of Medicines
 - CVS Health, AMA, Prime Therapeutics, Cardinal Health
 - Hill briefings, Administration Outreach, Chamber of Commerce Event
- Pain Care Forum
- Meeting, Monitoring and Acting

■ **MM-GA Summit**

- Alignment on Priority States
- Consistent Messaging
- Tools We Need



Public Affairs Landscape Review

- Golin is conducting a review of the federal public affairs and policy landscape as it relates to opioids, abuse, and abuse deterrence.
- Help determine public affairs needs for 2015
- Inform an upcoming Public Affairs working session

Overview:

- Policy Media
 - Assessment of how opioids and abuse issues are reported, specifically as it relates to public policy issues
 - Key reporters driving policy discussion
- Stakeholders
 - Leading stakeholders represented in and driving policy reporting
- Policy
 - Identify key federal legislators on opioid issues and their positions
 - Leadership / Committee Jurisdiction
 - Personal interest in opioid issues
- Identify Opportunities
 - Thought leadership
 - Stakeholder alignment

Immediate Priorities (Next 3 Months)

- *Prep Teva leadership for Senate Prescription Drug Abuse Task Force meeting*
- *Develop legislative briefings for California, Washington, & Pennsylvania legislatures*
- *Receive CARE approval of “Pain Matters” screening program events for Q1 2015*
- *Develop program content for Alliance-U.S. Chamber of Commerce briefing*





Derek Moe

MANUFACTURING

■ Manufacturing & Supply Plan for Launch

- Aligned with PDUFA approval – June 2015
- 3 Validation batches will be manufactured for each strength to support the launch
 - Intermediate validation to be completed - November 2014
 - Manufacturing of first strength completed (15mg) – December 2014
 - Manufacturing of last strength completed (90mg) – April 2015
- Bottling to be completed in Forest, VA – April/May 2015
- Final packaging to be completed upon approved label – 2-3 weeks to print; 2-3 week to ship

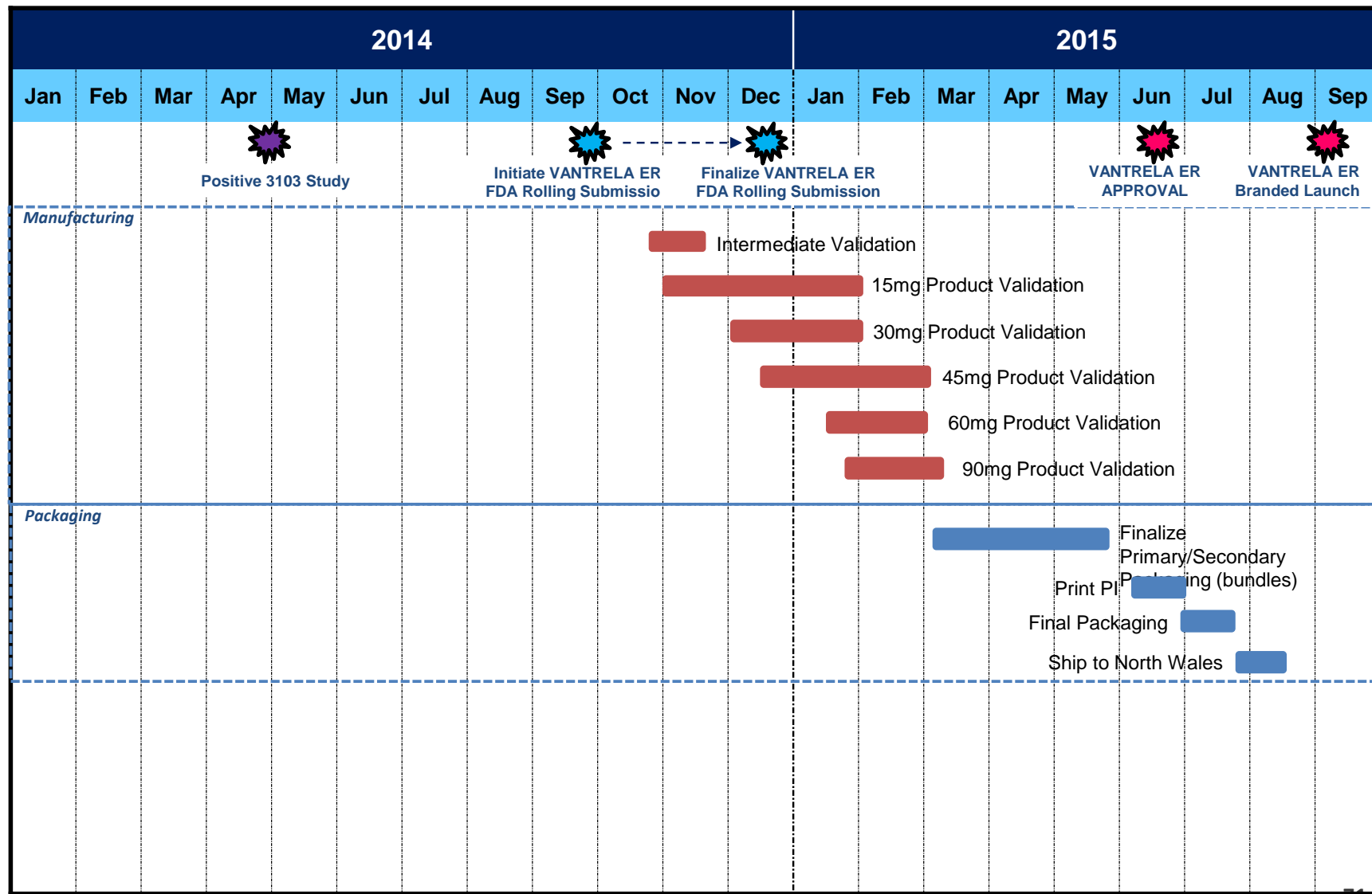


Launch Key Performance Indicators

KPI 1: Successful production of 5 doses by April 2015

KPI 2: Product availability/capacity: Inventory and Production of safety stock for launch







Jason Jones

TRADE

Goals and Objectives

1. Develop trade & distribution strategy to ensure 100% availability to retail and patients
2. Develop/recommend Trade launch, engagement, and awareness programs

Immediate Priorities (Next 3 Months)

- *Provide CII market dynamics overview for Brand and Commercial considerations*
- *Finalize Go-to Retail/Wholesaler Trade strategy*

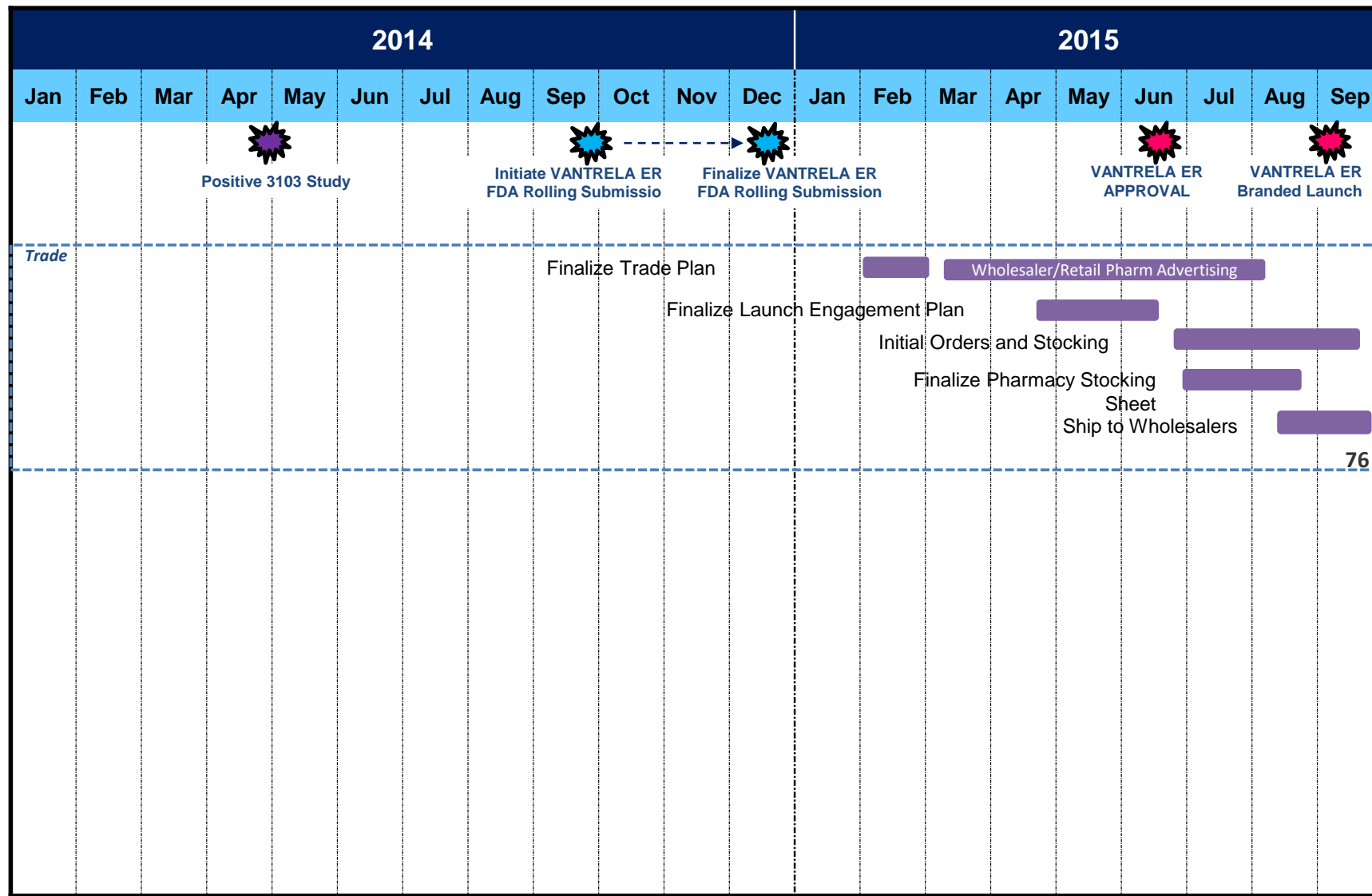


Launch Key Performance Indicators

KPI 1: Finalized Retail Pharmacy/Wholesaler strategy approved by Feb 2015

KPI 2: Finalized Launch /Engagement plan by April 2015







Matt Day

MARKETING

Objectives

Strategic Imperatives

1

Educate on Appropriate Use, Abuse Potential and Deterrence technology

- Educate marketplace about appropriate opioid prescribing, abuse potential
- Educate marketplace about AD technology, FDA guidelines
- Help to shape, establish AD industry & market standards

2

Develop a differentiated brand

- Establish and differentiate Teva AD technology
- Integrate AD technology branding into VANTRELA™ profile
- Build differentiated, ownable and unique positioning, message platform
- Clearly define appropriate patient
- Collaborate with clinical team to optimize data to align with unmet market needs

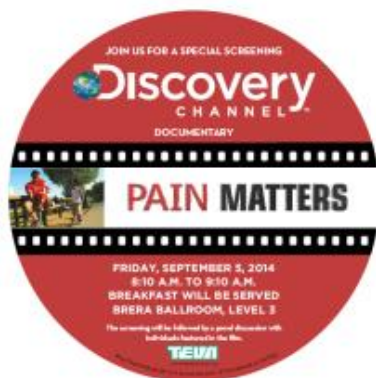
3

Ensure reimbursement access for HCPs and appropriate patients

- Differentiate brand through clinical profile, compelling value proposition, optimal pricing and contracting platform
- Partner with key constituents to strengthen access landscape

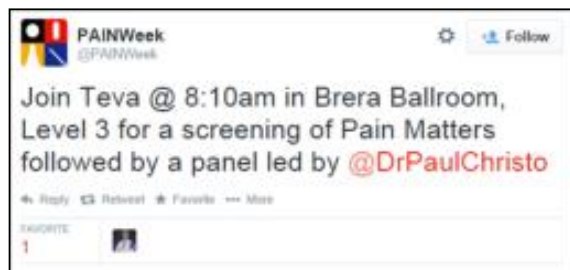
Recent Accomplishments

- *Pain Week, September 3-6*
 - *Pain Matters Screening & Panel Discussion*
 - *Evolving roles, Same Goals Symposium*
- *AAPM, September 18-20*
 - *Evolving roles, Same Goals Symposium*
- *Positioning Statement and Research*
- *Logo Development*
- *HCP Patient Segmentation & Pharmacy Research*



“Film did a great job of showing the many dimensions of how pain affects not only the patient but also the caregiver.”

235+ attendees





Average Evaluation Scores*:

4.62 The event was relevant to my work as a health care provider

4.49 The panel discussion provided valuable insight into the film and the issues explored

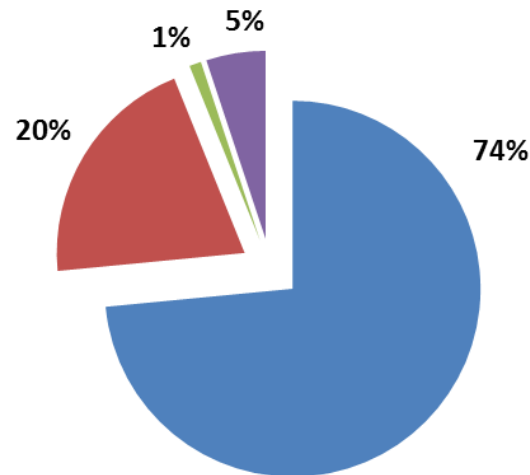
4.6 Overall, I found the event to be valuable, educational, and time well spent

“I’m learning how to be a better provider by understanding the patient's perspective on pain”

How likely are you to talk with a patient or colleague about today's event and the film "Pain Matters"?

■ A - Very Likely

■ B - Somewhat Likely



“It gives hope to people at the beginning of the journey.”

*Scale of 1 to 5

DRAFT - CONFIDENTIAL – FOR INTERNAL DISCUSSION PURPOSES ONLY – NOT FOR USE IN PROMOTION


EVOLVING ROLES, SAME GOALS:
 THE CHANGING LANDSCAPE OF PAIN MANAGEMENT

DATE/TIME:
 Saturday, September 6, 2014
 12:00 PM – 1:30 PM
 Lunch will be served

LOCATION:
 The Cosmopolitan of Las Vegas
 Las Vegas, NV
 Brera Ballroom, Level 3

Pain management continues to evolve in response to patient, provider, and societal needs. Please join us as three experts in pain management discuss these developing perspectives.


Michael Brennan, MD
 Chief Medical Officer
 The Pain Center of Fairfield
 Fairfield, CT
 Associate Medical Director
 Chronic Pain and Recovery Center
 Silver Hill Hospital
 New Canaan, CT


Christopher Gharibo, MD
 Associate Professor of Anesthesiology and Orthopedics
 NYU School of Medicine
 Medical Director of Pain Medicine
 NYU-Hospital
 New York, NY


Steven Simon, MD, RPh
 Assistant Clinical Professor of Physical Medicine and Rehabilitation
 Kansas University Medical Center
 Kansas City, KS

This is not a CME program.
 In order to maintain the professional and educational nature of our program, Teva is unable to accommodate family members, office staff, or other guests of healthcare professionals at our program.
 Teva is required to disclose all items of value provided to healthcare providers and to disclose these amounts publicly.
 By attending this speaker program, you are accepting the disclosure of the cost of the meal.

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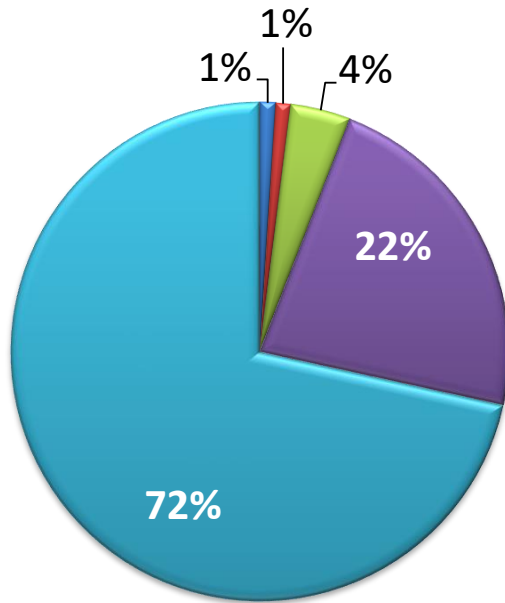


PainWEEK (Sept 6):

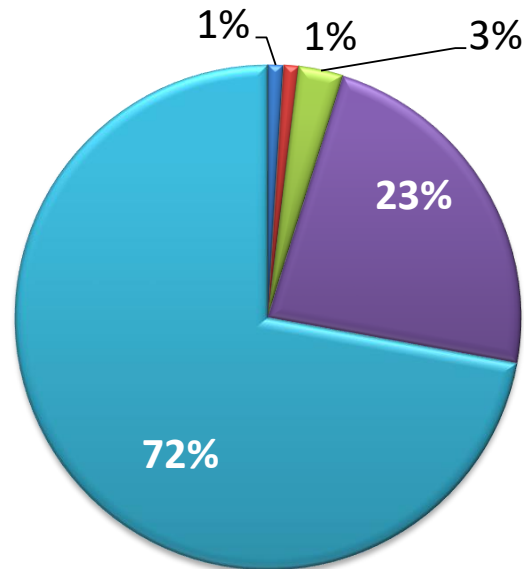
- Drs. Gudin, Argoff, & Brennan
- 210 attendees
- Several requests for slides
- Positive feedback...

AAPM (Sept 19):

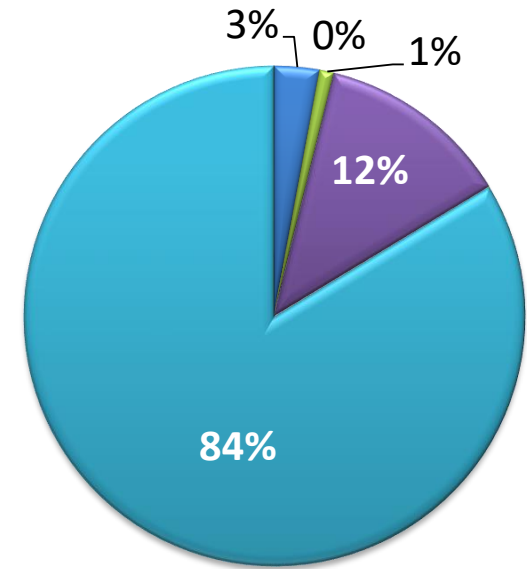
- Drs. Simon, Gharibo, and Gudin
- 384 attendees
- Several requests for slides
- Positive feedback...



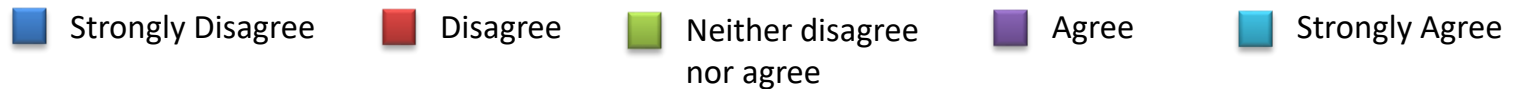
The presentation was clear and relevant to my clinical practice.

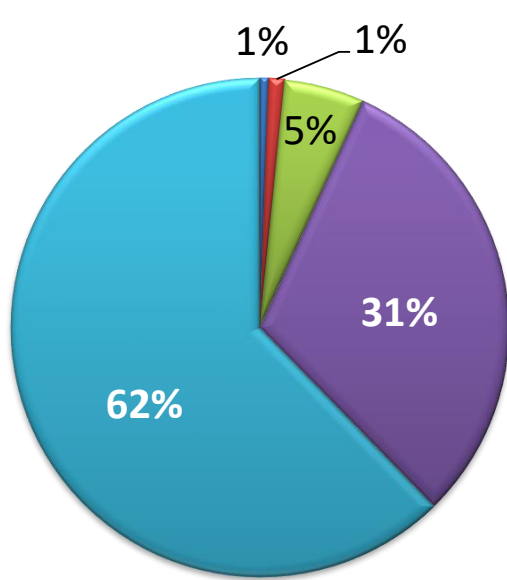


I found the program educational and informative.

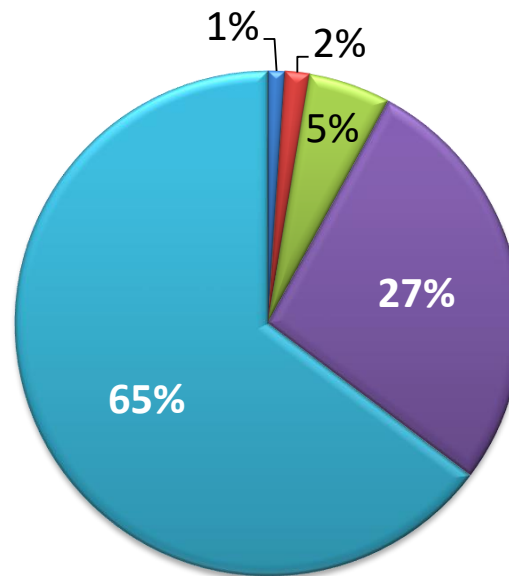


The three faculty were effective and knowledgeable presenters.

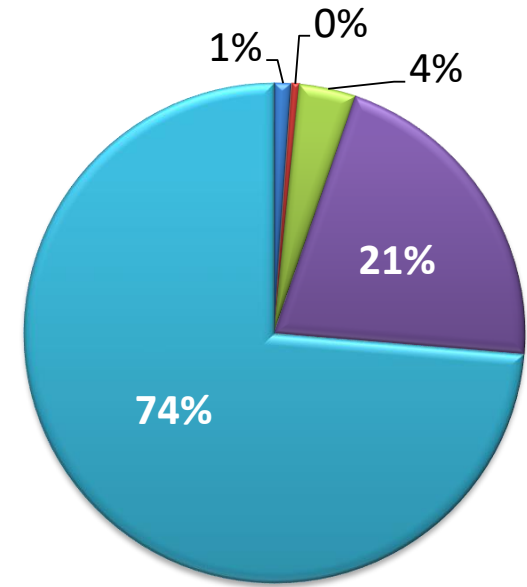




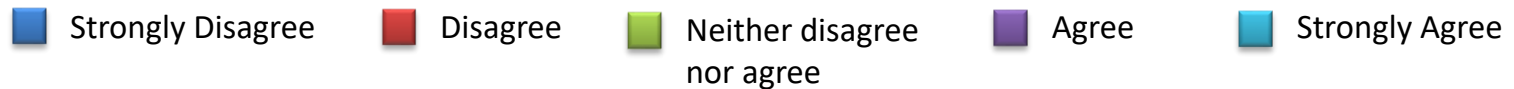
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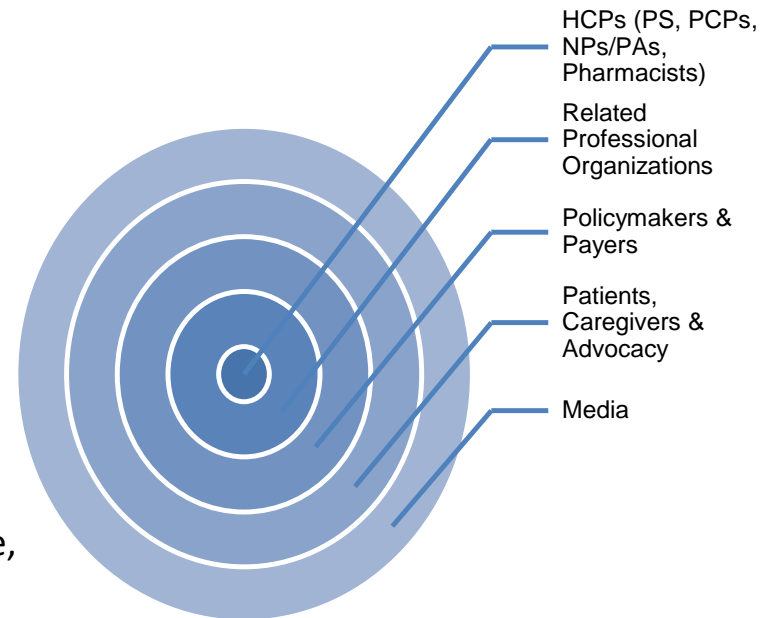


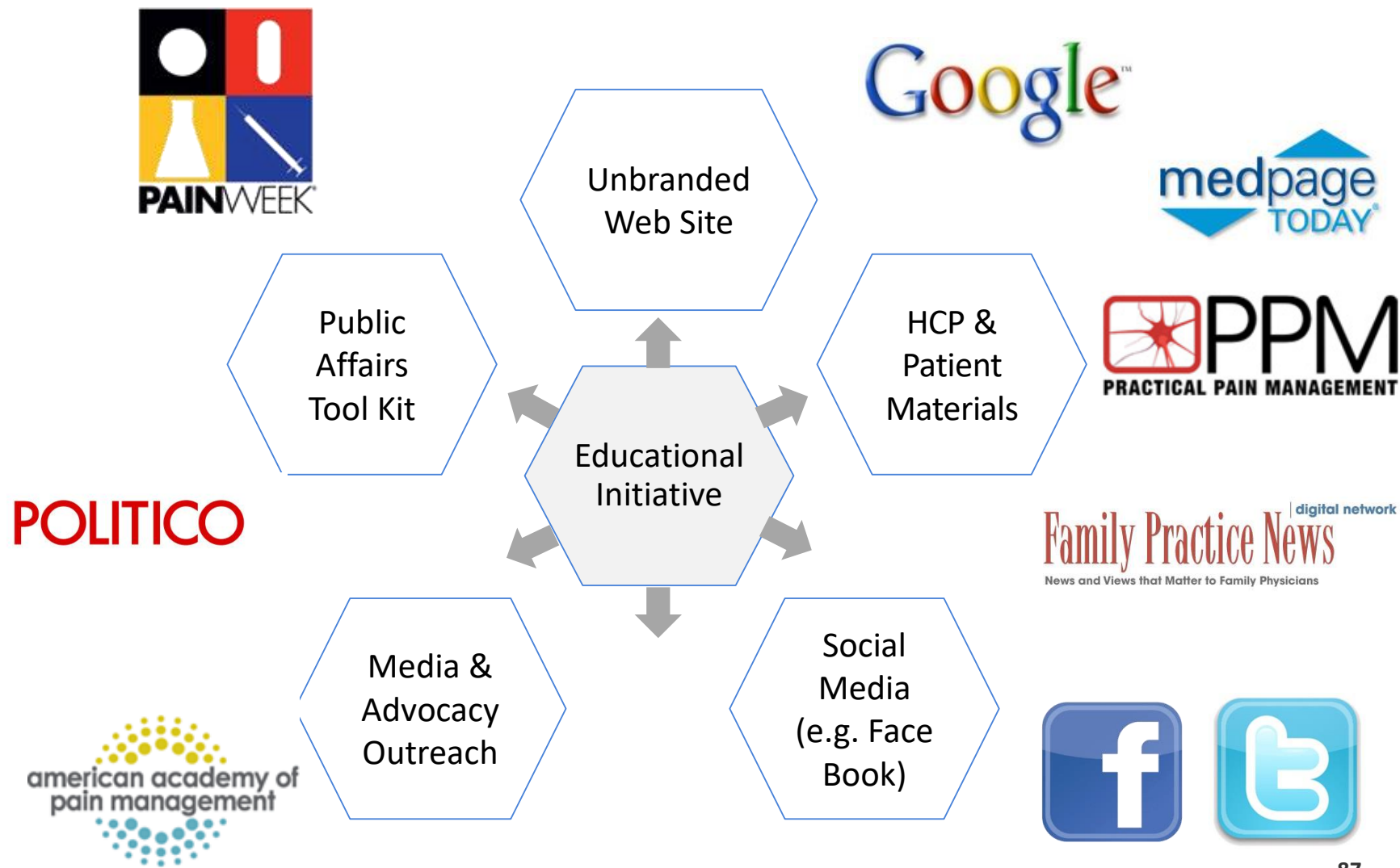
Objectives:

- Provide overview of pain and ***the role of opioids*** in appropriate pain management
- Review the ***societal implications*** of prescription drug abuse and ***FDA guidance***
- Increase knowledge of ongoing initiatives to help deter abuse and ***Abuse Deterrent Technologies***

KPIs:

- Measure traffic/engagement to Pain Matters microsite, including number of inbound links from external sites
- Downloads and views of materials/assets
- Track overall media impressions/audience reach





Sponsorship Request: \$50,000 (level 1)

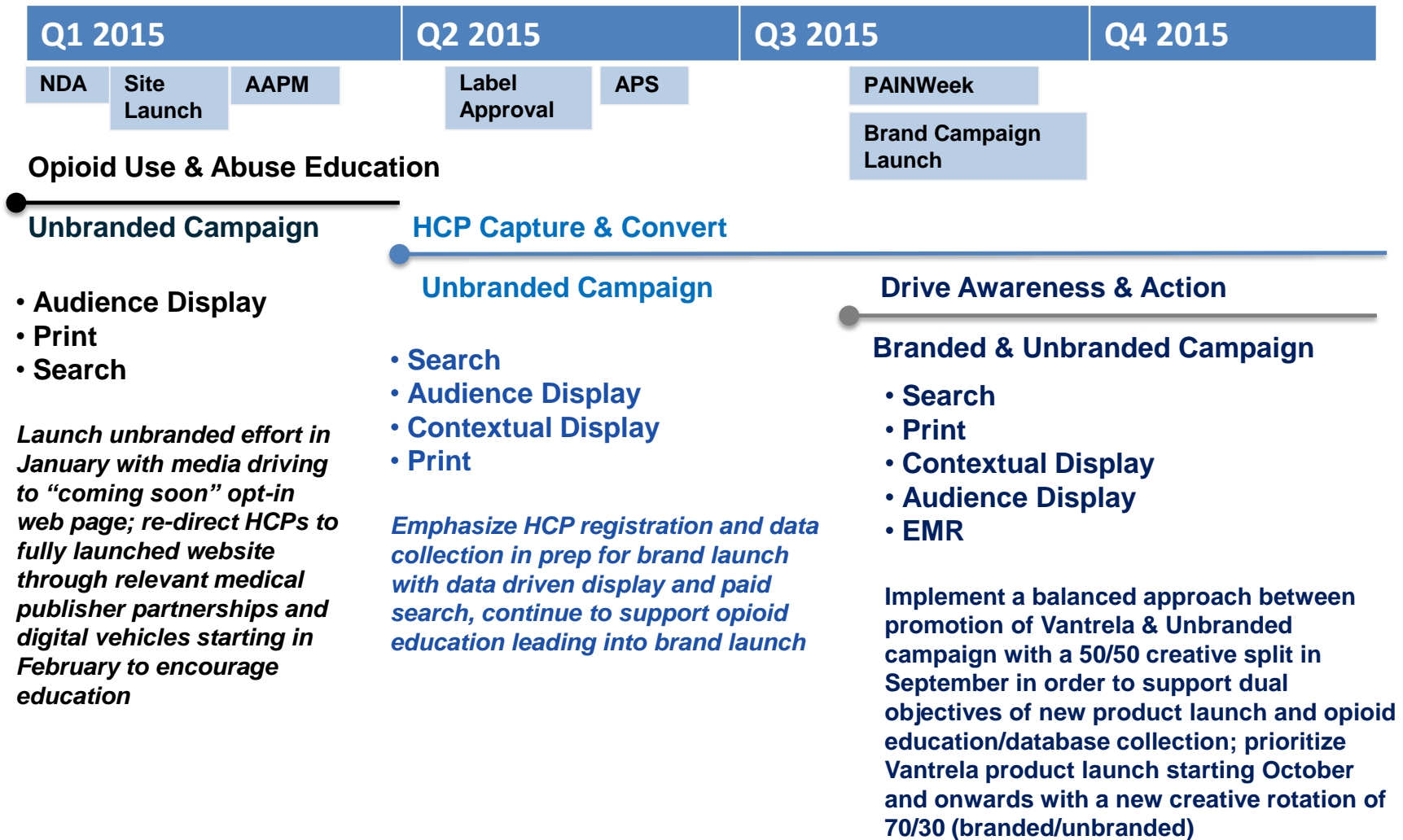
- 15 second company descriptions at the top of each hour
- Company description during commercial breaks
- Company logo on program website
- Five other pharma companies currently provide financial support, including: DC2 Healthcare, Medtronic, Purdue Pharma, Depomed and Millennium Labs
- Teva was a level 1 sponsor last year

Opportunities to Maximize Sponsorship

- Leverage to promote the educational initiative to a targeted audience and drive microsite traffic
 - ✓ Feature “Pain Matters” documentary with panel discussion of those featured in film
 - ✓ Feature content from “Evolving Roles; Same Goals” presentation with on-air faculty interviews
 - ✓ Introduce the educational initiative on air and direct listeners to website (on air, a tweet, Facebook post)



- Weekly program (Saturdays 8-9 a.m. ET)
- Airs on Family Talk Channel 131 on SIRIUS XM
- 13 million estimated listeners (Consumer/HCP split)
- Focuses on pain and pain relief with interviews with patients, celebrities, specialists and authors
- More than 5,100 followers on Twitter and 740 Facebook Likes
- More than 89,000 podcast downloads
- 120,000 website page views and over 51,000 visits from 108 countries



Search, Display, Print

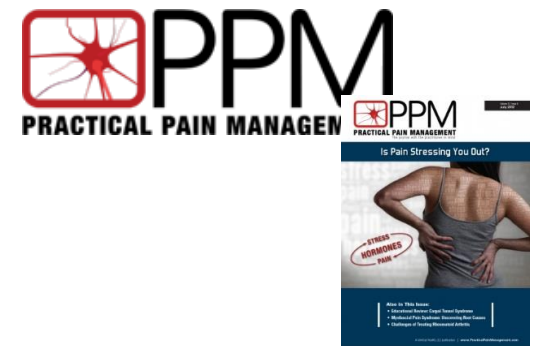
- **Display:** Utilize advanced targeting solutions with data partnerships (i.e. IMS) to reach HCPs across the web at scale and with greater efficiency for both unbranded and branded initiatives
- **Search:** Implement paid search coverage across tiered search structure to reach HCPs looking for relevant LAO/Abuse Deterrent & branded terms; focus coverage on core branded keywords and conquest competitive brands with branded campaign launch
- **Print:** Develop strong branded presence with high impact units (e.g. cover tips, bellybands, cover positions) in key pain & PCP publications at Vantrela launch to reach key specialties
 - Utilize target list to ensure limited waste and messaging to qualified HCPs

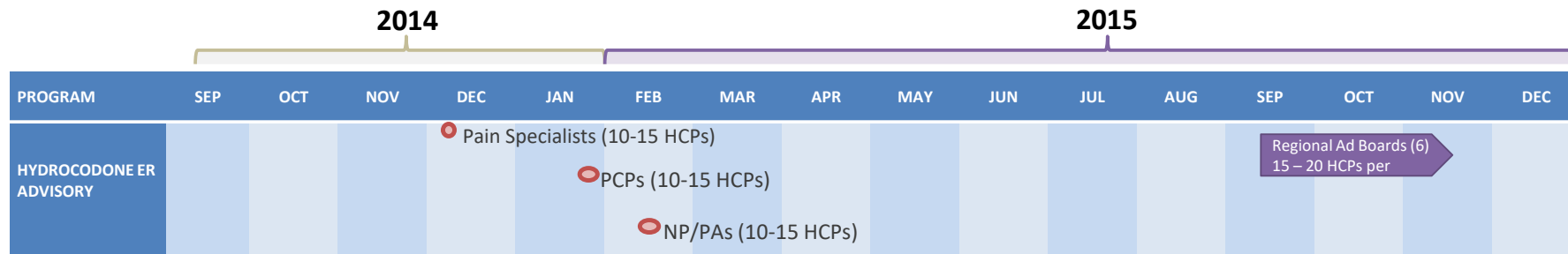
CADREON

Google™

bing™ YAHOO!

haymarket®





Pre-Launch

- Three pre-launch advisory boards with local/regional HCPs:
 - Pain Specialists /Primary Care Physicians /ILPs
- Meeting Objectives:
 - Gain understanding of the impact of recent regulatory changes and competitive launches on the pain market
 - Explore current knowledge and perceived strengths/limitations of abuse deterrent technologies
 - Evaluate initial HCP reaction to Hydrocodone ER product profile for use in developing launch slide deck
- Programs start in late 2014 and are completed early 2015

Post-Launch

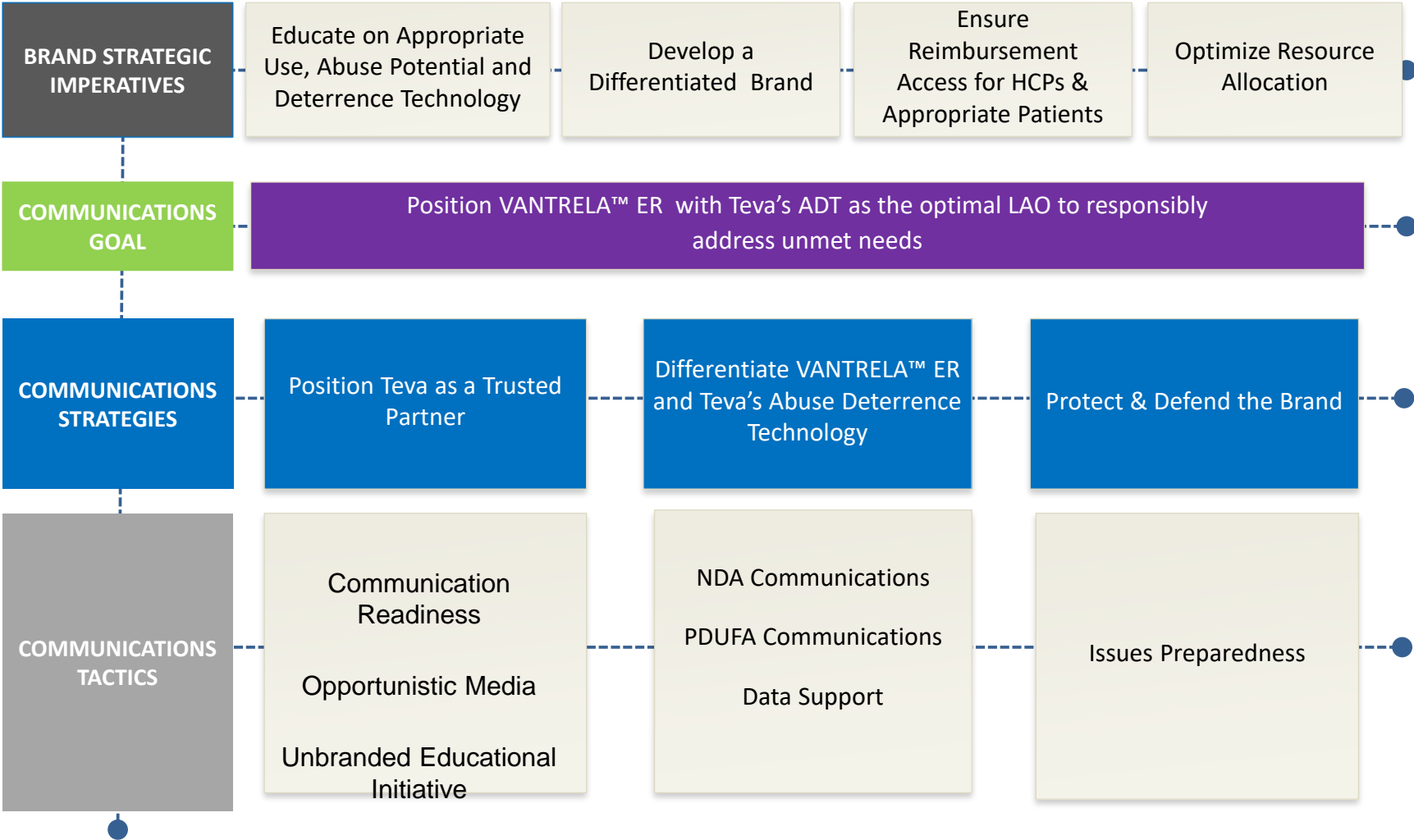
- A series of 6 RABs (one for each Region) to ascertain the effectiveness of our launch efforts and to identify any course corrections that might be needed
- Each meeting will be 2 hours from 7-9pm
- 15 HCPs to attend each meeting
- Programs to feature both a professional moderator and a KOL presenter
- Each meeting will be multi-disciplinary (Pain Specialists, PCPs, ILPs)
- Total reach approximately 90 HCPs

Next Meeting: Educational Module Development, November 2014

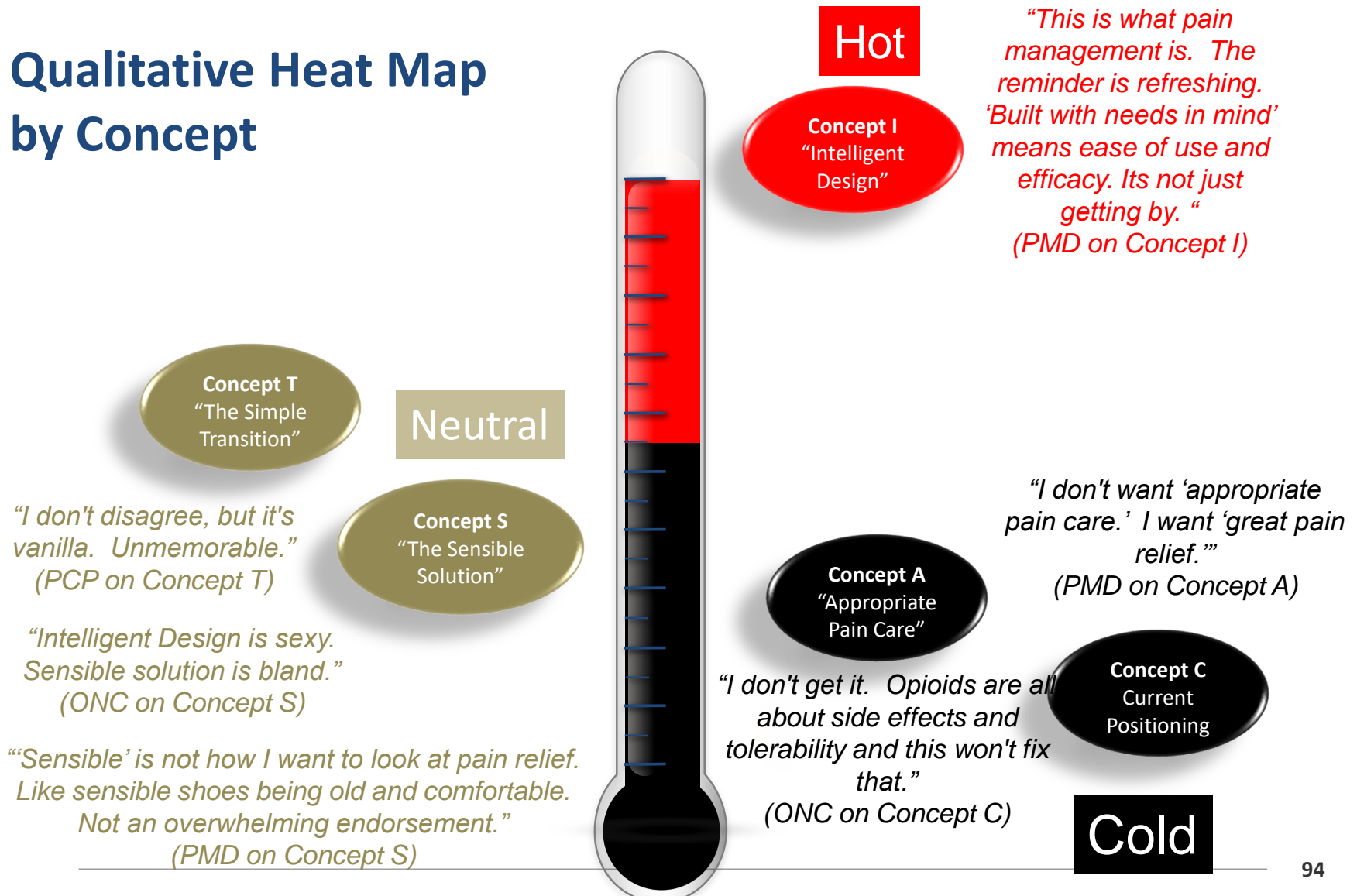
- Follow-up to our success with the Pain Week/AAPM Disease Awareness programs
- Convene meeting of 10 Experts to develop additional Disease Awareness Modules for 2015
 - Present Strategic Vision and working session to create draft outlines
- Meeting scheduled for November 16-17

Attending Experts	
Jeff Gudin, MD	Sri Nalamachu, MD
Charlie Argoff, MD	Penny Tenzer, MD
Mike Brennan, MD	Greg Holmquist, PharmD
Chris Gharibo, MD	Bonnie Wilensky, NP
Steve Simon, MD, RPh	Jen Bolen, Esq

- Preliminary modules to be developed include:
 - FDA Guidance
 - Abuse Deterrent Technologies
 - Practical Considerations when prescribing opioids



Qualitative Heat Map by Concept



Immediate Priorities (Next 3 Months)

- *Conduct pain specialist, PCP advisory boards*
- *Design and build “Pain Matters” microsite*
- *Develop disease awareness education modules*
- *Finalize HCP segmentation*
- *Conduct VANTRELA ER logo & message testing*
- *Research VANTRELA ER creative concept*



Launch Key Performance Indicators

KPI 1: Reach 60% of target HCPs with 'Pain Matters' educational program touchpoint

KPI 2: Drive aided AD awareness among target physicians > 30%

D 9-10 > 50%

D 5- 8 > 25%

KPI 3: Quantitative verification of differentiated profile, patient type

KPI 4: Exceed industry benchmarks to measure message relevance, believability & credibility

KPI 5: Initiation of conversion study by Q1, completion by Q4 2015





Matt Day

CLOSING THOUGHTS



THANK YOU ALL FOR YOUR CONTINUED DEDICATION AND SUPPORT!