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Advancing Immunotherapy Combinations

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No Relationships to Disclose

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The opportunity

Multiple agents targeting different mechanisms or pathways may result in better outcomes for patients

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The current landscape: Yervoy

	Adv	Brea	Cerv	Gast	Leuk Lym	Lung	Mela	Ovar	Panc	Prost	Rena	Sarc	Urot	Total	%
0							1							1	0.9
I	4	1	1		6	1	17		2	3	1	2	1	39	34.2
I/II					2		14			2				18	15.8
II		1	1	1	1	3	28	2	1	6	1	1	1	47	41.2
III						2	5			2				9	7.9
Total	4	2	2	1	9	6	65	2	3	13	2	3	1	114	100
%	3.5	1.7	1.7	0.9	7.9	5.3	57	1.7	2.6	11.4	1.7	2.6	1.75	100	

www.clinicaltrials.gov

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Yervoy:
In a nutshell

- 114 clinical trials (www.clinicaltrials.gov , February 2013)
- >50% in melanoma
- >50% opened since Yervoy approved by FDA (Q1,2010)
- Combination studies enabled after:
  - single agent approval and
  - primarily focused on studies in the approved indication

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Current challenges

- Clinical agents are owned by different parties
- Drug safety
- Resource management
- Information sharing
- Intellectual property

Create incentives for combination studies dealing with these legitimate concerns and barriers

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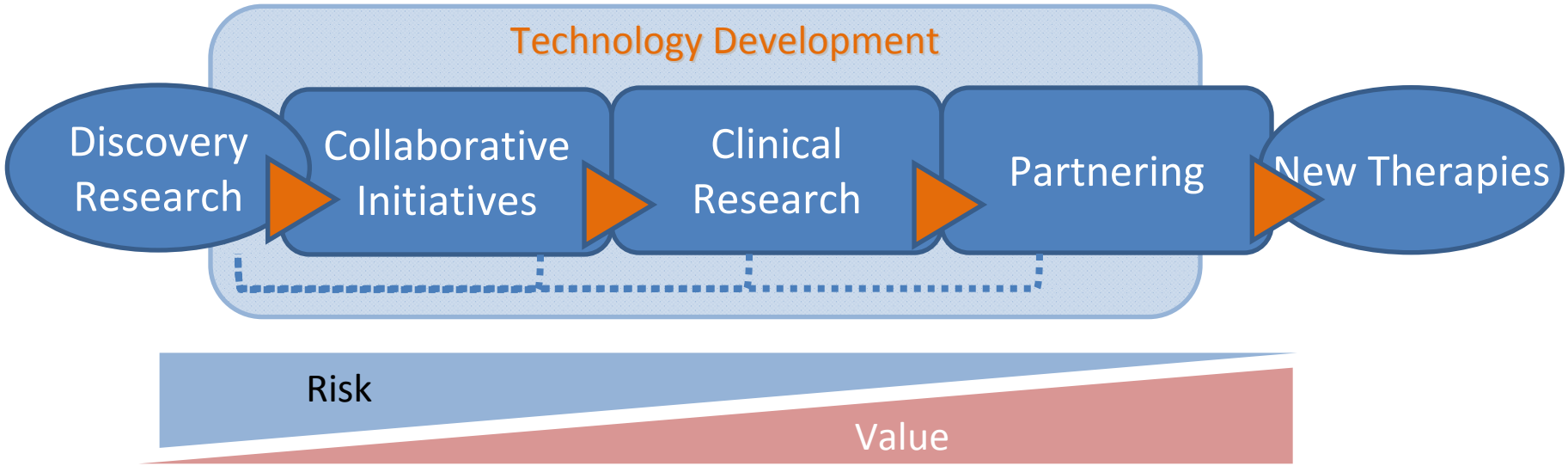
Ludwig Technology Development



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Case Study 1: First attempt

- Conducted extensive series of clinical trials leading to the design of a highly immunogenic cancer vaccine based upon NY-ESO-1/poly-ICLC
- Clinical research findings (*Juan et al. PNAS. 2011)* supported combination with immune checkpoint blockade to maximize immunological/clinical impact

…..many years later,

- Together with partners, initiated study of NY-ESO-1 vaccine in combination with Ipilimumab (Yervoy) in patients with unresectable or metastatic melanoma (NCT01810016)

Need a more effective mechanism to enable future combination studies

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Case Study 2: Second time's a charm

Collaboration between MedImmune,

the Ludwig Institute for Cancer Research and the Cancer Research Institute

- Access to novel drug combinations to advance immunotherapy research
  - Clinical agents from MedImmune - αCTLA-4 (Treme), αPD-L1, αOX40
  - Clinical agents from the Ludwig and other third parties
  - Not limited by commercial development transaction(s)
- Approval, management and conduct of early stage clinical trials
- Leveraging non-profit and for-profit resources & funding
- Clinical trials of novel combinations, indications & defined patient populations
- Additive & complementary to standard clinical development strategy

Meaningful product combinations which enhance patient therapy

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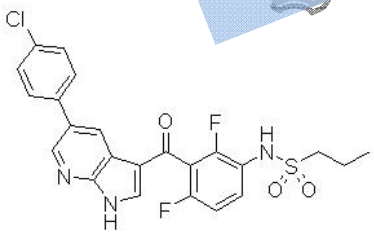
In summary

Opportunity

Complementary clinical agents



Solution

- Oncology & immunology expertise
- Clinical trial execution & safety
- Resource requirements
- Relationship management
- Intellectual property
- Data sharing & publication

Impact

- Reagent access for experts in oncology & Immunology
- New biological insights, data & research
- Development of smarter, effective combination patient therapies