

Assessing the Risk and Potential of Future Vaccine Markets

Clinton Health Access Initiative (CHAI)
DCVMN Annual Meeting
Buenos Aires, October 2016



Agenda

1. **Framework** for assessing risk and potential of future vaccine markets

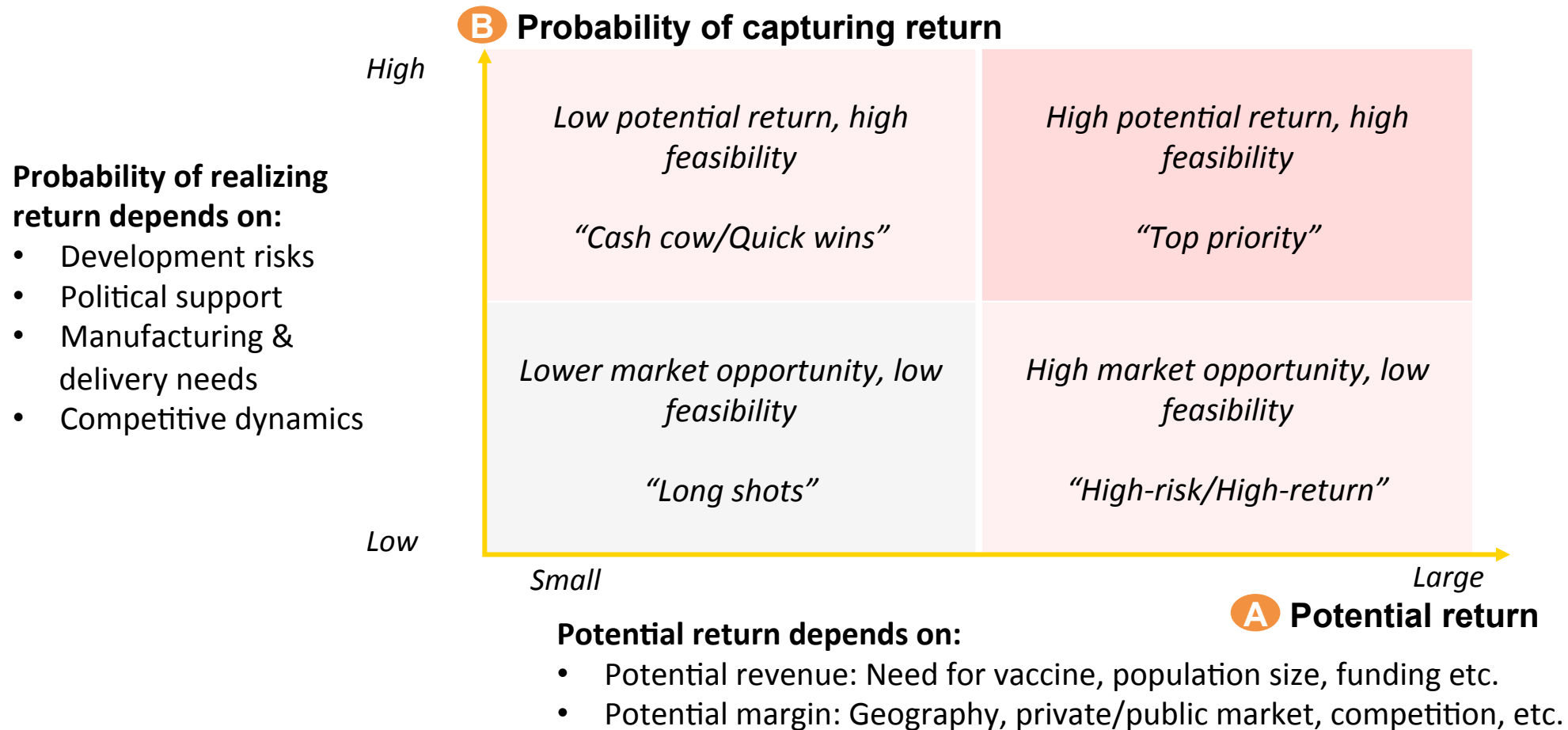
2. Examples of assessment **inputs**

3. Illustrative assessment **outputs**

4. Summary: “**Know thyself, know thy market**”

Understanding key factors that drive expected return is needed to make investment decisions across disparate antigens (new or current) with multiple, shifting and non-quantifiable factors...

Expected return = **A** Potential return X **B** Probability of realizing return



Broadly, new antigens have less competition-driven risk (i.e., higher potential return for early entrants), but also higher technical, regulatory and funding risks

... in addition, underlying management factors, e.g., competitive advantages, investment priorities, risk tolerances and long-term strategies, need to be taken into account

Management considerations	Competitive Advantages	<ul style="list-style-type: none">• Core R&D capabilities• Manufacturing advantage• Markets/channels strength• Functional excellence		Assessing expected return and management factors (“know thyself, know thy market”) enable companies to <ul style="list-style-type: none">• Risk optimization and portfolio balancing• Make informed go/no-go ‘best guess’ in highly uncertain and fluid space• Align pipeline with broader company strategy
	Strategic portfolio decisions	<ul style="list-style-type: none">• Fiscal limits• Expansion vs. ‘doubling down’• Balancing portfolio		
	Risk tolerance	<ul style="list-style-type: none">• Company risk limits and tolerance		
	Long-term strategy	<ul style="list-style-type: none">• Business unit goals• Broader company strategy		

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Macro level trends around unmet needs, funding and delivery, target populations and rate of commoditization have important implications for portfolio development

EXAMPLES

Category	Trend	Implications
Unmet needs	<ul style="list-style-type: none"> Microbial resistance makes treatment increasingly challenging for bacterial diseases 	<ul style="list-style-type: none"> Partners looking to vaccines even for antibiotic-treatable bacterial conditions
	<ul style="list-style-type: none"> Increasing awareness of the threat of epidemics 	<ul style="list-style-type: none"> Increasing awareness of the threat of epidemics and need for vaccine as a health security tool
	<ul style="list-style-type: none"> Many products still do not meet LMIC needs on efficacy and presentation 	<ul style="list-style-type: none"> Opportunity to shift large LMIC markets with optimize products
Funding and delivery challenges	<ul style="list-style-type: none"> ~70% of Gavi cohort scheduled to graduate by mid-late 2020's Potential for self-procuring 	<ul style="list-style-type: none"> Price sensitivity Potential fragmentation of market and regulatory requirements
	<ul style="list-style-type: none"> New pipeline vaccines often target populations across human life 	<ul style="list-style-type: none"> New delivery platforms face uptake risks
Rapid globalization and commoditization	<ul style="list-style-type: none"> New manufacturers have improved capabilities and ambitions for global market entry 	<ul style="list-style-type: none"> Awareness of global nature of competition landscape needed
	<ul style="list-style-type: none"> Expectation of vaccine equity & active market-shaping by global partners 	<ul style="list-style-type: none"> More rapid transition from development to widespread use in LMIC markets
	<ul style="list-style-type: none"> Successful entry of low-cost manufacturers 	<ul style="list-style-type: none"> More rapid commoditization

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Assessing individual candidates for relative return and probability of success is not purely a science and the tool is meant to be the basis for debate/discussion

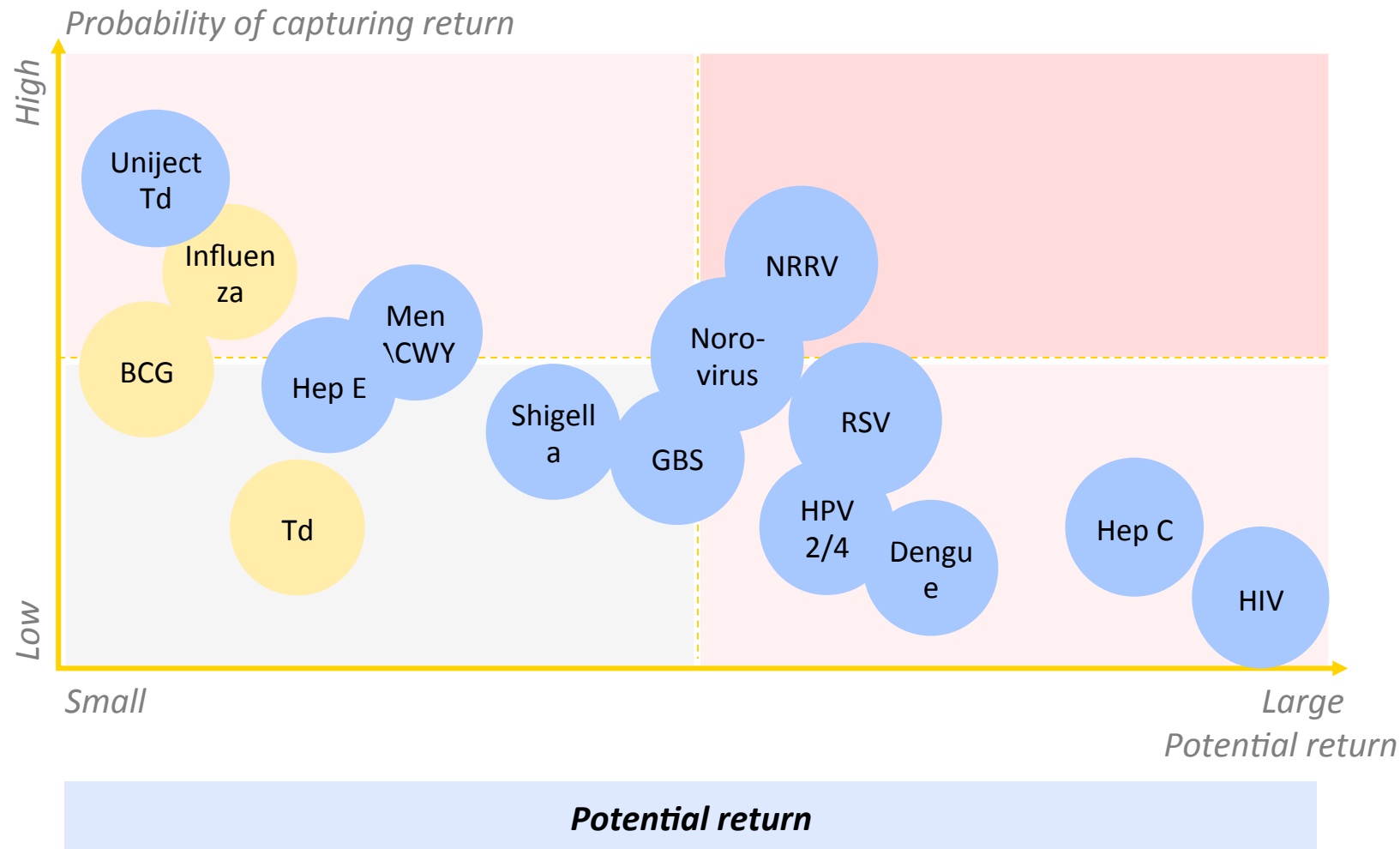
ILLUSTRATIVE

Probability of realizing return

- Development risks
- Political support
- Manufacturing & delivery needs
- Competitive dynamics
- Management considerations

Current

Potential



- Potential revenue: Need for vaccine, population size, funding probability
- Potential margin: Geography, private/public, competition

Part of the process is building hypotheses based on analyses about candidates, then testing key assumptions/hypotheses with experts and partners

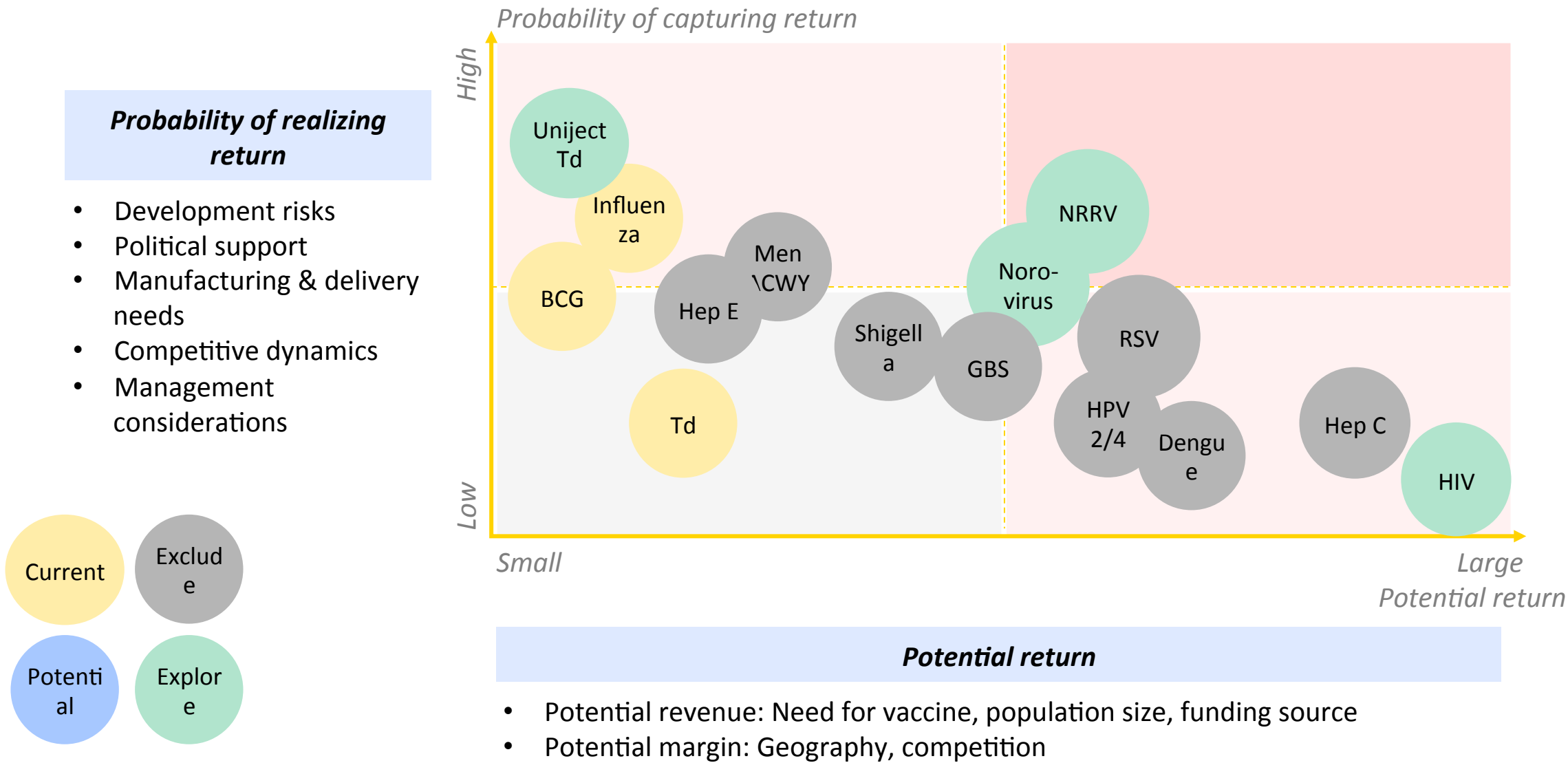
ILLUSTRATIVE

	High-risk/return	High priority	Quick wins	
	Potential return		Probability of realizing return	Management & Conclusion
Uniject Td	Low <ul style="list-style-type: none">Niche market for MNT eliminationSome political will and funding potential	Medium-Low <ul style="list-style-type: none">Modest investmentShort-timelineDomestic marketMaternal delivery	“Quick win” <ul style="list-style-type: none">Potential quick win	
NRRV	High-medium <ul style="list-style-type: none">High unmet need in LMICHistoric precedent for pathogen-area funding	Medium <ul style="list-style-type: none">High-medium investment (E Coli platform)Domestic marketSwitching risksInfant schedule	“Potential” <ul style="list-style-type: none">High potential vaccinePotential for combined vaccinesEntry to EDD markets	
Norovirus	Medium <ul style="list-style-type: none">Likely large but unquantified unmet needHighly infections, low/middle income marketsFunding as yet unclear	Medium <ul style="list-style-type: none">One candidate in Phase III but pipeline scarceHigh investment	“Potential” (alternate) <ul style="list-style-type: none">Low-income market version neededPotential for combined vaccinesEntry to EDD markets	
HIV Follow-me	Extremely high <ul style="list-style-type: none">Huge unmet disease burdenDiverse marketsVery high political will and funding potential	Extremely low <ul style="list-style-type: none">Very high technical risksPotentially large investmentAdolescent/adult delivery	“Hold for future exploration” <ul style="list-style-type: none">Long-term opportunityInternational partner relations	

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ILLUSTRATIVE



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Summary: Know thy self, know thy market

Structure to assess expected returns and strategic implication



Processes and market intelligence to drive to optimized, company-specific decisions

More focused, responsive, optimized portfolios

1. Expected return (“Know thy market”)

$$\text{Expected return} = \frac{\text{Potential return} \times \text{Probability of realizing return}}$$

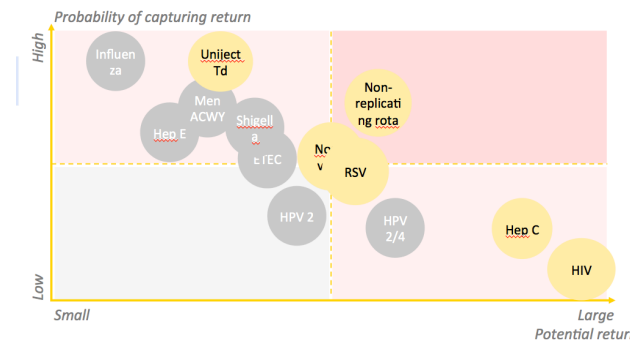
2. Management considerations (“Know thy self”)

- *Competitive advantages/weaknesses*
- *Balancing the portfolio*
- *Risk tolerance*
- *Overall strategy*

- Clearly articulating priorities
- Discussions on relative weight of intangibles and testing key assumptions
- Engagement with experts on core factors
- Iterative process where key events triggering reassessment

Know thyself, know thy ~~enemy~~ markets,

And you will not be imperiled in a 100 battles¹



¹ Adapted from quote “知彼知己，百戰不殆” from Sun Tzu’s “The Art of War”

Gracias por su atención

Thank you for your attention

Obrigado pela sua atenção

여러분의 관심에 감사드립니다

感谢您的关注

உங்கள் கவனத்திற்கு நன்றி

ध्यान देने के लिए आपका धन्यवाद



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