



Halteres Associates

Roadmap to Value Creation in Molecular Diagnostics

February 2014



Halteres from Ancient Greece
National Archaeological Museum in Athens

This document contains the proprietary information of Halteres Associates, LLC . It is distributed to the recipient for informational use only and may not be reproduced in any form without the express written permission of Halteres.



Halteres
Associates, LLC

Understanding The “Value” in Value Creation

“Anything that won't sell, I don't want to invent. Its sale is proof of utility, and utility is success” - Thomas Edison

❑ Questions addressed in this presentation...

- You have a great new diagnostics product idea, but..
- What else do you need to know before you develop it?
- How can you attract investor or partner interest?
- How can you assure sustainability and maximize value?



❑ Key learnings from this presentation...

- An appreciation for the value creation process in molecular diagnostics
- How to augment your existing product development process
- An understanding of what strategic partners and investors will expect

The Ideal

Maximizing value requires understanding and implementing a disciplined process addressing several key areas

Unmet Needs

- Clear Understanding
- Product Requirements

Competitive and Market Barriers

- Ecosystem Map
- Market Adoption Influencers

Impact Analyses

- Medical and Clinical Impact
- Pricing and Reimbursement
- Value

Development Milestones

- Product Development
- Market Development
- Financial Requirements

But where does one start?

The Problem

The temptation is for technology-driven companies to engage in only portions of the value creation process

Unmet Needs

- Clear Understanding
- Product Requirements

Impact Analyses

- Medical and Clinical Impact
- Pricing and Reimbursement

Competitive and Market Barriers

- Ecosystem Map
- Market Adoption Influencers

These are all critical components of the value creation process

But...this is where development programs primarily focus

Development Milestones

- Focused on Product Development

The Need for a Value Creation Roadmap

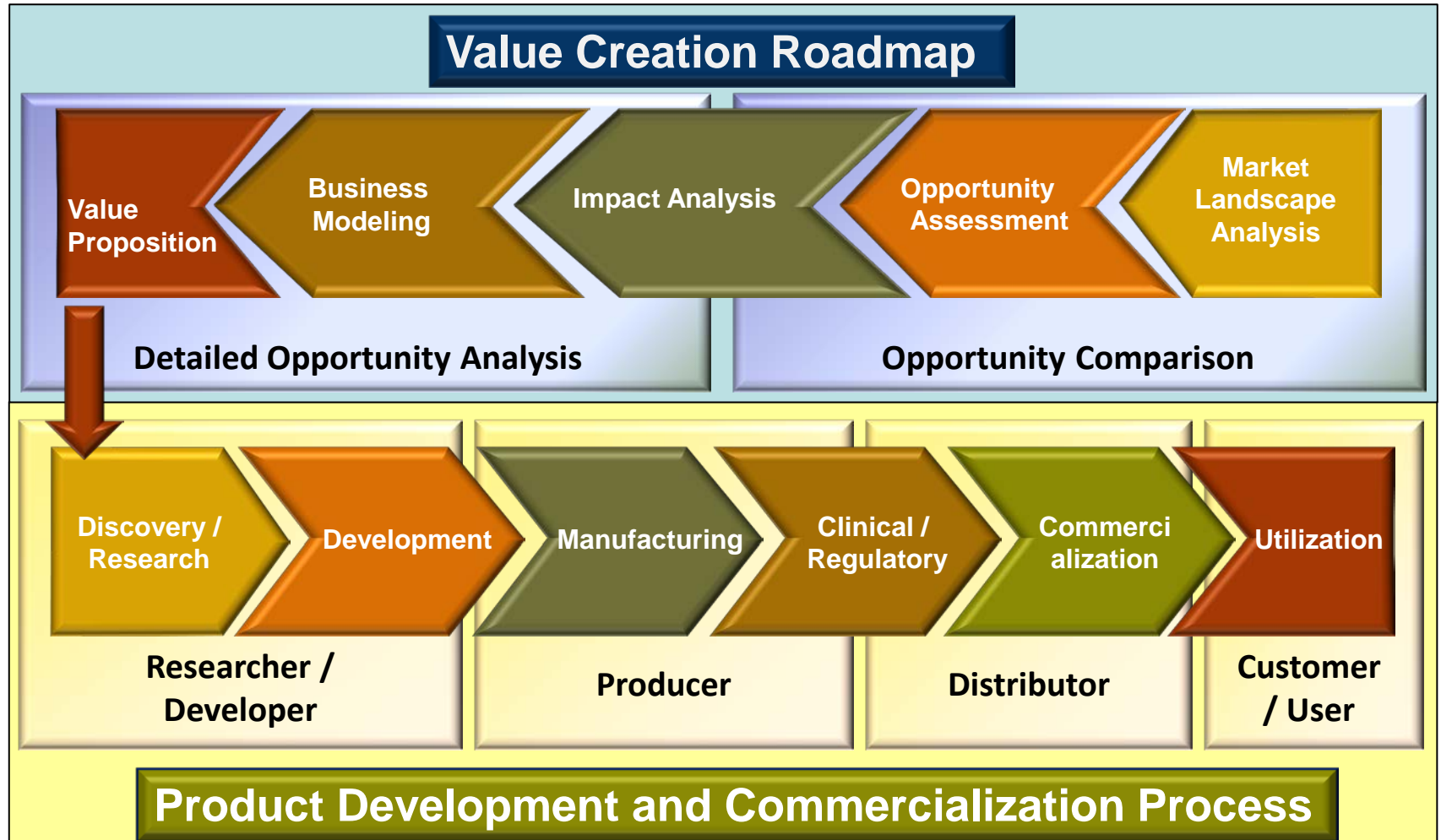
The **Value Creation Roadmap** will guide product development and help attract quality partner and investor interest

- ❑ Great technology is certainly necessary, but....
 - Without knowing its utility and how it should be positioned, you cannot know if it will sell
- ❑ Unfortunately, focusing on development milestones remains a hallmark of business plans but does not always correlate to product success
- ❑ The **Value Creation Process** highlights what requirements to satisfy when turning your technology into a marketable product

So, what is the Value Creation Roadmap.....?

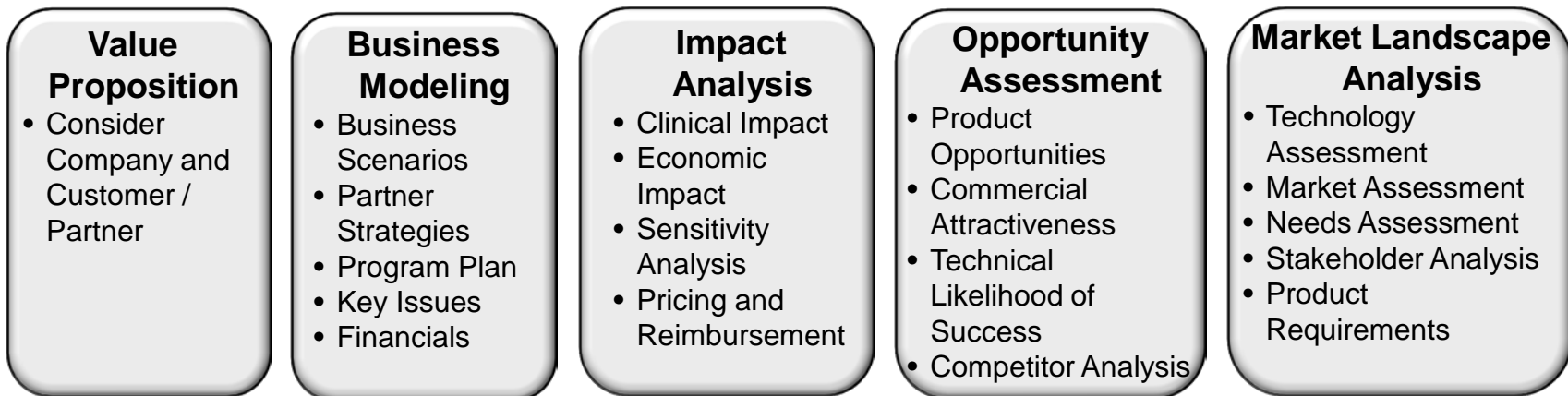
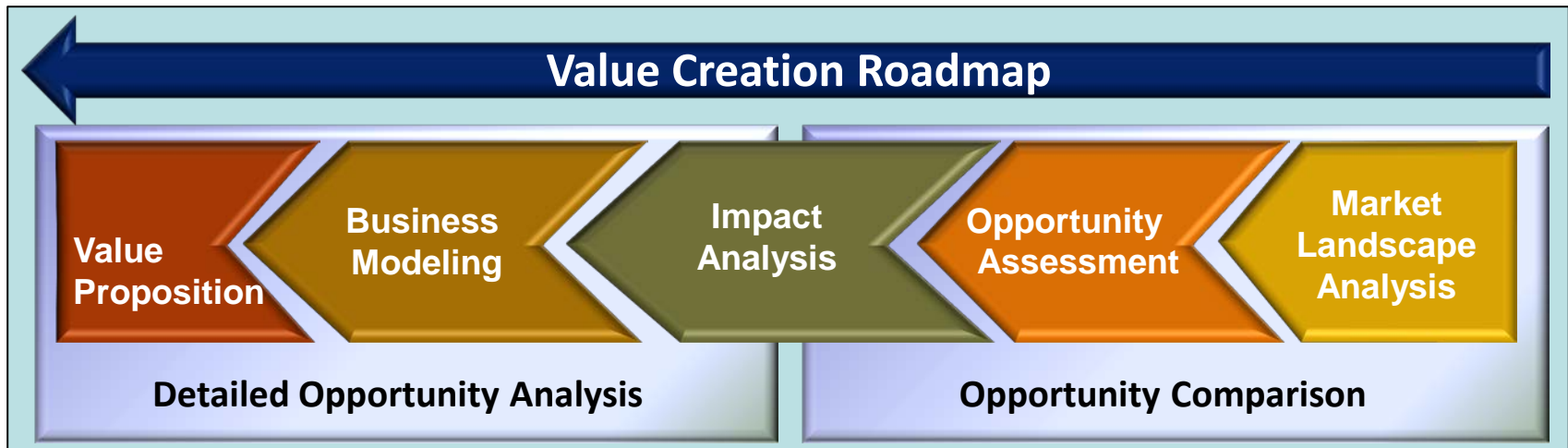
The Halteres Process Overview

Integrating the value creation and development processes



The Value Creation Roadmap Overview

A pre-requisite for [Value Creation](#) and investor / partner interest



Example Case Study: CNS Diagnostics, Inc.

Case Study: Implementing the Value Creation Roadmap

Company Name: CNS Dx, Inc.



When Founded: 2009

Focus: Identification of biomarkers linked to Central Nervous System (CNS) diseases and development of proprietary assays for disease diagnosis and therapy monitoring

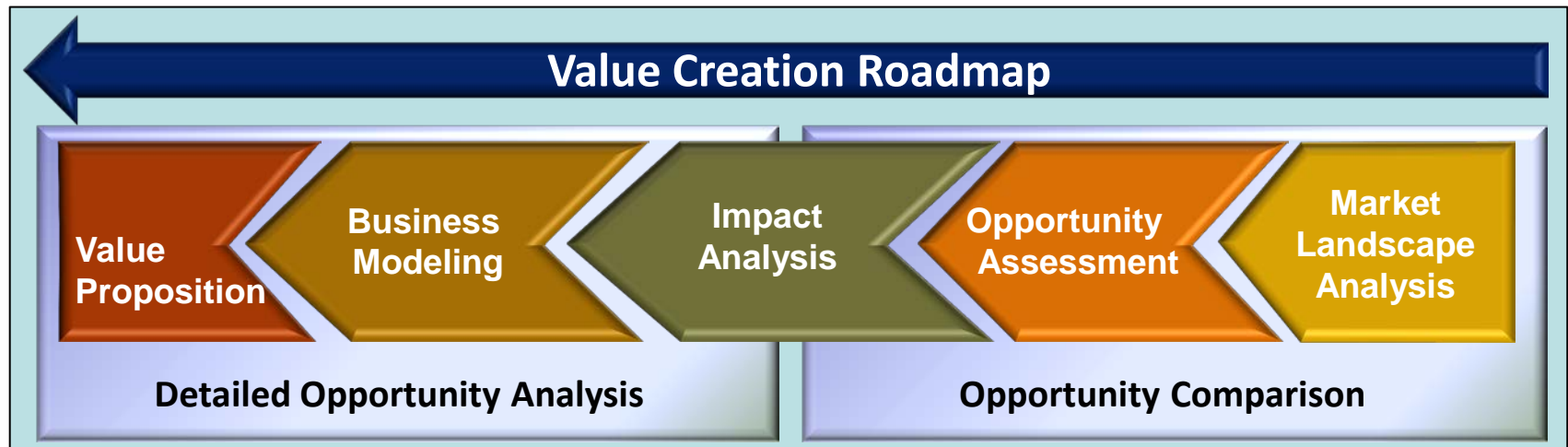
Stage : CNS Dx is a development stage, privately held company

Development Status: CNS Dx has identified several candidate biomarkers for early diagnosis of Alzheimer's Disease and is now evaluating their development path forward.

Founders: Dx industry executives with successes in HPV and Colorectal cancer IVD companies

Market Landscape Analysis: Overview

Complete understanding of the market landscape is required to establish proper product requirements



Market Landscape Analysis

- Technology Assessment
- Market Assessment
- Needs Assessment
- Stakeholder Analysis
- Product Requirements

Landscape Analysis: Technology Assessment

The importance of being technology-enabled, not technology-driven

❑ Technology feasibility

- Importance of understanding basic performance capabilities
- Not to be confused with product development

❑ Data Generation

- Sufficient to understand how technology might be productized
- Entice investor / partner / customer understanding and interest

❑ Competing technologies

- Strengths and weaknesses vs. competition
- Consider what is on the market and in development

CNS Dx Result

- Initial interest:
Early AD Dx
- Good correlation in small cohort of AD patients
- Population controls are negative
- Blood based test
- NA markers found in AD cohorts
- Good KOL contacts
- No direct competition

Landscape Analysis: Market Assessment

Understand how your technology could potentially impact the market

- ❑ Determine market segments of interest, e.g.:
 - Pharmaceutical research
 - Clinical diagnostics
 - Bio-defense
 - Food / Agriculture / Veterinary
- ❑ Understand key market drivers and trends
 - Today and expected at time of launch
- ❑ Overview of other *high level* considerations
 - Market size / target customers
 - Market structure / access
 - Key competitors
 - Also consider geography, price, regulations

CNS Dx Result

- ~5MM AD sufferers in US
- Mkt growing at ~10% per yr
- Estimated cost to US healthcare system \$125B / yr
- Dx via MMSE today; no IVD
- Pharma needs better Dx to ID and stratify
- Strong ex-US market

Landscape Analysis: Unmet Needs

Determine which unmet needs will drive user purchase decision and what product requirements must be met to satisfy those needs

❑ Medical needs

- The medical conditions at the end user location

❑ Clinical needs

- The practice or delivery of medicine at the end user location (decision points, interventions, outcomes)

❑ End User needs

- Can integration of new molecular diagnostics improve the practice of medicine?
- Or improve the quality of life for the end user?

❑ Initial product requirements

- Arise from understanding of unmet needs
- Compare to technology capabilities
- Required before product specifications can be set

CNS Dx Result

- Rx failures attributed to late start of treatment
- Dx test needed for earlier diagnosis
- No IVD test exists; reliance on MMSE and rule outs
- Need for blood-based Dx for early ID of patients and proper therapy management

Landscape Analysis: Stakeholder Analysis

Understand the key players influencing the purchase decision and their impact on product requirements

- ❑ Understand the needs and interrelationships of all key stakeholders / influencers
- ❑ Common stakeholder examples:
 - End user customer/laboratory
 - Supply chain partners
 - Marketing, sales and distribution partners
- ❑ Other key players might also include:
 - Payers
 - Government authorities
 - Regulatory bodies
 - Consumer and advocacy organizations
 - Opinion and community leaders
 - Competitors

CNS Dx Result

Interrelationships identified:

- Strong Pharma interest
- Academic / KOL involvement
- Medicare funding
- Menu portfolio gap for Dx manufacturers
- Imaging companies
- Advocacy groups
- Reference labs

Landscape Analysis: Product Requirements

Using the landscape analysis to establish clear product requirements

- ❑ Draft initial product requirements based on:
 - Unmet needs of likely target customers
 - Market trends, including the expected future state
 - Technology advancements, especially from competition
 - Needs of key influencers in the purchase decision
- ❑ Remember, this is a starting point
 - Refine after final product applications are selected
 - Revisit based on impact analysis findings
 - Finalize after business modeling is complete
 - Reference throughout the product development process as the situation evolves

CNS Dx Results

- Blood test
- Panel of nucleic acid markers
- High NPV to rule out AD
 - High sensitivity with adequate specificity
- Central lab test
- LDT for first gen.
- IVD for second gen.

Conclusion: Market Landscape Analysis

Pursuing a market-driven, technology-enabled process yields success

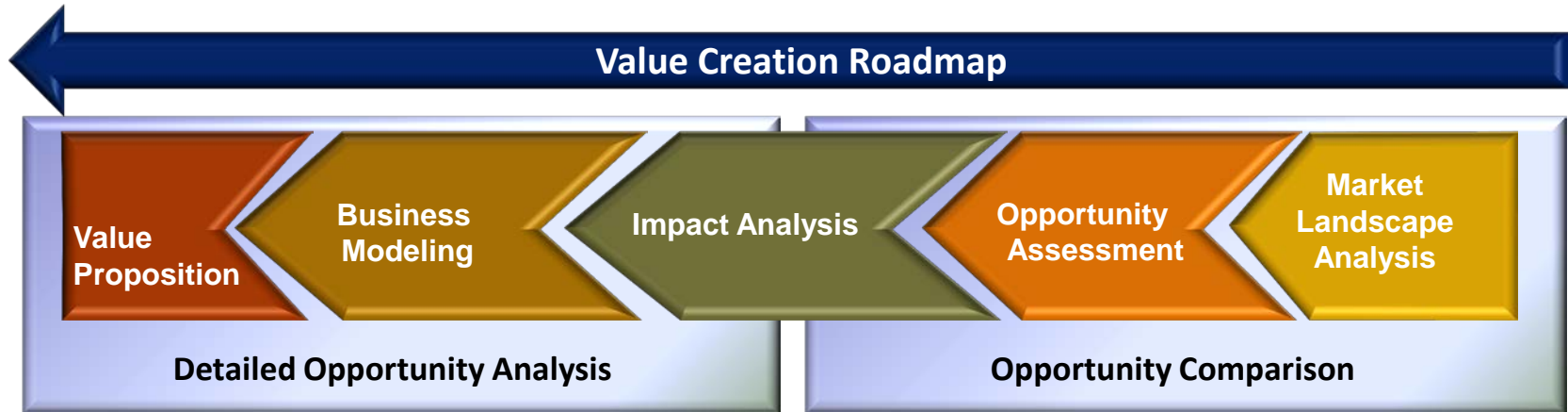
- ❑ You have a solid foundation for **Value Creation**
 - Unmet needs clarified
 - Market opportunities and drivers mapped
 - Key stakeholders identified
 - Initial product requirements have been established
- ❑ Other key findings might include:
 - Whether paradigm changes will be needed in medical or business practice
 - The need for external events to drive success
 - The opportunity to adopt a “franchise mentality”
- ❑ The company is prepared to choose product applications and develop its technology to address the unmet needs ...

“Nearly every man who develops an idea works it up to the point where it looks impossible, and then he gets discouraged. That's not the place to become discouraged.”

- Thomas Edison

Opportunity Assessment: Overview

Selecting the most commercially attractive new product opportunities that can be developed with the least amount of technical risk



Opportunity Assessment

- Evaluation of potential product opportunities
- Commercial Attractiveness (CA)
- Technical Likelihood of Success (TLS)
- Competitor Analysis

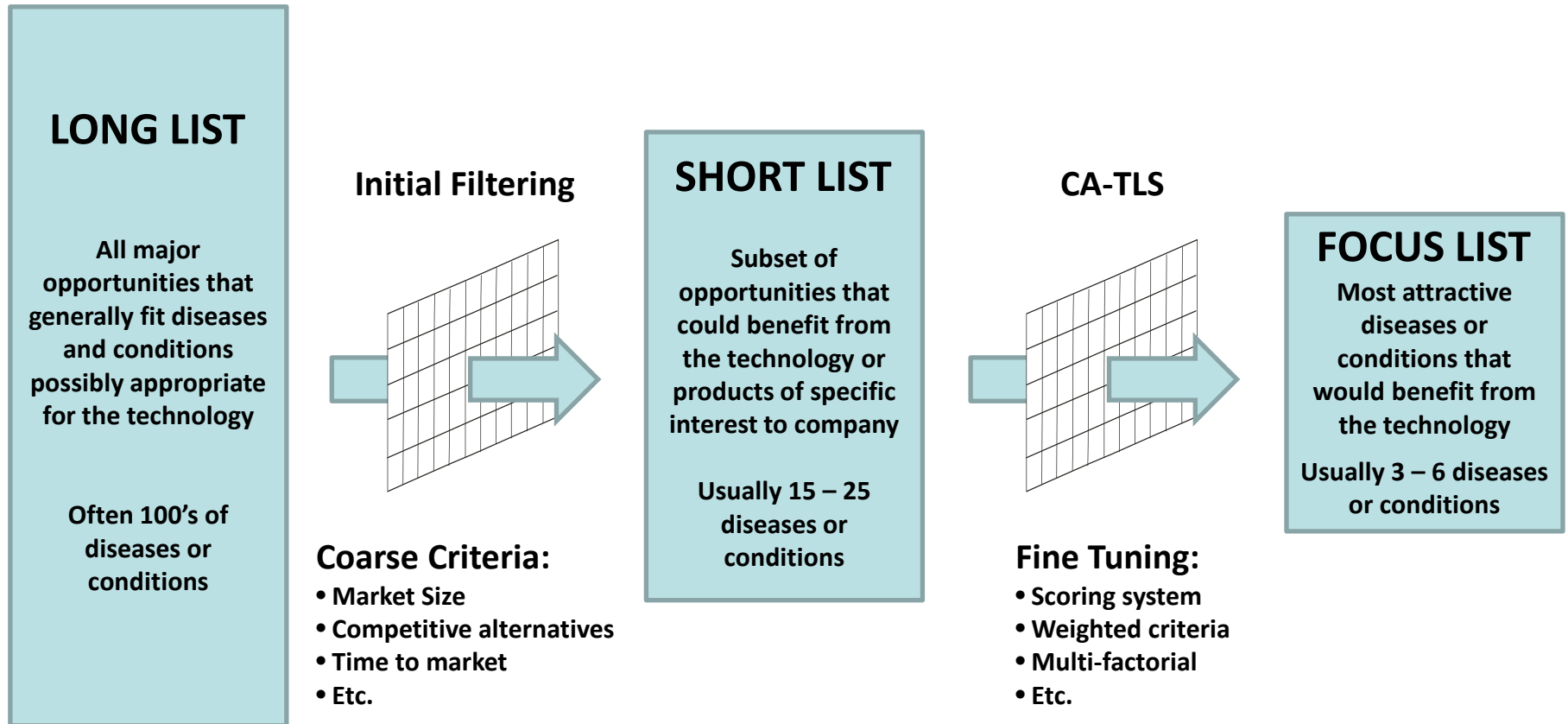
Opportunity Assessment: Overview

“The way to get good ideas is to get lots of ideas, and throw the bad ones away.” - Linus Pauling

- ❑ Systematic process for selecting lead product(s)
- ❑ Deep dive into those factors influencing the commercial attractiveness (CA) of the potential product opportunities
- ❑ Deep dive into those factors influencing the technical likelihood of success (TLS) of the potential product opportunities
- ❑ Quantitative comparison of multiple factors influencing CA and TLS
- ❑ Provides justification for lead product selection, even if you already have a product idea that you want to pursue (comparison to other opportunities)
- ❑ Compares applications directed toward different diseases, or different indications within a particular disease area

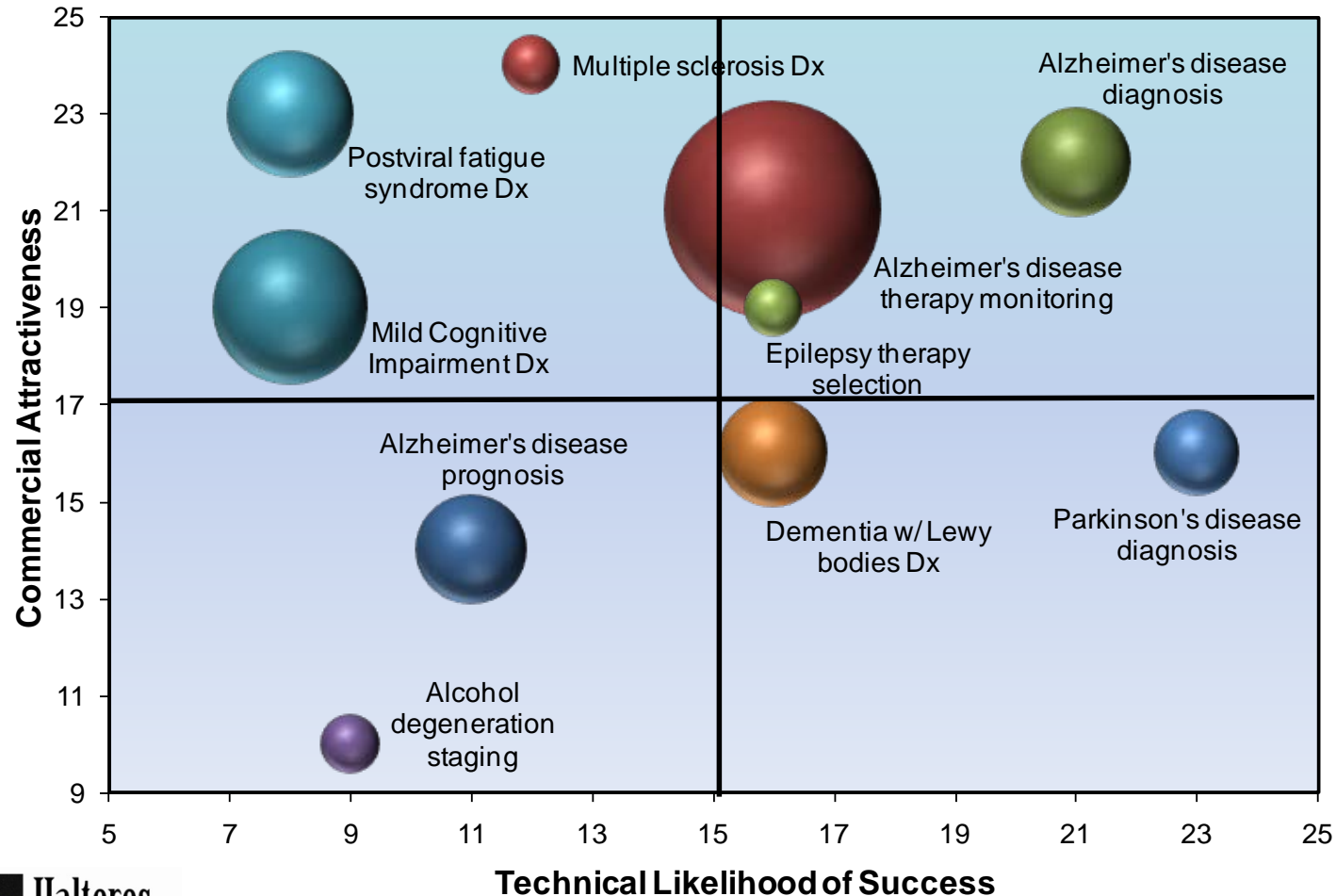
Opportunity Assessment: Process

Systematic process for screening out less attractive product opportunities and focusing in on those offering the greatest ROI



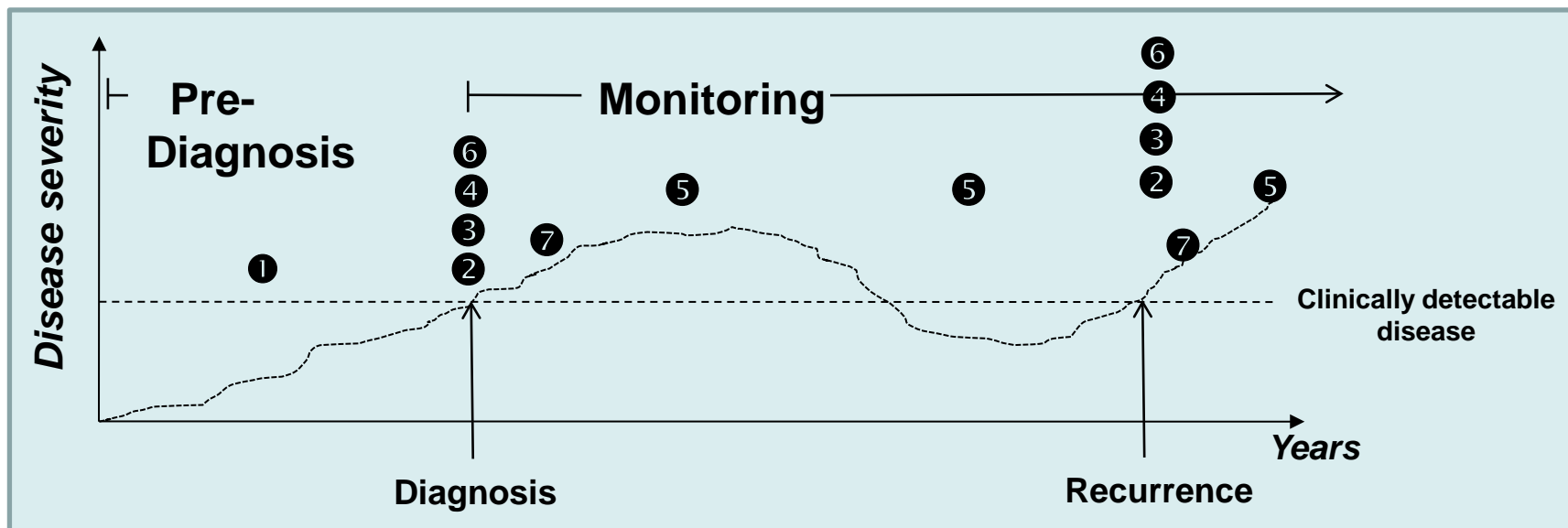
CNS Dx Example: Outcome of CA-TLS Analysis for CNS Disease Indications

Highlighting those opportunities that are the least technically difficult yet offer the highest commercial attractiveness



Opportunity Assessment: Product Portfolio Strategy

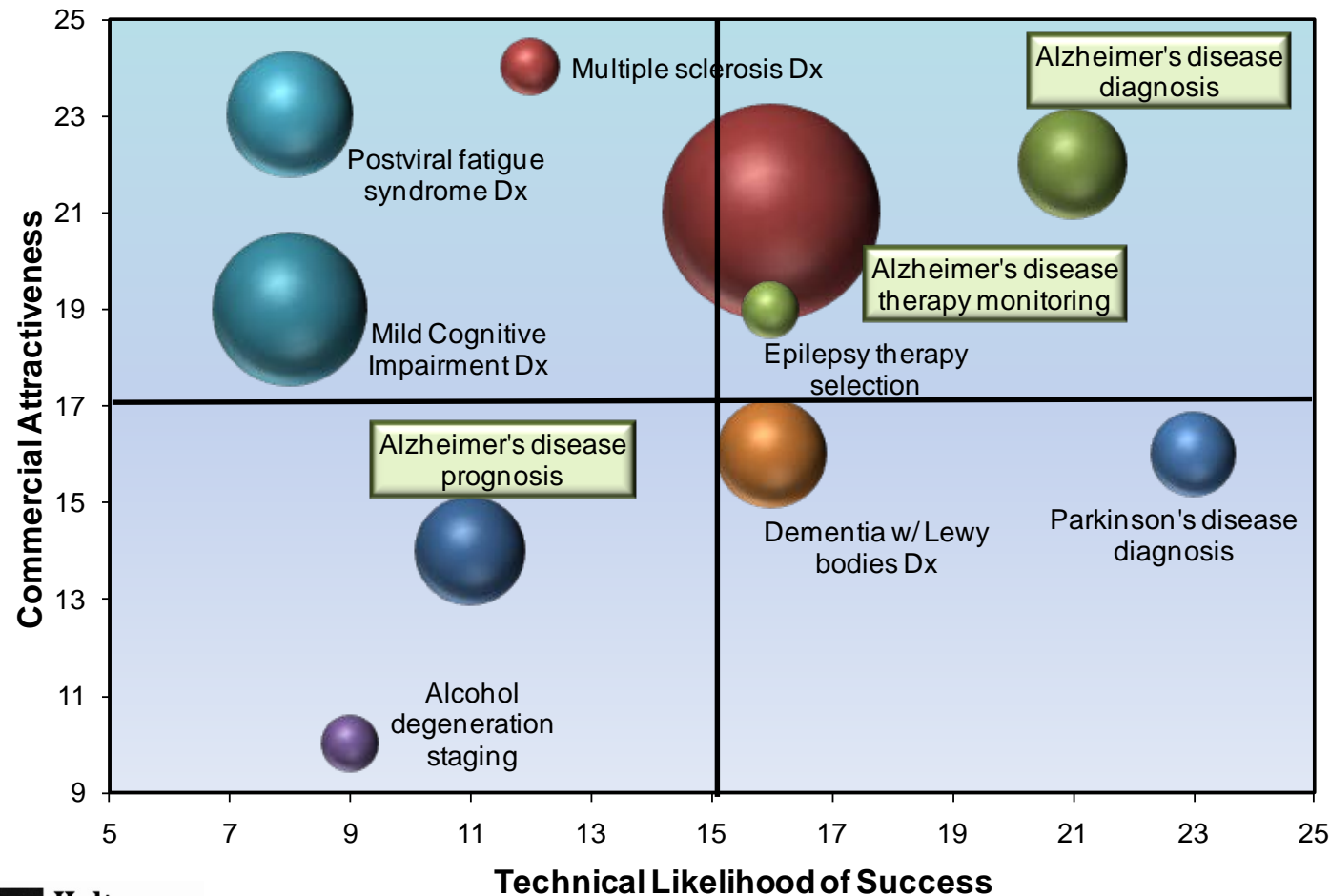
Different clinical intervention points are one means for defining a portfolio strategy and/or a “franchise approach”



| Potential Applications | |
|--|---|
| 1 Screening (broad or targeted) | 5 Disease Monitoring (detect recurrence) |
| 2 Diagnosis (symptomatic disease) | 6 Therapy Selection (targeted therapy) |
| 3 Staging (degree or advancement of disease) | 7 Therapy Monitoring (progression/efficacy of intervention) |
| 4 Prognosis (predict outcomes of disease) | 8 Others? |

CNS Dx Example: Disease Franchise Approach

Portfolio strategy: to become the premier diagnostics provider in the Alzheimer's Disease area



Opportunity Assessment: Competitor Analysis

A focused competitor assessment will identify potential barriers to entry and product positioning options

- ❑ Who are the major players in the selected space?
- ❑ What is the competitive situation today?
- ❑ What is the competitive situation expected to be like after launch of your new product?
- ❑ What are the pros and cons of competitive technologies relative to your technology?
- ❑ What are the advantages and disadvantages of competitive business models?

Opportunity Assessment: Competitor Analysis

Comparison of product features and business approaches will aid in establishing your own product specifications and business model

CNS Dx Result

| Product Feature | Your Product | Competitor A | Competitor B |
|----------------------|-----------------------------------|---|---|
| Business Model | Improved CNS-Disease Dx | Biomarkers of infection and sample prep | High value, esoteric MDx assays in CLIA lab |
| Automated | Sample in, result out | Pre-analytics only | Sample in, result out |
| Multiplex capability | 12-plex | No | 4-plex |
| Turnaround time | 2 hours | 30 min sample prep | 4 hours |
| Watch for... | Will biomarkers continue to lead? | Will they add assay dev capacity? | Will they adopt CNS focus? |
| Etc. | | | |

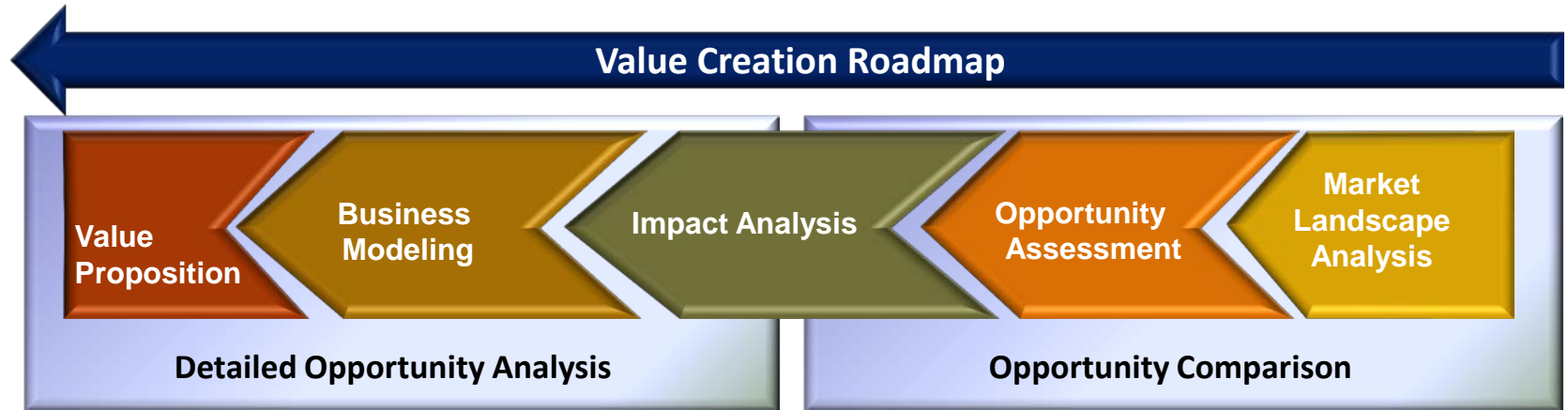
Opportunity Assessment: Summary

With the most attractive product opportunities identified, you are now ready to understand potential clinical and economic impact

- ❑ Following a systematic process for screening product opportunities, one can focus resources on the most commercially attractive and least technically difficult potential products.
- ❑ Opportunities exist for creating a franchise in a particular area, either across diseases (e.g., a respiratory disease panel) or within a particular disease area (e.g., different indications for Alzheimer's disease).
- ❑ The opportunity assessment analysis can be fine-tuned following completion of a focused competitor analysis and identification of potential barriers to entry.

Impact Analysis: Overview

Determining the value of the new product based upon its impact on healthcare costs and quality of life metrics



Impact Analysis

- Clinical Impact
- Economic Impact
- Sensitivity Analysis
- Pricing and Reimbursement

Impact Analysis: Definitions

Understanding the clinical and economic impact is critical for positioning the product for maximum benefit and value

□ Clinical impact

- Current practice of medicine or standard of care
- Practice of medicine with new product/indication
- Impact of new product/indication on clinical decisions, interventions or patient outcomes



□ Economic Impact

- Current healthcare costs associated with disease/indication
- Healthcare costs associated with new product/indication
- Impact of new product/indication on healthcare costs
 - Cost effectiveness
 - Cost savings



Impact Analysis: Cost Saving v. Cost-Effective Outcomes

Payers in the US generally are willing to pay about \$50,000 - \$60,000 per QALY (the cost-effectiveness threshold)

Cost-Effectiveness is quantified:

“Cost per incremental quality-adjusted life year” (QALY)

Dominant/”cost saving”:

- Cost saving and provide incremental QALYs

Cost effective:

- Cost per QALY: <\$50,000 - 60,000

Marginally cost

effective/”expensive”:

- Cost per QALY: \$50,000 - \$100,000

Not cost effective/”unattractive”:

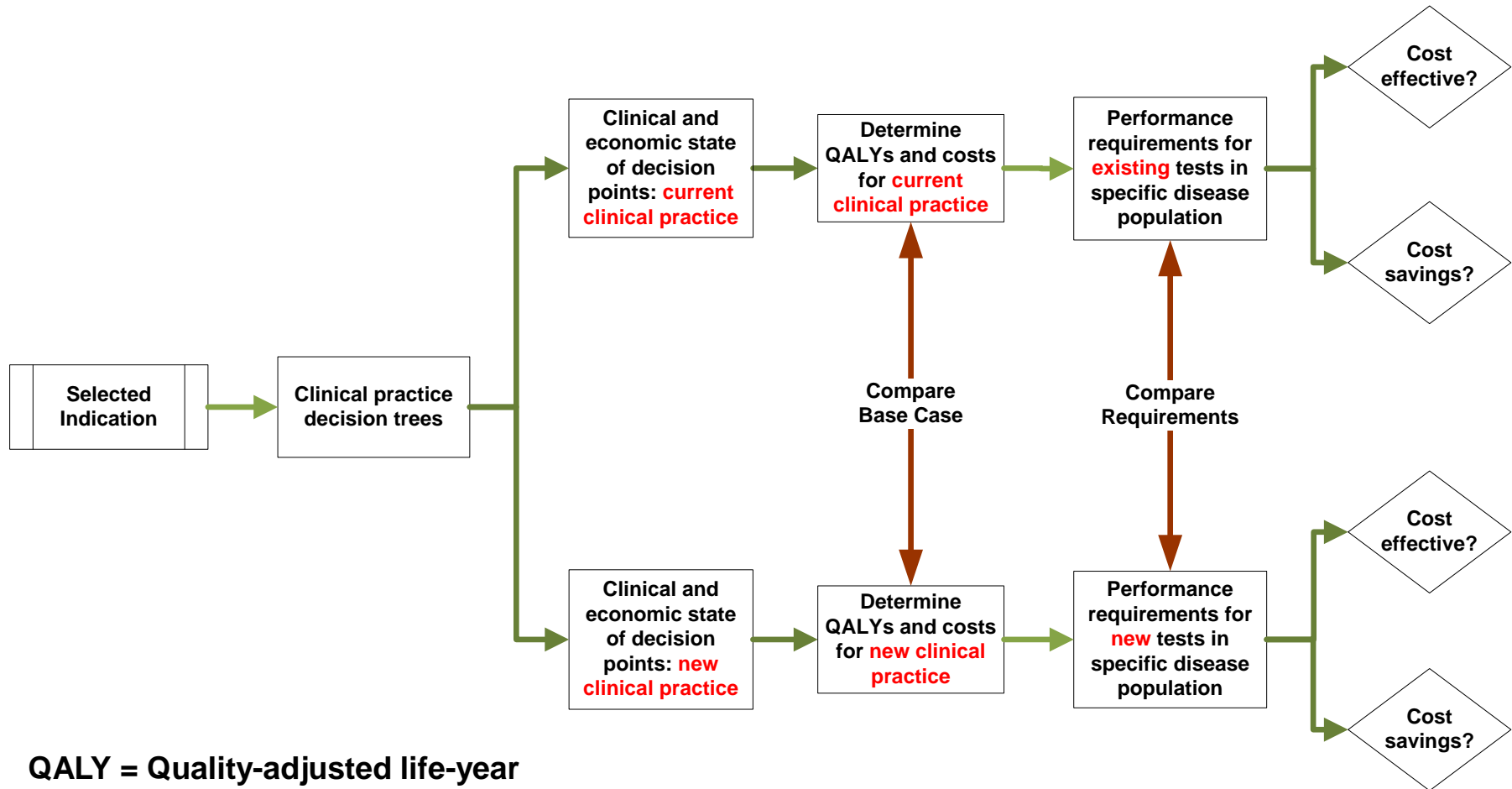
- Cost per QALY: >\$100,000

| Intervention | Cost-Effectiveness (Cost/QALY) |
|---|--------------------------------|
| Influenza vaccine | Cost saving |
| Pneumococcal vaccine | Cost saving |
| Beta-blockers after myocardial infarction | <\$10,000 |
| Mammographic screening | \$10,000 - \$25,000 |
| Colon-cancer screening | \$10,000 - \$25,000 |
| Osteoporosis screening | \$10,000 - \$25,000 |
| Management of antidepressant medication | Cost saving - \$30,000 |
| Hypertension medication (DBP >105 mm Hg) | \$10,000 - \$60,000 |
| Cholesterol management, as secondary prevention | \$10,000 - \$50,000 |
| Implantable cardioverter–defibrillator | \$30,000 - \$85,000 |
| Dialysis in end-stage renal disease | \$50,000 - \$100,000 |
| Lung-volume–reduction surgery | \$100,000 - \$300,000 |
| Left ventricular assist devices | \$500,000 - \$1.4 million |

Table adopted from: N Engl J Med 353;14. October 6, 2005. Peter J. Neumann, Allison B. Rosen, and Milton C. Weinstein. Medicare and Cost-Effectiveness Analysis.

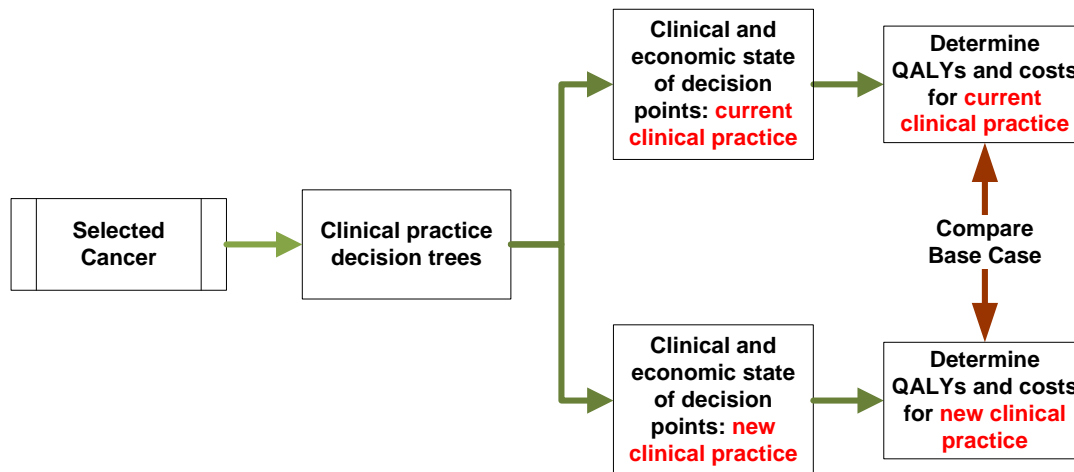
Impact Analysis: Clinical and Economic Impact

Understanding and demonstrating the impact on healthcare costs and /or quality of life will help to support a high value



QALY = Quality-adjusted life-year

Impact Analysis: CNS Dx Example



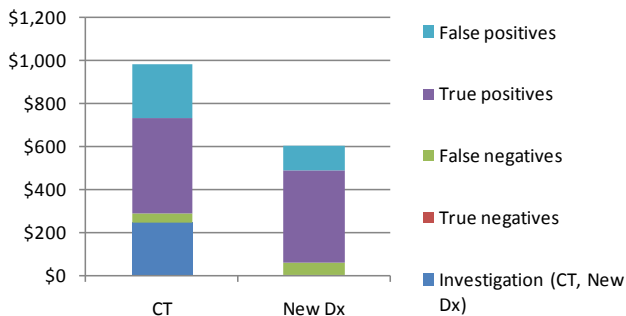
CNS Dx Result

Benefits of “new practice” per patient:

- Cost savings: \$380
- Incremental QAL days: 7
- Value of incremental QAL days*: \$1,150

* Assumes willingness to pay per QALY: \$60,000

Cost per patient



Life years lost per patient



Impact Analysis: Sensitivity Analysis

Changes in product performance can affect cost effectiveness and cost savings associated with the new practice of medicine

- ❑ Outcomes modeling is used to compare current medical practice to future medical practice incorporating the new diagnostic procedure
- ❑ Outcomes endpoints might include:
 - Impact on life years
 - Quality of life / quality adjusted life years (QALYs)
 - Total healthcare cost and cost per incremental QALY
- ❑ The impact of changes in test sensitivity and specificity on the economic impact metrics (cost savings, cost effectiveness) can be determined
- ❑ The sensitivity analysis model can be used to:
 - Guide development by targeting performance characteristics
 - Establish the cost effective price level based on performance

Impact Analysis: Sensitivity Analysis

Reduction in healthcare cost per patient can be shown as a function of changes in assay sensitivity and specificity

CNS Dx Result: Reduction in Healthcare Costs per Patient*

| | | Specificity | | | | | | | | | | | | |
|-------------|-------|-------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| | \$383 | 76% | 78% | 80% | 82% | 84% | 86% | 88% | 90% | 92% | 94% | 96% | 98% | 100% |
| Sensitivity | 76% | \$215 | \$237 | \$258 | \$280 | \$302 | \$324 | \$345 | \$367 | \$389 | \$411 | \$432 | \$454 | \$476 |
| | 78% | \$217 | \$239 | \$261 | \$282 | \$304 | \$326 | \$348 | \$369 | \$391 | \$413 | \$435 | \$456 | \$478 |
| | 80% | \$219 | \$241 | \$263 | \$285 | \$306 | \$328 | \$350 | \$372 | \$393 | \$415 | \$437 | \$459 | \$480 |
| | 82% | \$222 | \$243 | \$265 | \$287 | \$309 | \$330 | \$352 | \$374 | \$396 | \$417 | \$439 | \$461 | \$483 |
| | 84% | \$224 | \$246 | \$268 | \$289 | \$311 | \$333 | \$355 | \$376 | \$398 | \$420 | \$442 | \$463 | \$485 |
| | 86% | \$226 | \$248 | \$270 | \$292 | \$313 | \$335 | \$357 | \$379 | \$400 | \$422 | \$444 | \$466 | \$487 |
| | 88% | \$229 | \$250 | \$272 | \$294 | \$316 | \$337 | \$359 | \$381 | \$403 | \$424 | \$446 | \$468 | \$490 |
| | 90% | \$231 | \$253 | \$274 | \$296 | \$318 | \$340 | \$361 | \$383 | \$405 | \$427 | \$448 | \$470 | \$492 |
| | 92% | \$233 | \$255 | \$277 | \$298 | \$320 | \$342 | \$364 | \$385 | \$407 | \$429 | \$451 | \$472 | \$494 |
| | 94% | \$235 | \$257 | \$279 | \$301 | \$322 | \$344 | \$366 | \$388 | \$409 | \$431 | \$453 | \$475 | \$496 |
| | 96% | \$238 | \$260 | \$281 | \$303 | \$325 | \$347 | \$368 | \$390 | \$412 | \$433 | \$455 | \$477 | \$499 |
| | 98% | \$240 | \$262 | \$284 | \$305 | \$327 | \$349 | \$371 | \$392 | \$414 | \$436 | \$458 | \$479 | \$501 |
| | 100% | \$242 | \$264 | \$286 | \$308 | \$329 | \$351 | \$373 | \$395 | \$416 | \$438 | \$460 | \$482 | \$503 |

*Mock data used to illustrate output of analysis

Impact Analysis: New Product Pricing

“Price is what you pay. Value is what you get.” - Warren Buffett

□ Product pricing

- “Cost plus” based pricing
 - Based on COGS plus a standard margin
 - Includes commodity products in current practice of medicine
- Value based pricing
 - Based upon the impact on healthcare costs
 - Could include disruptive products that change practice of medicine

CNS Dx Result

- AD Dx cost estimate, at volume, is <\$10 per test. A cost plus model will generate marginal return per test
- Value pricing based on economic impact could justify >\$200 per test, based on modeling
- This 10x pricing differential may drive investor interest

Impact Analysis: Payer Reimbursement

A well-executed impact analysis is necessary to support and sustain high level reimbursement

❑ Cost savings will need to be divided amongst stakeholders:

- Manufacturer
- Distributor
- Testing lab

❑ Some options for billing molecular diagnostics tests:

- Code stacking
- Unique CPT code
- Miscellaneous or “Not Otherwise Classified” codes

CNS Dx Result

- Primary target population: Medicare-eligible
- Pursue CPT code stacking at first
- Submit unique CPT code once health economic impact data is published

Impact Analysis: Summary

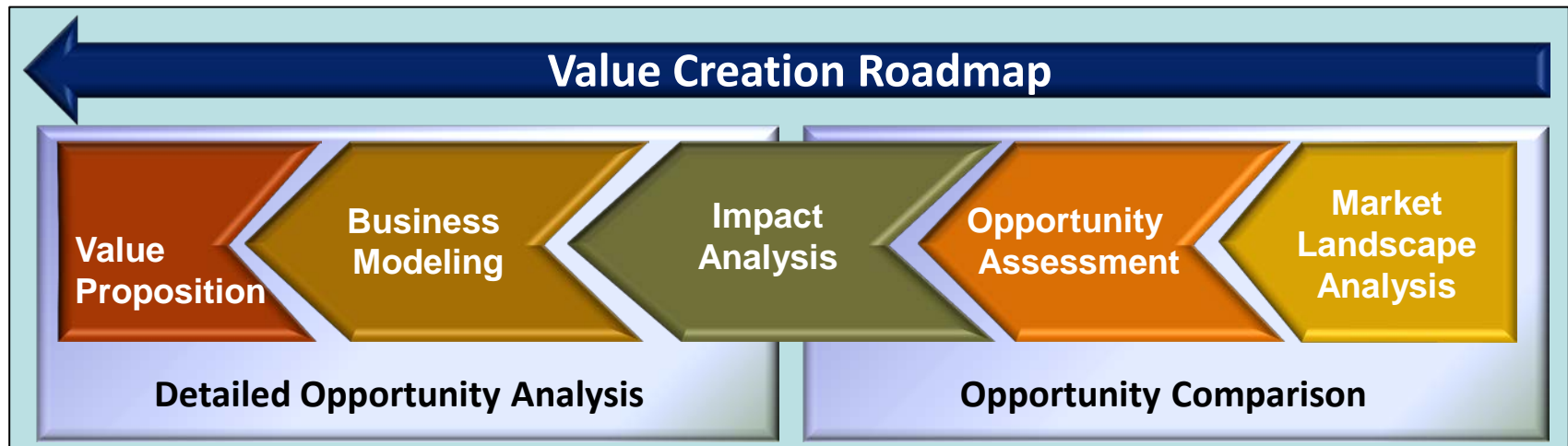
Impact analyses are increasingly positioned as tools to establish and justify pricing and reimbursement strategies based on medical impact

- ❑ Compare practice of medicine with and without your new product
 - Understand clinical impact
 - Clinical decisions and/or interventions
 - Clinical outcomes
 - Determine economic impact
 - Cost effectiveness
 - Cost savings
- ❑ Use a careful sensitivity analysis to guide product performance targets and help direct product development objectives
- ❑ Use clinical and economic impact to drive value-based pricing and reimbursement strategies

“That which costs little is less valued.”
– Miguel de Cervantes

Business Modeling: Overview

Choosing the right business scenario will help minimize risk and maximize value



Business Modeling

- Business Scenarios
- Partner Strategies
- Program Plan
- Key Issues
- Financials

Business Modeling: Scenarios

“Make vs. buy”: deciding the best way to bring your technology to market

❑ Preparation

- Complete a core competency assessment
- Follow up with a gap analysis
- Decide what you want to do

❑ Potential go to market strategy examples:

- Research products
- Service model – CLIA lab or CRO
- Licensed / cleared IVD kit sales

❑ Common business model options

- Organic growth
- Strategic partners
- Mergers and acquisitions

CNS Dx Result

- CNS lacks an instrument platform and commercial infrastructure
- Launch 1st gen. LDT via CLIA lab
- Establish Dx mfg partner for 2nd gen. IVD product
- Develop follow-on menu using core technology

Business Modeling: Portfolio Strategy Rationalization

The lead product drives customer interest; menu availability drives the sale

❑ Points to Consider

- Breadth vs. depth of product menu
- Medical practice limitations
- Physician channel focus
- Target laboratory
- Other: turnaround time, sample type, etc.

❑ Leverage scalability of core technology

❑ Determine clinical study requirements

- Sample cohort availability
- Scope, patient availability, timing

❑ Determine regulatory requirements

- 510(k), IVD-MIA, PMA

CNS Dx Result

- Single disease panels (multiple-disease panels require complex clinicals)
- Expand AD menu with therapy monitoring and disease staging
- Consider partnering with imaging companies
- Evaluate protein-based assays for AD
- Add other CNS diseases; e.g., Parkinson's Disease
- Channel focus; e.g., no psychiatric disorders

Business Modeling: Partner Strategies

Demonstrating product and market feasibility drives value

- ❑ Generally speaking, the closer to market a product is, the more value will be realized
- ❑ When deciding whether to partner, consider:
 - True internal expertise and interest
 - Time to market and time to peak sales projections
 - Sustainability and scalability factors
 - Financial and risk factors
- ❑ Strategic partners can be found anywhere, e.g.:
 - Key suppliers
 - Channel partners
 - Competitors
 - Other industries
 - Strategic funders

CNS Dx Result

Partner with:

- IVD kit manufacturer for instrument system *and* market access
- Pharma for CDx program and sample access
- AD Assoc. for awareness
- CMS (Medicare) for reimbursement

Business Modeling: Partner Strategies (2)

Properly established partnerships create a natural fit between partners

| Partner Model | Definition | Typical Business Model |
|------------------------------|---|---|
| Development | <ul style="list-style-type: none">• Make technology available to partner(s) for application dev.• Your focus: technology dev. | <ul style="list-style-type: none">• Technology license or sale• Royalty / Milestone payments• Market /geographic segmentation |
| Manufacturing | <ul style="list-style-type: none">• Transfer to third party for scale-up and full scale mfg• Your focus: tech. and prod. dev.; maybe commercialization | <ul style="list-style-type: none">• Contract mfg relationship• Cost plus transfer pricing is typical• Consider royalty component |
| Sales & Distribution | <ul style="list-style-type: none">• Commercial partner handles all selling, support and dist. activities• Multiple geographic partners• Your focus: product and market dev. | <ul style="list-style-type: none">• Straight contract relationship• Finished product transferred at agreed to price• Consider escalated support needs |
| Manufacturing, Sales & Dist. | <ul style="list-style-type: none">• Partner handles all manufacturing and commercialization activities• Your focus: product development | <ul style="list-style-type: none">• Frequently role assumed by diagnostics manufacturers• Strategic partnerships; e.g. joint venture, license agreements etc |
| Market Segment | <ul style="list-style-type: none">• Geographic focus, field of use, customer segment etc | <ul style="list-style-type: none">• Frequently a restricted product license agreement |

Business Modeling: Other Key Issues

Strategic and funding partners will be interested in other key activities

❑ Management Team

- A key deciding factor for funders
- Highlight related diagnostics experience
- Show command of factors influencing path to success

❑ Intellectual Property

- Protect the market you build
- Or pursue first mover advantage

❑ Hiring and facilities plans

❑ Global expansion projections

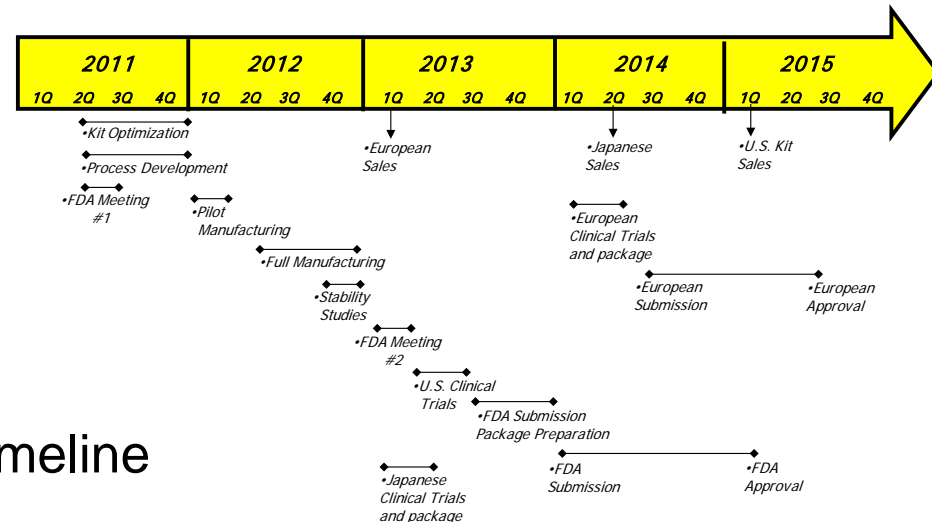
CNS Dx Result

- Well-known mgmt team: CEO is HPV Dx company founder and CCO is CRC assay market developer
- Funding from key strategic partners
- Proprietary algorithms
- Hire Bus Dev and Market Dev teams
- EU expansion beginning year 3

Business Modeling: Program Plan

Completing a program plan forces a disciplined approach to development

- ❑ Develop firm value creation goals for each funding period
- ❑ Determine major milestones
 - Product, process, market development
 - Regulatory
 - Commercialization
 - Funding
 - Other
- ❑ Include all functional areas
 - Ensure gaps are addressed
- ❑ Determine resource needs and timeline
 - Calculate critical path
 - Perform sensitivity analysis
 - Mitigate risk: identify alternatives for critical path steps



Business Modeling: CNS Dx Program Plan

Completing a program plan forces a disciplined approach to development and realistic funding needs

| Milestone | Year 1 | Year 2 | Year 3 |
|------------------------------|---------------------------|---|-----------------------------|
| Market/Business Development | RUO dev. deals | New biomarker access | Pharma CDx deals |
| Product Development | AD Dx LDT test | AD Rx monitor | Parkinson's Dx |
| Clinical Development | AD Dx pre-clinical | AD Dx clinicals AD Rx monitor pre-clinical | AD Rx monitor clinicals |
| Manufacturing | LDT reagent manufacturing | cGMP facility | AD Dx IVD kit manufacturing |
| Quality Systems & Regulatory | Design Control / QSR | CLIA Lab for Pharma Trials | AD Test FDA Filing |
| Organization | VP BD CSO | CFO VP Sales/Mktg CLIA Lab Director | CMO VP Operations |
| Supply Chain & Partners | Oligos, OEM manufacturers | New biomarkers | Instrument system |

Business Modeling: Financials

A credible and accepted reference model for benchmarking success is an essential component of a funding strategy

❑ Funding plan

- Key value creation goals for each tranche
- Major milestones and use of proceeds

❑ Business Financial Model

- Detailed P&L
- Working capital
- Return calculations (ROI, NPV)
- Sensitivity analysis
- Dry well(s) – include cushion for each tranche

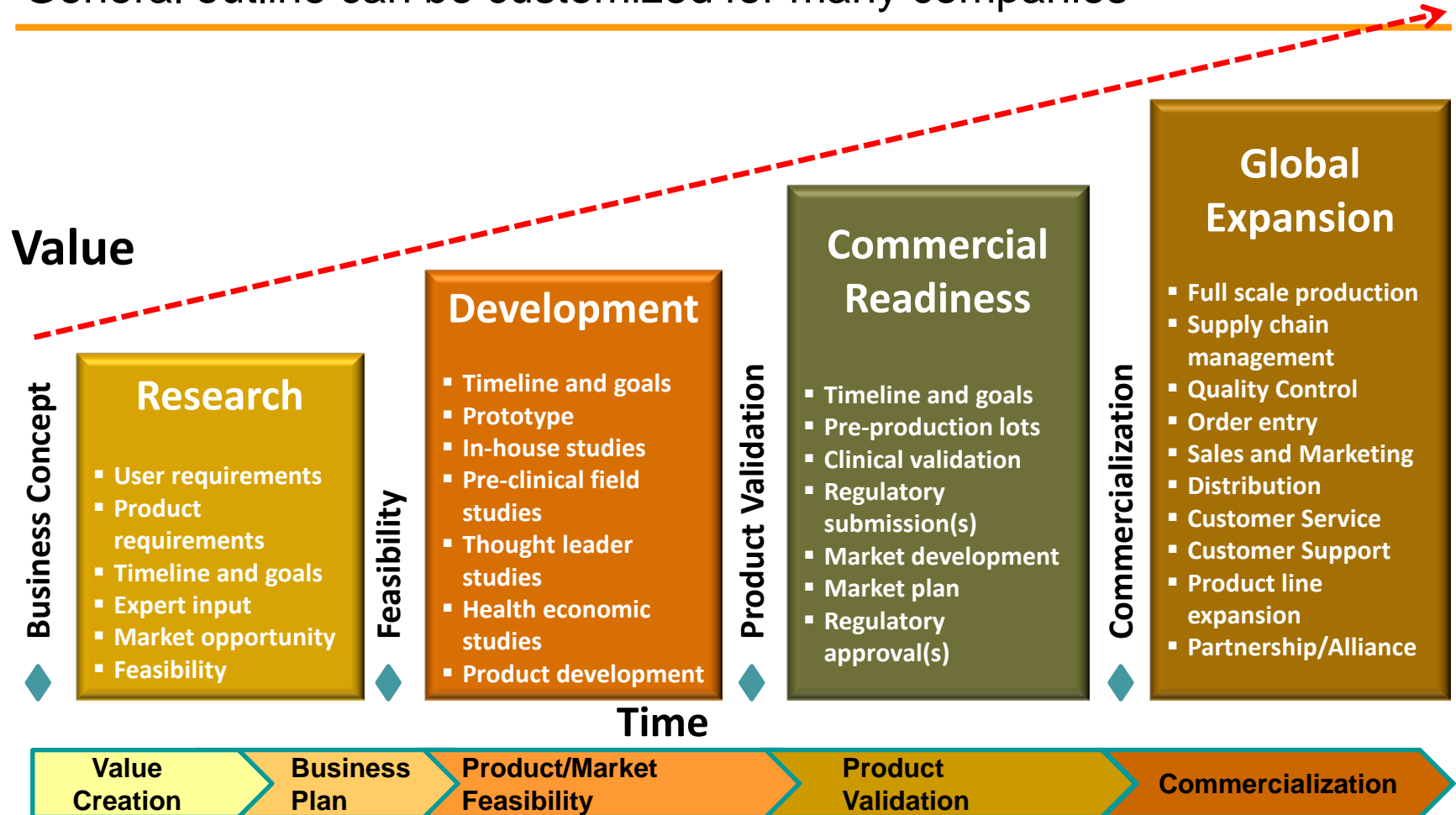
❑ Critical

- Accepted reference model for success
- Clear assumptions

“If you know how to spend less than you get, you have the philosopher’s stone” – Benjamin Franklin

Business Modeling: Planning Development Stages With Value Creation Goals

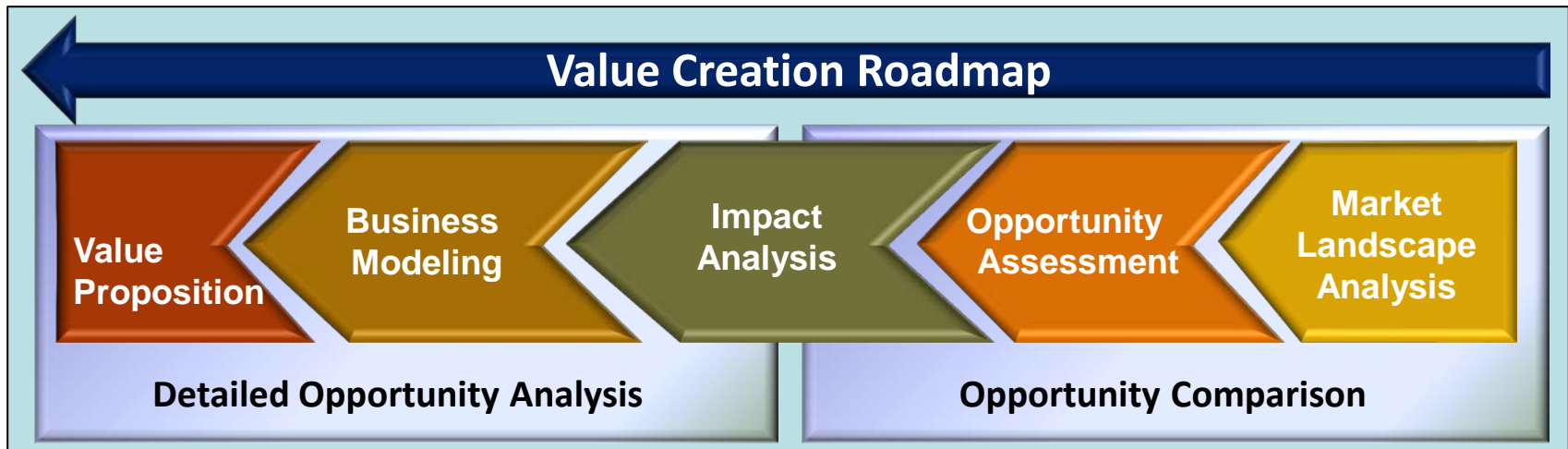
General outline can be customized for many companies



◆ Value Creation Milestones

Value Proposition: Overview

Bringing it all together in a compelling story for value creation



Value Proposition

- **Company offering**
- **Partner / customer needs**

Value Proposition: Objectives

Why a strategic partner or investor should pay attention to your offering

- ❑ Concise and easily understood statement
- ❑ Prepared from the perspective of the audience
- ❑ Include metrics of success supporting:
 - Attainable value for your partner
 - Achievable success for your company

“I conceive that the great part of the miseries of mankind are brought upon them by false estimates they have made of the value of things”

- Benjamin Franklin

Value Proposition: CNS Dx Example

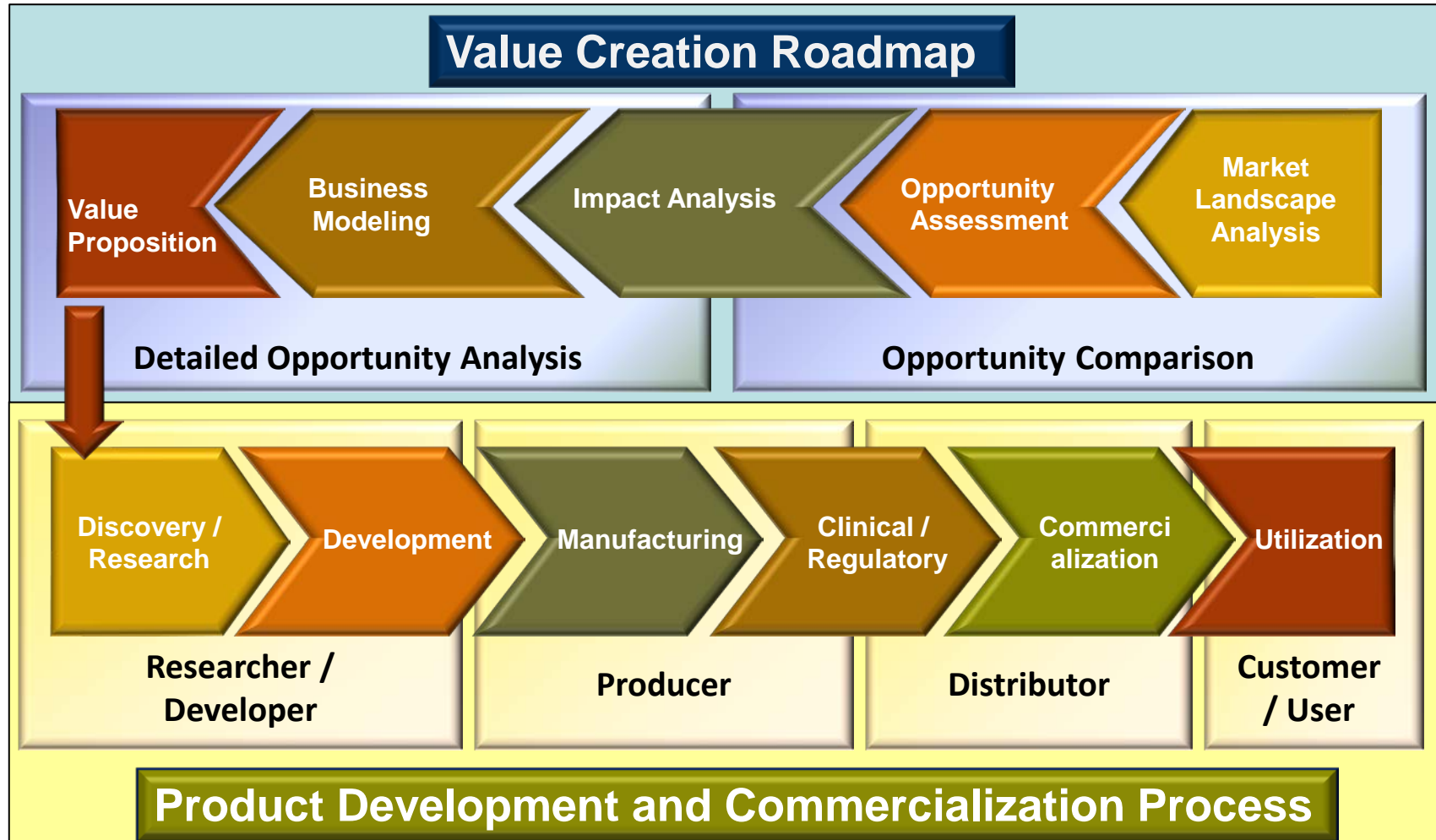
A compelling reason for partnership and investment

CNS Dx Example:

“Our proprietary, first of its kind blood test is intended to definitively diagnose Alzheimer’s Disease (AD) in the estimated 5MM AD suffers in the US. With the number of AD patients growing at an estimated 10% per year, early diagnosis could help to save the US healthcare system a projected \$100-125B per year based on reduced complications from the disease and associated co-morbidities. Earlier identification and more aggressive treatment of AD has been shown to slow disease progression. Based on these projections, the CNS Dx AD Test could help increase sales in the already hot \$20B US AD therapeutics market by 20-25% per year.

Summary: The Halteres Process for Value Creation

Integrating the **Value Creation** and Development Processes



Summary: Recapping the Process

A [Value Creation Roadmap](#) can be used to generate a compelling and unique story to gain partner and investor interest

- ❑ A market landscape analysis
 - Technology fit
 - Market assessment and unmet needs
 - Stakeholder map
 - Product requirements
- ❑ The most attractive, least risky product opportunities
- ❑ The anticipated impact to medical practice and healthcare costs
 - Health economics, pricing and reimbursement
- ❑ Business model and partnering options
 - Good understanding of product development and commercialization path
 - Including key financials and program plan
- ❑ Your unique value proposition



CNS Dx Conclusion

The [Value Creation Process](#) creates path to success

Armed with the confidence brought by a clear understanding of the value creation milestones and how they interact to inform the traditional product development and commercialization process, CNS Dx is now ready to follow a credible path to market and to achieve funding and commercial success.

About Halteres Associates, LLC

www.halteresassociates.com

Halteres Associates is a leading bioscience consultancy comprised of more than 150 professionals with extensive, long-term, direct operating experience in a broad spectrum of areas of expertise, including the development and commercialization of diagnostics, medical devices, therapeutics, research reagents and bioscience tools. Halteres team members have been personally involved, at direct operating and senior management levels, in the planning and growth phases of several of the industry's most successful diagnostics ventures, including Abbott, ABI, Bayer, Chiron, Ciba Corning, Life Technologies, Ortho, Roche, Siemens, and others. Areas of core competency include strategic planning, business development, product and market development, portfolio planning, business and financial modeling, impact analyses, including health economics and reimbursement, clinical study design and management, regulatory strategy, sales and marketing, clinical laboratory management, global health and much more. Halteres leverages these individual skills by assembling customized consulting teams that best meet the unique needs of our clients. The interactions of these experienced team members and the resulting syntheses of ideas and actions provide our clients with the greatest value and set us apart from other consulting firms. To date, Halteres Associates has assisted clients in achieving more >\$1B in cumulative M&A and funding transactions.



Halteres Associates: Contact Information



Mickey Urdea, Founder and Partner:

510-708-7478

murdea@halteresassociates.com



Richard Thayer, Managing Partner:

925-487-3247

rthayer@halteresassociates.com



Paul Neuwald, Principal & Contracts Manager:

925-586-0486

pneuwald@halteresassociates.com

Web Site: www.halteresassociates.com