

Team 07

I-Corps @ NIH – Dec 10, 2014

BCN Biosciences

Team - Andrew Norris (PI), Mai Brooks (IE), Sudip Chakraborty (CL)



Validating Business Model for – ***Drug that increases anti-cancer effect of radiation in lung cancer (and/or reduces normal tissue damage by at least 40% compared to current standard of care)***

Interviews total= 100

Avg/wk = 10

What we thought going into of ICorps

1 indication – Radiation Mitigation

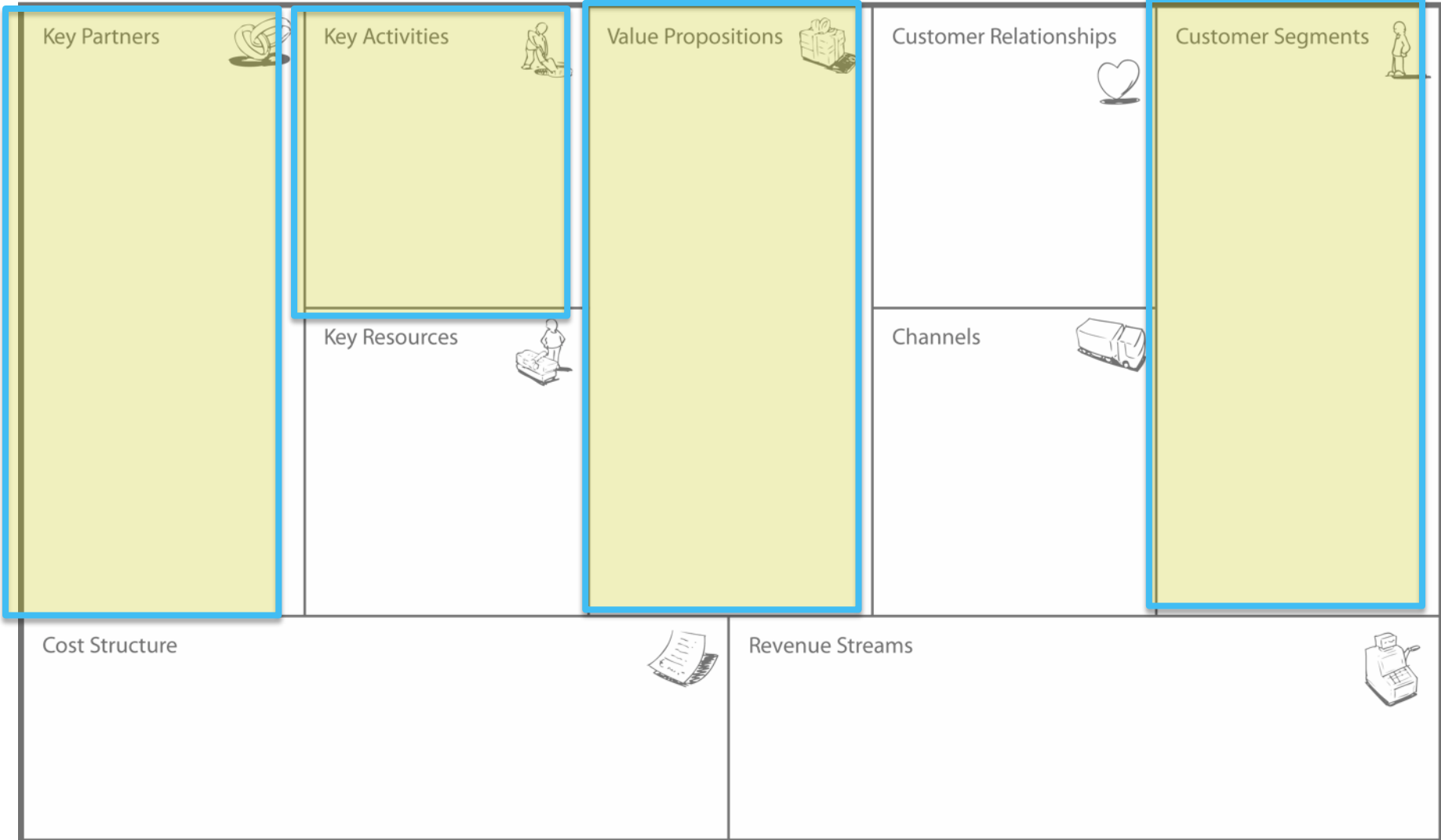
Radiation Oncologists the main customer segment

Minimal MOA data is important for preclinical



Phase1 Clinical Trials data required to license out the molecule

We need to raise \$5M+ to take the technology forward and it would take 6 years

The ICorps Journey – Customer Discovery



Week 1 Canvas

Week << 1 >> Business Model Canvas   + Add New

Key Partners	Key Activities	Value Propositions	Customer Relationships	Customer Segments
		★ Reduces normal tissue damage from radiation therapy by at least		★ Radiation & Medical Oncologists ★ C - Oncologists focused on Chemotherapy - Medical
	Key Resources		Channels	

Value Propositions + ▶

★ Reduces normal tissue damage from radiation therapy by at least 40%-50% over


Customer Segments + ▶

★ Radiation & Medical Oncologists


★ C - Oncologists focused on Chemotherapy - Medical Oncologists

Cost Structure

Revenue





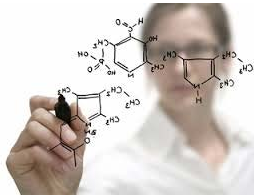
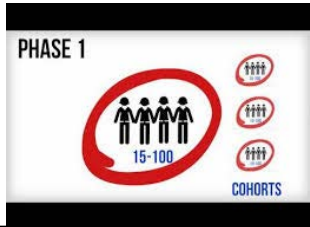
Right Side Canvas Week 1

Indication	Customer segment	Value Proposition	Minimal Viable Product	Investment Readiness
Normal Tissue Protection from Radiation	Radiation & Clinical Oncologists	Protects lung / normal tissue from radiation	Lung fibrosis and pneumonitis	<ul style="list-style-type: none">• 8 

Left Side Canvas Week 3

Value Prop	Key Activities	Key Partners	Minimal Viable Product
Normal tissue protection	Show tissue protection in various animal models. Limit Lung fibrosis and pneumonitis	Academic	<ul style="list-style-type: none">• Animal models showing normal tissue protection.

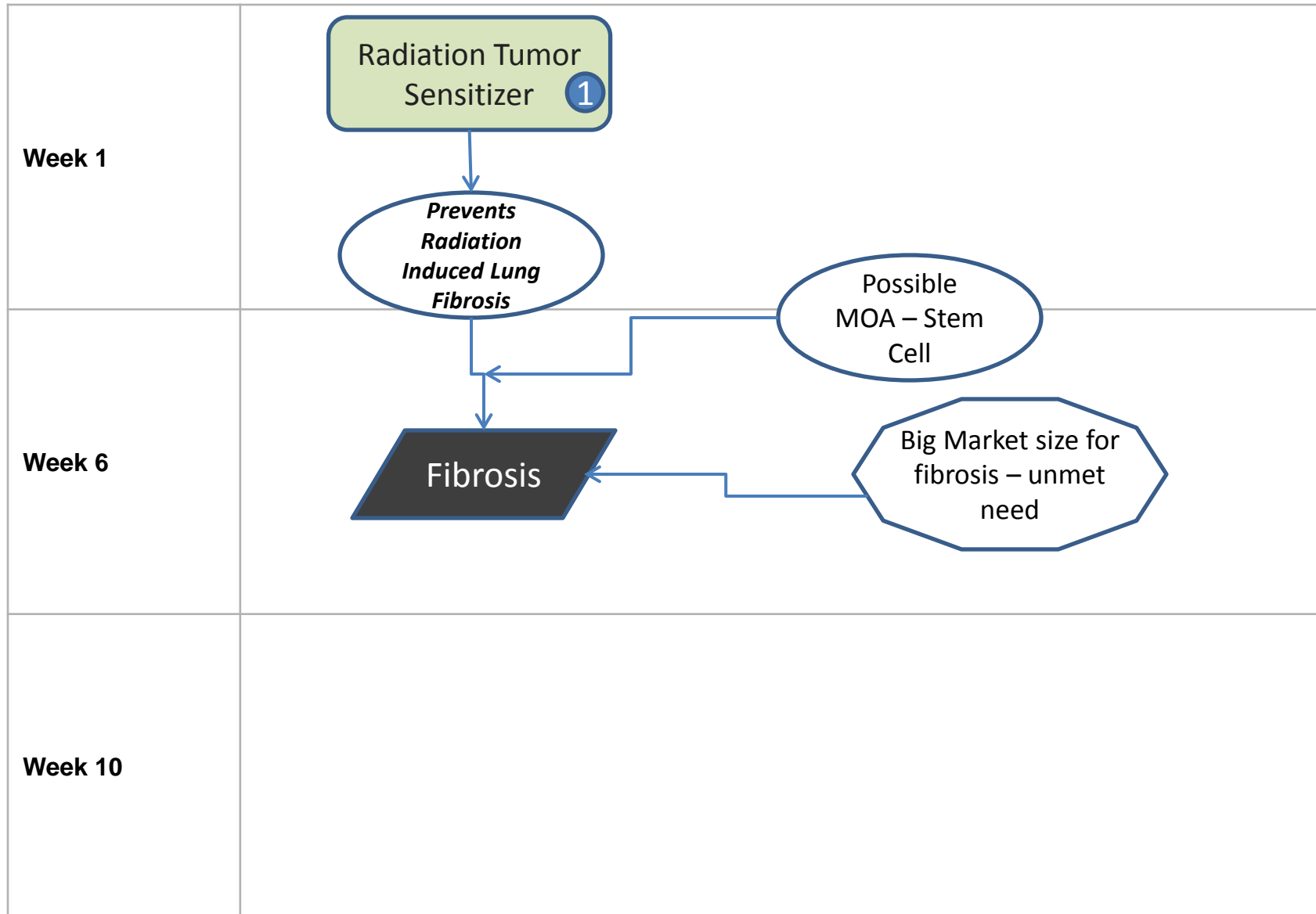
What we did - Archetypes of Customer & Partners

	Doctors	Pharma Biz Dev	Pharma Prod Dev / Science	Development Partners
				
Archetype	<p>Pulmonologists</p> <ul style="list-style-type: none"> - patients with post radiation fibrosis - patients with IPF <p>Skin Doctors</p> <ul style="list-style-type: none"> - Dermatologists - Plastic Surgeons 	<p>Big Pharma/Biotech</p> <ul style="list-style-type: none"> - Pitched hundreds of times each year - Looking for \$1B market molecules - Disease modifying <p>Medium Pharma/Biotech</p> <ul style="list-style-type: none"> - Actively engaged in pre-clinical scouting - Interested in supportive care also 	<p>Big & Medium Pharma/Biotech</p> <ul style="list-style-type: none"> - Conducts pre-clinical MOA studies - Conducts Efficacy & Safety studies - Designs in-human clinical trials and regulatory path - Primary Science/Regulatory/manuf decision influencers 	<p>CROs</p> <ul style="list-style-type: none"> - Radiation CROs - PK, Tox & Efficacy CROs - Drug Formulations - Drug manufacturing <p>Govt. Agencies</p> <ul style="list-style-type: none"> - Development partner - Free resources <p>Disease Foundations</p> <ul style="list-style-type: none"> - Basic Research support mandate - Orphan Indications
Interviewees	26	34	18	22

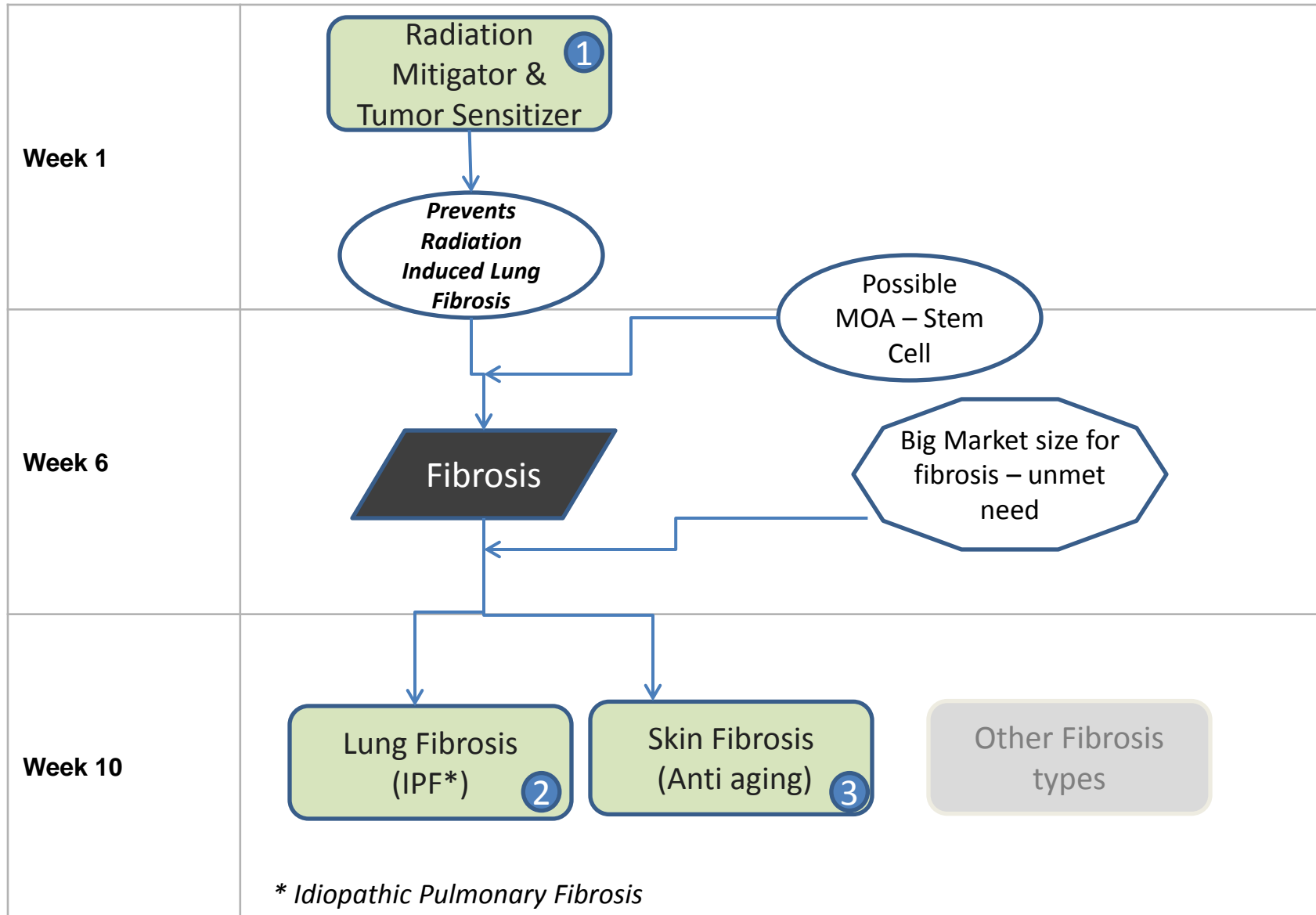
The BCN Strategy evolution at ICorps@NIH

Week 1	<p>Radiation Mitigator & Tumor Sensitizer ¹</p> <p>↓</p> <p><i>Prevents Radiation Induced Lung Fibrosis</i></p>
Week 6	
Week 10	

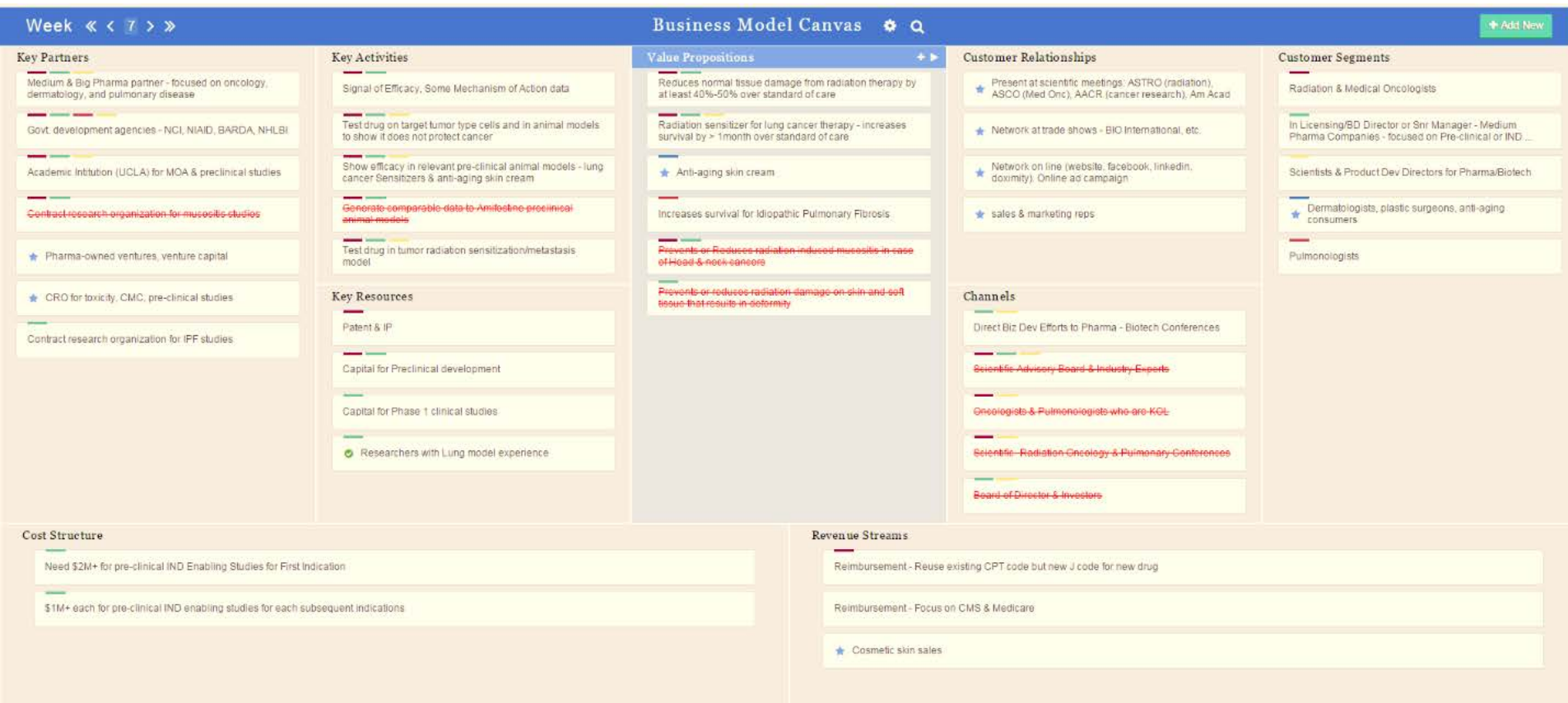
The BCN Strategy evolution at ICorps@NIH



The BCN Strategy evolution at ICorps@NIH



Week 7 Canvas



6 Hypothesis Validated, >15 invalidated

Week 10 Canvas

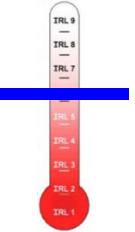
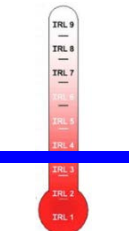
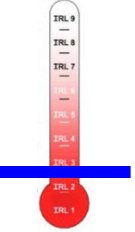
Week << < 11 > >> Business Model Canvas ⚙️ 🔍 + Add New

Key Partners <ul style="list-style-type: none">Medium & Big Pharma partner - focused on oncology,Govt. development agencies - NCI, NIAID, BARDA, NHLBIAcademic Institution (UCLA) for MOA & preclinical studiesPharma-owned ventures, venture capitalCRO for toxicity, CMC, pre-clinical studiesContract research organization for IPF studies	Key Activities <ul style="list-style-type: none">Mechanism of ActionTest drug on target tumor type cells and in animal models toShow efficacy in relevant pre-clinical animal models - lung ...Test drug in tumor radiation Key Resources <ul style="list-style-type: none">Patent & IPCapital for Preclinical developmentCapital for Phase 1 clinical studiesResearchers with Lung model	Value Propositions <ul style="list-style-type: none">Reduces normal tissue damage from radiation therapy by at leastRadiation sensitizer for lung cancer therapy - increasesAnti-aging skin creamIncreases survival for Idiopathic Pulmonary Fibrosis	Customer Relationships <ul style="list-style-type: none">Present at scientific meetings: ASTRO (radiation), ASCO (Med ...Network at trade shows - BIO International, etc.Network on line (website, facebook, linkedin, doximity). Online ad ... Channels <ul style="list-style-type: none">Direct Biz Dev Efforts to Pharma - Biotech ConferencesDoctors' officesPhysical pharmacies	Customer Segments <ul style="list-style-type: none">Radiation & Medical OncologistsIn Licensing/BD Director or Snr Manager - Medium Pharma ...Scientists & Product Dev Directors for Pharma/BiotechDermatologists, plastic surgeons, anti-aging consumersPulmonologists
Cost Structure <ul style="list-style-type: none">Need \$2M+ for pre-clinical IND Enabling Studies for First Indication\$1M+ each for pre-clinical IND enabling studies for each subsequent indications	Revenue Streams <ul style="list-style-type: none">Pharma/Biotech In-Licensing - Upfront, Milestone, RoyaltiesReimbursement - Focus on CMS & MedicareCosmetic skin sales			

<https://www.launchpadcentral.com/home/redirect>

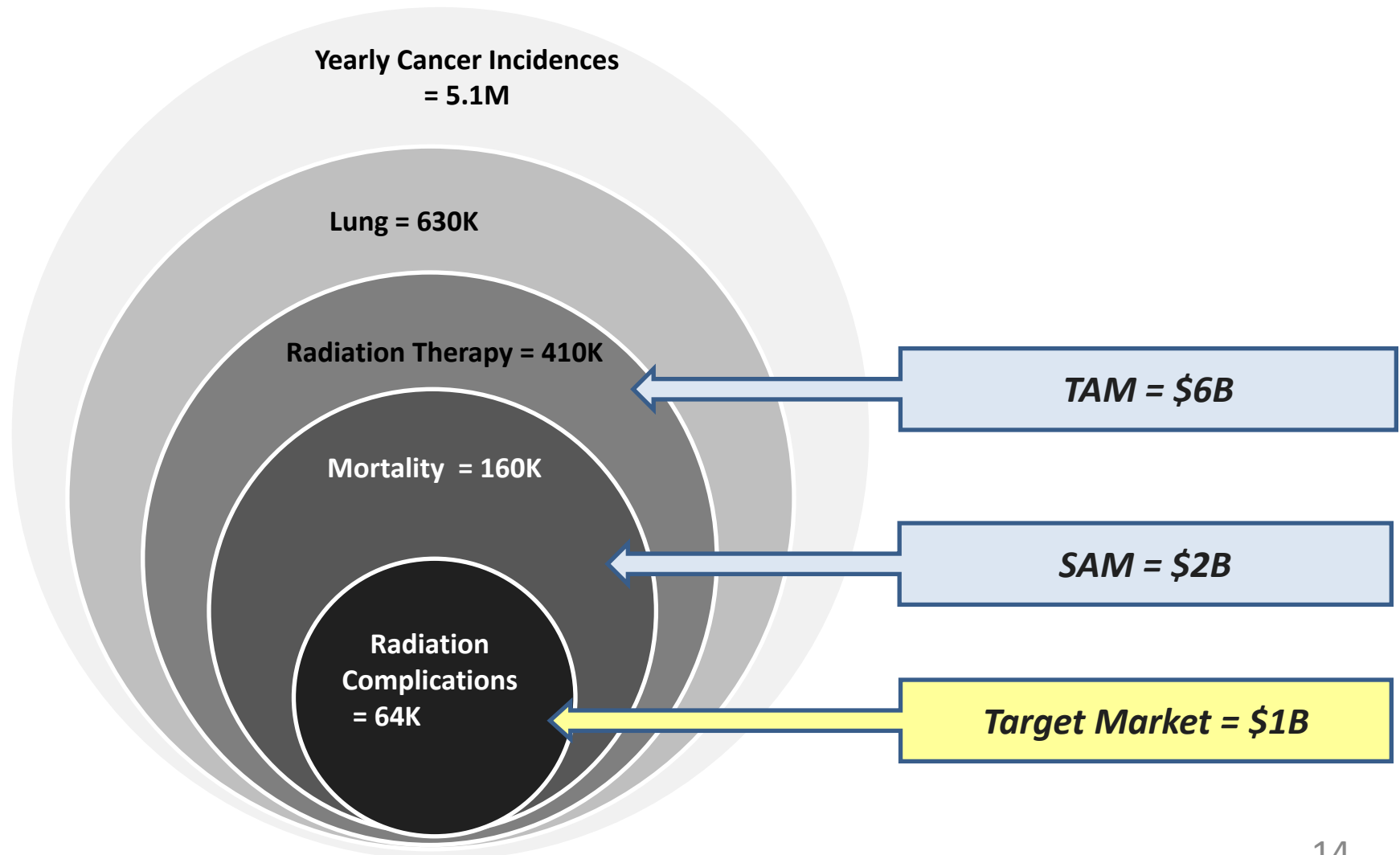
16 Hypothesis Validated, 10+ validation still in progress

Right Side Canvas Week 10

Value Prop	Customer segment	Value Proposition	Minimal Viable Product	Investment Readiness
Tumor Sensitizer	Radiation Oncologists In-License/BD	Increase survival >3 months vs. SOC	<ul style="list-style-type: none"> Reduces tumor burden vs Radiation. MOA 	<ul style="list-style-type: none"> 5-6 
IPF	Pulmonologists In-License/BD	Reduce pulmonary fibrosis > SOC	<ul style="list-style-type: none"> 2 more animal models for IPF MOA 	<ul style="list-style-type: none"> 2-3 
Anti-aging	Dermatologists	Reduces age related markers	<ul style="list-style-type: none"> Mini pig skin injury model. Human test- reduce collagen over 6 months 	<ul style="list-style-type: none"> 2 

Market Size – TAM, SAM, Target

Indication – Radiation Sensitizer for Lung Cancer Tumors



Left Side Canvas Week 10

Value Prop	Key Activities	Key Partners	Minimal Viable Product
Tumor Sensitizer	<p>MVP =</p> <ul style="list-style-type: none"> • MOA, • Animal (reduces tumor burden vs radiation alone). • (TPP) Tumor sensitizer that increases life by at least 3 months in conjunction with SOC. 	Cleveland Bio UCLA,	<ul style="list-style-type: none"> • Sensitizes tumor tissue to radiation vs radiation alone. • Lung fibrosis and pneumonitis
IPF	<p>MVP = MOA!!, two other models that show better efficacy than standard of care, work with*(Companies Names)</p>	Lovelace	<ul style="list-style-type: none"> • MOA • 2 more animal models for IPF
Anti-aging	<p>MVP (strong prelim data showing reduction in collagen production in mouse model and human skin (over 6 months).</p>	CitoxLab North America.	<ul style="list-style-type: none"> • Mini pig skin injury model. • Human test-reduce collagen over 6 months

Companies & KOL

1

Radiation sensitizer,
target companies that
sell lung cancer drugs

2

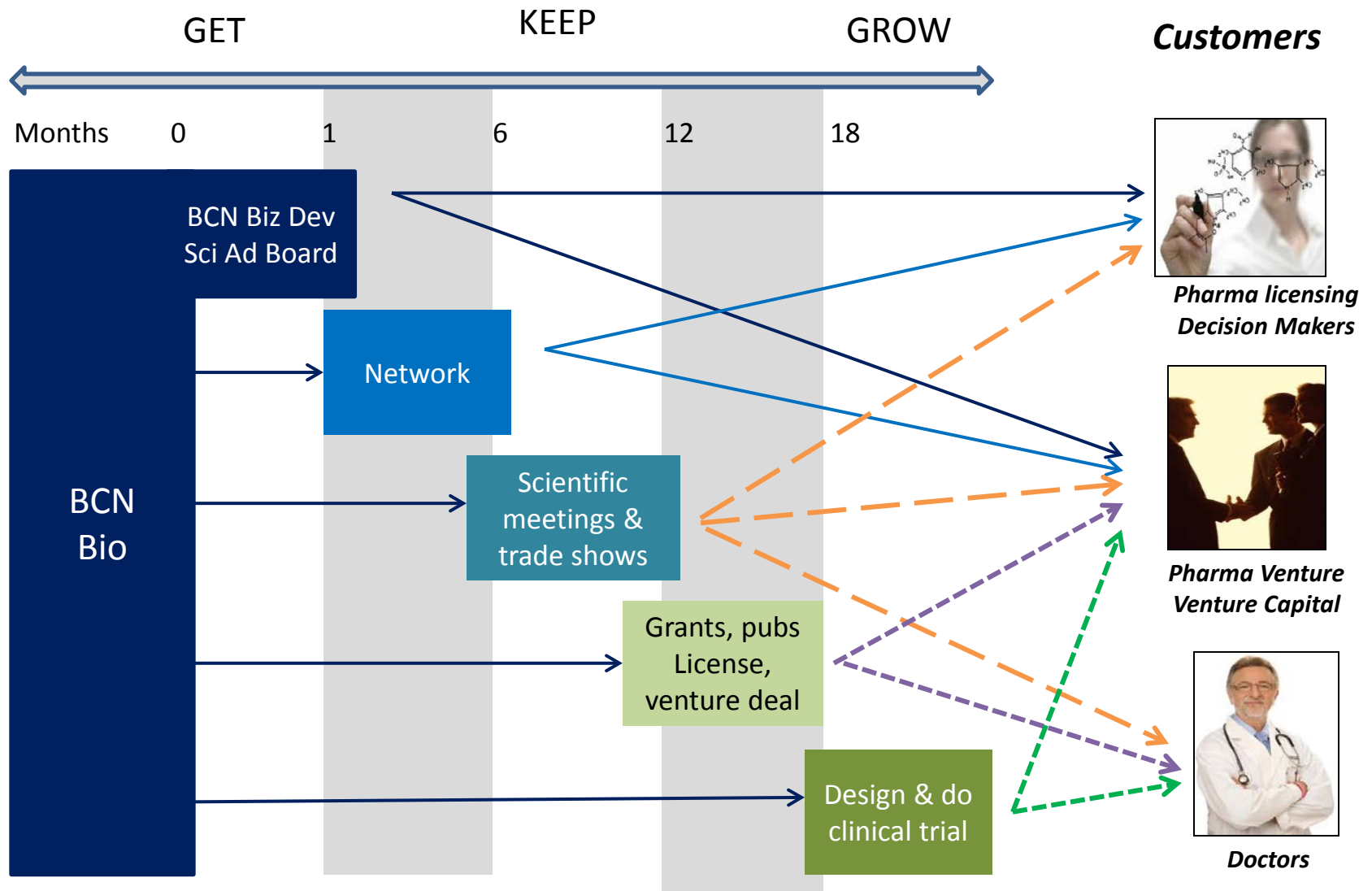
IPF, target companies
that sell drugs for lung
disease

3

Anti-aging cream,
target companies that
sell skin products

<p>Possible Customers</p>			
<p>Competitors</p>			
<p>KOL</p>	<p>Dr. Andre Gudkov Dr. Robert Figlin</p>	<p>Dr. Luca Richeldi Dr. Talmadge King</p>	<p>Dr. Richard Fitzpatrick</p>

Customer Relationship-Commitment Diagram



Partners – Preclinical /Phase 1 Clinical

<i>Partner Type</i>	<i>Partner Name</i>	<i>Why Partner & What Risk</i>	<i>Why BCN & Costs</i>	<i>Incentives</i>
CRO	<i>CML & AAI Pharma – Formulation & Drug product</i>	- Industry standard & GMP - No in-house facilities @ BCN Risk - Partner Project Management	- CRO business model - New areas to show expertise & publish (radiation & IPF) Costs ~ \$600K (pre-clin)	- Revenue Model - New Business possibilities
	<i>CiToxLAB/SNBL – Radiation & Cancer Efficacy & Safety</i> <i>Lovelace – Pulmonary Indication Efficacy & Safety</i>	- Industry Standard & GLP - No in-house facilities Risk – Partner Project Management & IP share on any new animal model	- CRO business model - New areas to show expertise & publish (radiation & IPF) - Potential shared IP on animal model Costs ~ \$1.1M (pre-clin)	- Revenue Model - Potential IP - New Business possibilities
Academia	UCLA	Expertise in Radiation Sensitizer Animal Model & related MOA	- BCN team has significant Pharma expertise in the relevant fields - Not many pharma or biotech working on this field Unique ability to bring Academia, Govt. & Industry together Costs ~ \$500K (sponsored research)	- In the Academic institutions best interest to help commercialize IP originally funded by grants - Publications - Extra funding in form of sponsored Research
	Albert Einstein College of Medicine	Expertise in Head & Neck animal model (Mucositis)		
	University of Maryland (probable)	Expertise in Pulmonary Fibrosis Animal model & related MOA		
		Risk – Potential IP issues		

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		<i>Risk</i> – Potential IP issues		

There are Risks in Partnerships also - we need to be aware

Partners – Preclinical /Phase 1 Clinical

Partner Type	Partner Name	Why Partner & What Risk	Why BCN & Costs	Incentives
Govt. Agencies	<p>NCI SBIR & Next program - For Radiation & Cancer</p> <p>NHLBI SBIR and other program – For IPF indication</p>	<ul style="list-style-type: none"> - Phase 1 & Phase 2 funding - Access to World Class facilities for free <p>Risk - Risk of not getting selected, so need plan B</p>	<ul style="list-style-type: none"> - One of the promising your SB biotech working on other indications for Radiation Mitigators - Govt. mandate <p>Costs – No costs to BCN</p>	<ul style="list-style-type: none"> - Stimulating economy through fundamental research
	NIAID & BARDA	<ul style="list-style-type: none"> - NIAID funding covers most IND enabling studies - BARDA Contracts can be utilized for Clinical trials using Animal Rule <p>Risk – Risk of not getting selected, Tech Readiness Level 5 required</p>	<ul style="list-style-type: none"> - BARDA especially looking for molecules with other in-human indications <p>Costs – No costs to BCN</p>	<ul style="list-style-type: none"> - Public Safety - Maximum return on tax payer dollars
Pharma & Biotech	Pharma & Biotech interested in Radiation Sensitizer & Cancer indications	<ul style="list-style-type: none"> - Perform MOA studies pre-IND (research) - Scale up GMP formulation & drug product pre-IND 	<ul style="list-style-type: none"> - BCN team has pre-eminent Prod Dev expertise in the relevant fields - Orphan Indication (IPF) - Smart use of partnerships <p>Costs – Giving up control and big future Revenue Potential</p>	<ul style="list-style-type: none"> - Potential Radiation Sensitizer & Head & Neck cancer indication market big - Picking up a multi-indication molecule for cheap
	Pharma & Biotech interested in Pulmonary Fibrosis	<ul style="list-style-type: none"> - Experts in IP protection - Expertise in Clinical Trials & Regulatory - Sales & Marketing Channels - License out within 3 years <p>Risk – They might kill the project</p>		

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<p>Partnership is a 2 way street – Partners expect specific things from BCN too</p>				
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What we thought going into of ICorps

1 indication – Radiation Mitigation

Radiation Oncologists the main customer segment

Some MOA data is important

Phase1 Clinical Trials data required to license out the molecule

We need to raise \$5M+ to take the technology forward and it would take 6 years

So what did we really learn in 10 weeks at ICorps

~~1 indication – Radiation Mitigation~~

3 possible indications – & Tumor Sensitization; IPF, Skin

~~Radiation Oncologists the main customer segment~~

Pharma company in-licensing Directors most important customer segment

~~Some MOA data is important~~

MOA data is required for 2 of the 3 indications

~~Phase1 Clinical Trials data required to license out the molecule~~

Its possible to license out or partner at a pre-IND stage

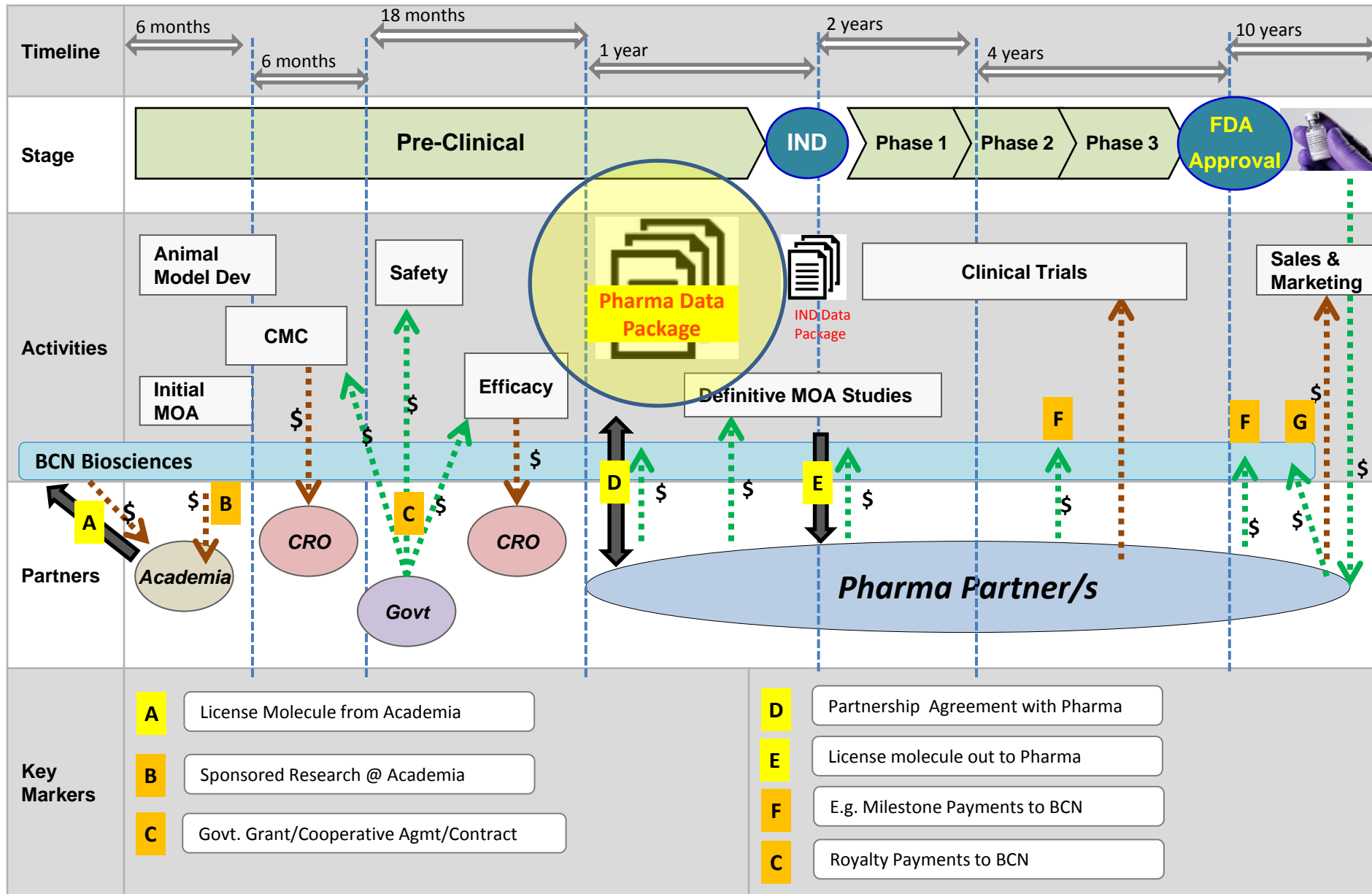
~~We need to raise \$5M+ to take the technology forward and it would take 6 years~~

We can do this in <\$2M and in <3 years

BCN Biosciences – Next Steps

- With respect to submitting an SBIR/STTR Phase II application, we will write on our primary indication of radiation sensitizer/protector in lung cancer.
- The feasibility data generated in the Phase I grant provide the appropriate technical foundation for a Phase II application, AND we are largely targeting the customer segments that we had originally anticipated
- TRL level 6

Timeline



Summary Video Link

BCN Biosciences ICorps @ NIH Video Summary – Dec 2014

<http://youtu.be/qKy7XM5eudA>