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| 1. REPORT DATE (DD-MM-YYYY)<br>04-01-2022 | 2. REPORT TYPE<br>Final Report | 3. DATES COVERED (From - To)<br>24-Aug-2020 - 23-Aug-2021 |
|---|--------------------------------|---|

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| 4. TITLE AND SUBTITLE<br>Final Report: Exploring the Commercialization of a Smart Antifungal Wound Therapy | 5a. CONTRACT NUMBER<br>W911NF-20-1-0329 |
|  | 5b. GRANT NUMBER                        |
|  | 5c. PROGRAM ELEMENT NUMBER<br>106011    |

|            |                      |
|------------|----------------------|
| 6. AUTHORS | 5d. PROJECT NUMBER   |
|            | 5e. TASK NUMBER      |
|            | 5f. WORK UNIT NUMBER |

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| 7. PERFORMING ORGANIZATION NAMES AND ADDRESSES<br>Brown University<br>Office of Sponsored Projects<br>Box 1929<br>Providence, RI 02912 -9093 | 8. PERFORMING ORGANIZATION REPORT NUMBER |
|--|--|

|  |  |
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| 9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS (ES)<br>U.S. Army Research Office<br>P.O. Box 12211<br>Research Triangle Park, NC 27709-2211 | 10. SPONSOR/MONITOR'S ACRONYM(S)<br>ARO                  |
|  | 11. SPONSOR/MONITOR'S REPORT NUMBER(S)<br>77600-SD-ICR.1 |

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| 12. DISTRIBUTION AVAILABILITY STATEMENT<br>Approved for public release; distribution is unlimited. |
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| 13. SUPPLEMENTARY NOTES<br>The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision, unless so designated by other documentation. |
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| 14. ABSTRACT |
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| 15. SUBJECT TERMS |
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|                                 |                   |                    |                                  |                     |   |
|---------------------------------|-------------------|--------------------|----------------------------------|---------------------|---|
| 16. SECURITY CLASSIFICATION OF: |                   |                    | 17. LIMITATION OF ABSTRACT<br>UU | 15. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON<br>Anita Shukla |
| a. REPORT<br>UU                 | b. ABSTRACT<br>UU | c. THIS PAGE<br>UU |                                  |                     | 19b. TELEPHONE NUMBER<br>401-863-5719           |

**RPPR Final Report**  
as of 06-Jan-2022

Agency Code:

Proposal Number: 77600SDICR

**Agreement Number: W911NF-20-1-0329**

**INVESTIGATOR(S):**

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**Principal:** N

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**Phone Number:** 9396458570  
**Principal:** N

Organization: **Brown University**

Address: Office of Sponsored Projects, Providence, RI 029129093

Country: USA

DUNS Number: 001785542

EIN: 050258809

**Report Date:** 23-Nov-2021

Date Received: 04-Jan-2022

**Final Report** for Period Beginning 24-Aug-2020 and Ending 23-Aug-2021

**Title:** Exploring the Commercialization of a Smart Antifungal Wound Therapy

**Begin Performance Period:** 24-Aug-2020

**End Performance Period:** 23-Aug-2021

**Report Term:** 0-Other

Submitted By: Anita Shukla

Email: anita\_shukla@brown.edu

Phone: (401) 863-5719

**Distribution Statement:** 1-Approved for public release; distribution is unlimited.

**STEM Degrees:**

**STEM Participants:**

**Major Goals:** We have developed an antifungal hydrogel product that provides a fungi-triggered release of encapsulated antifungal therapeutics. This controlled release technology can eradicate fungal infections before the development of an invasive infection, all while limiting exposure to antifungal therapeutics. The hydrogel is fabricated using a polymer-peptide backbone that degrades in the presence of fungal enzymes. Encapsulated therapeutics are only released when the hydrogel is degraded by these fungal enzymes. Our previous Department of Defense funded work has thoroughly characterized the in vitro and ex vivo release behavior and antifungal efficacy of this product. We are currently examining the in vivo antifungal activity in a fungal wound infection model and exploring properties including storage stability.

The major goal of this award was to investigate the commercialization pathway for this product through the Innovation Corps @ Department of Defense program and establish a path for commercialization sustainability following the program.

**Accomplishments:** Our I-Corps team successfully achieved the goals we set forward. We actively participated in the I-Corps course and completed 100+ interviews in the customer discovery process. We adapted and produced a successful business model canvas for our product, which will help us continue the translation of our product following the current pre-clinical testing we have ongoing.

## RPPR Final Report as of 06-Jan-2022

**Training Opportunities:** This project led to the mentorship and training of I-Corp team member, Dr. Noel Vera Gonzalez, a postdoctoral researcher at Brown University. Dr. Vera-Gonzalez is now a biomaterials scientist at a startup company (the first employee) and significantly benefited from his involvement in the I-Corps program.

This project also led to the mentorship and training of postdoctoral research, Dr. Kayla Campbell, who took over the project once Dr. Vera-Gonzalez had left to take on their new role.

**Results Dissemination:** Nothing to Report

**Honors and Awards:** Awarded the National Academy of Engineering Frontiers of Engineering Grainger Grant, which will help to further study the fundamental degradation behavior of the hydrogel product.

**Protocol Activity Status:**

**Technology Transfer:** Nothing to Report

### PARTICIPANTS:

**Participant Type:** PD/PI

**Participant:** Anita Shukla

**Person Months Worked:** 1.00

Project Contribution:

National Academy Member: N

**Funding Support:**

**Participant Type:** Postdoctoral (scholar, fellow or other postdoctoral position)

**Participant:** Noel Vera-Gonzalez

**Person Months Worked:** 4.00

Project Contribution:

National Academy Member: N

**Funding Support:**

**Participant Type:** Postdoctoral (scholar, fellow or other postdoctoral position)

**Participant:** Kayla Marie Campbell

**Person Months Worked:** 3.00

Project Contribution:

National Academy Member: N

**Funding Support:**

**RPPR Final Report**  
as of 06-Jan-2022

**Partners**

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I certify that the information in the report is complete and accurate:

Signature: Anita Shukla

Signature Date: 1/4/22 4:42PM

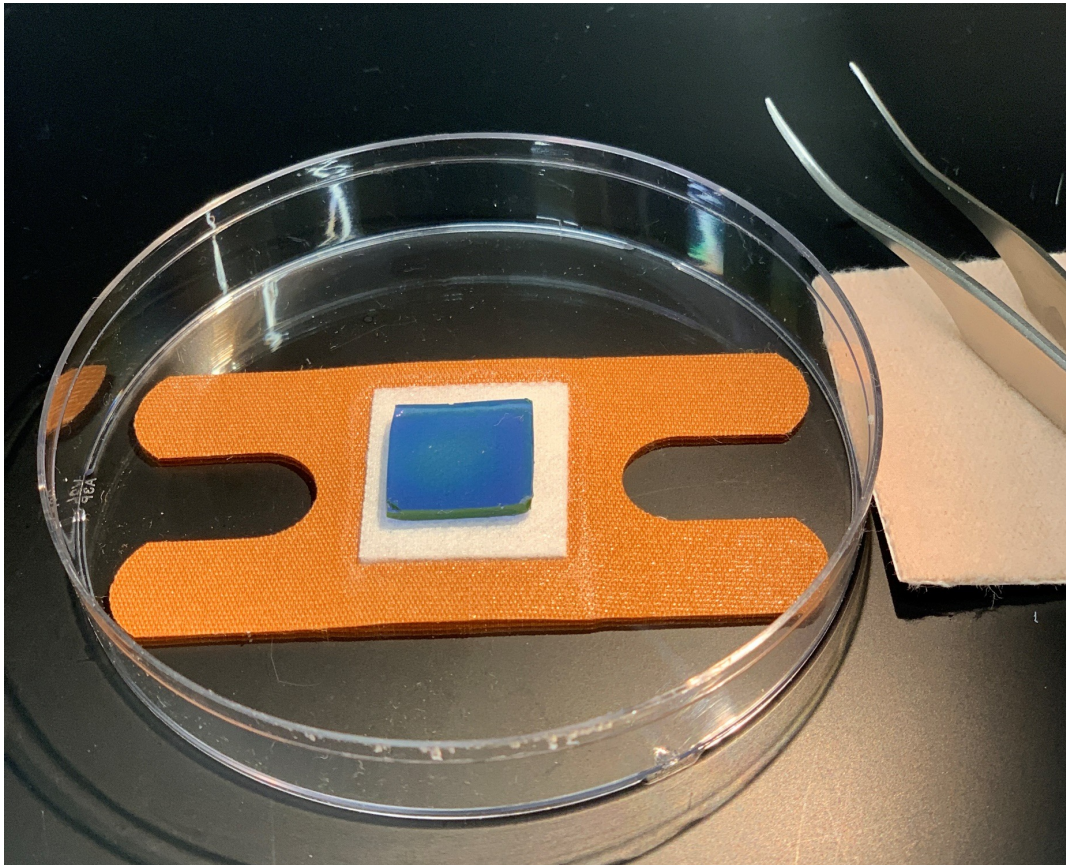
**Final Report Attachment (Contract Number: W911NF2010329)**  
**PI: Shukla, Anita**

The following pages provide the final presentation presented by our team in the I-Corps@DOD course.

# ResponsiGel

Team 2079

On-demand antifungal wound treatment



|       | #   | Video |
|-------|-----|-------|
| New   | 15  | 10    |
| Total | 101 | 57    |

Using an antifungal wound dressing to prevent nascent fungal infections in grade 1-2 diabetic foot ulcers that:

- Provides 7 days of hydration  
**saving ~\$1,500 to the patient per wound**
- Prevents wound microbial colonization  
**↓ healing times and costs by ~50%**

Initial estimated opportunity size: 1.5 billion USD

# ResponsiGel Team



**Noel Vera-González, EL**

Postdoc at Brown University  
Ph.D. in Biomedical Engineering  
Expert in biomaterials for  
drug delivery



**Anita Shukla, TL**

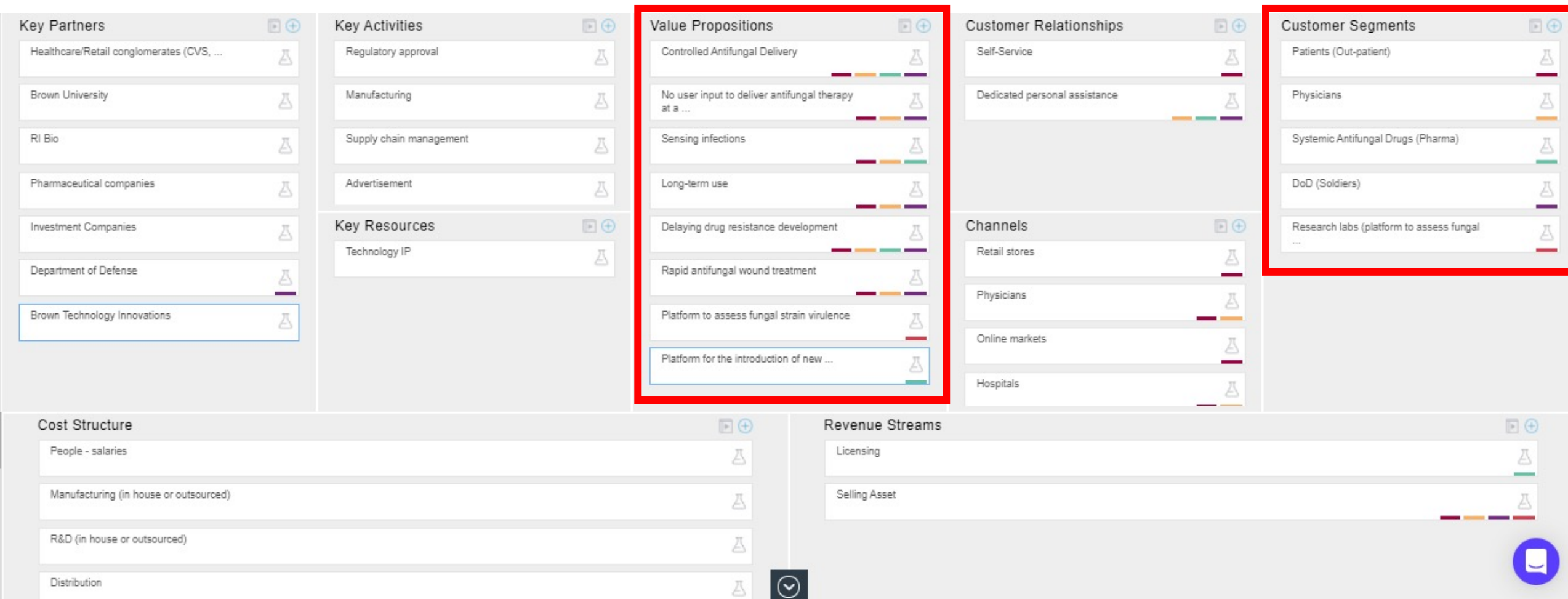
Assistant Professor of Engineering  
at Brown University  
Ph.D. in Chemical Engineering  
Expert in biomaterials for drug  
delivery, regenerative medicine,  
and biofunctional interfaces



**Carol Malysz, IM**

Executive Director at RI Bio  
M.B.A. in Entrepreneurship  
Expert in economic development,  
entrepreneurship, management,  
and marketing

# Where we started: Revolutionizing the treatment of life-threatening fungal infections using biomaterials

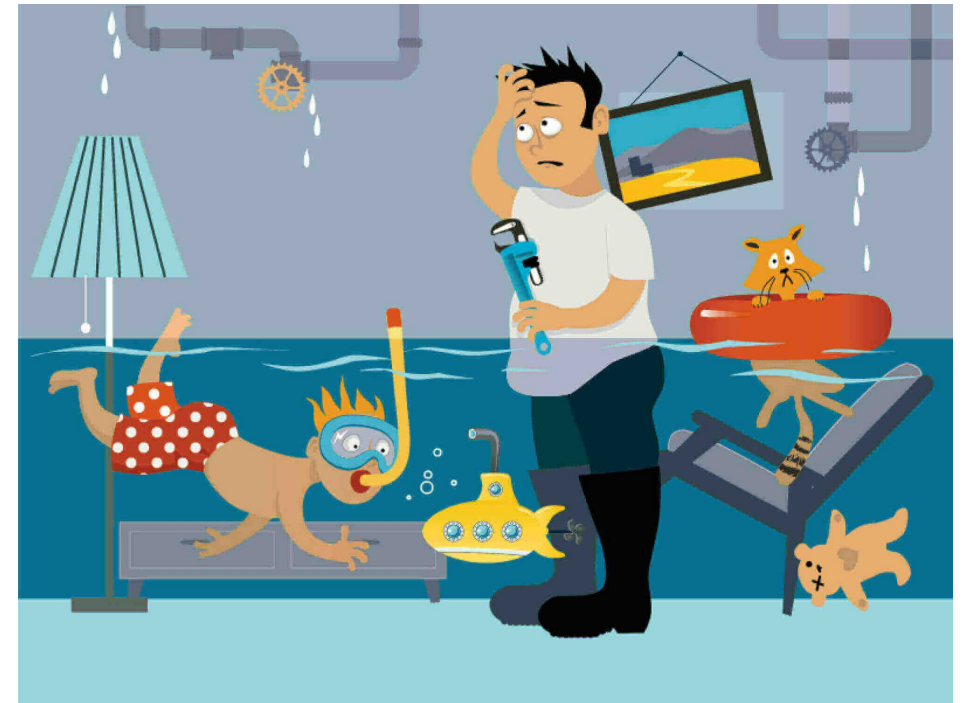




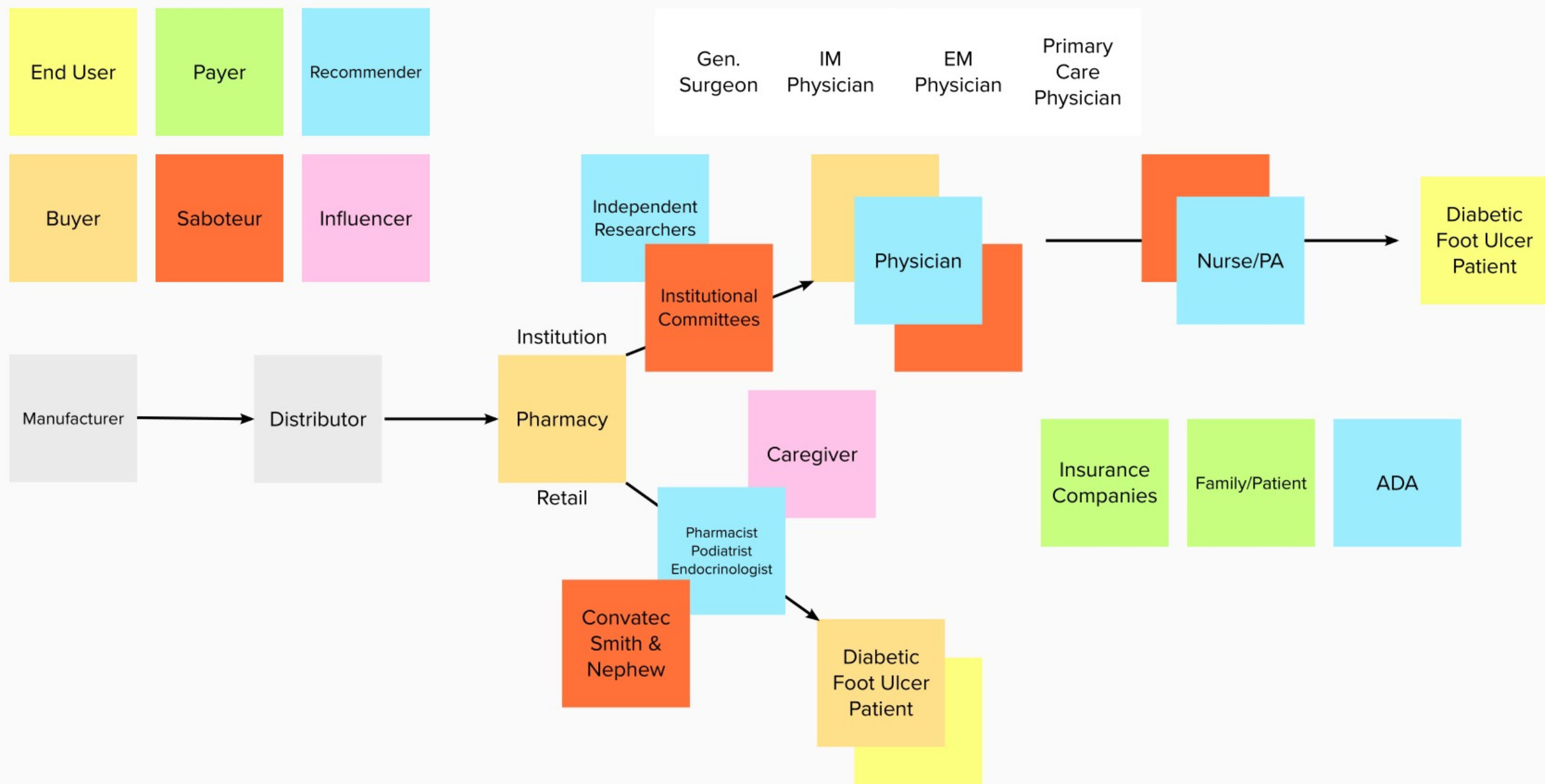
Beth Israel Lahey Health  
Beth Israel Deaconess Medical Center



Combining drops of knowledge from our many interviews gradually flooded us with understanding



# Ecosystem Map



# Diabetic foot ulcer (DFU) patients are not content with the current “standard” of care

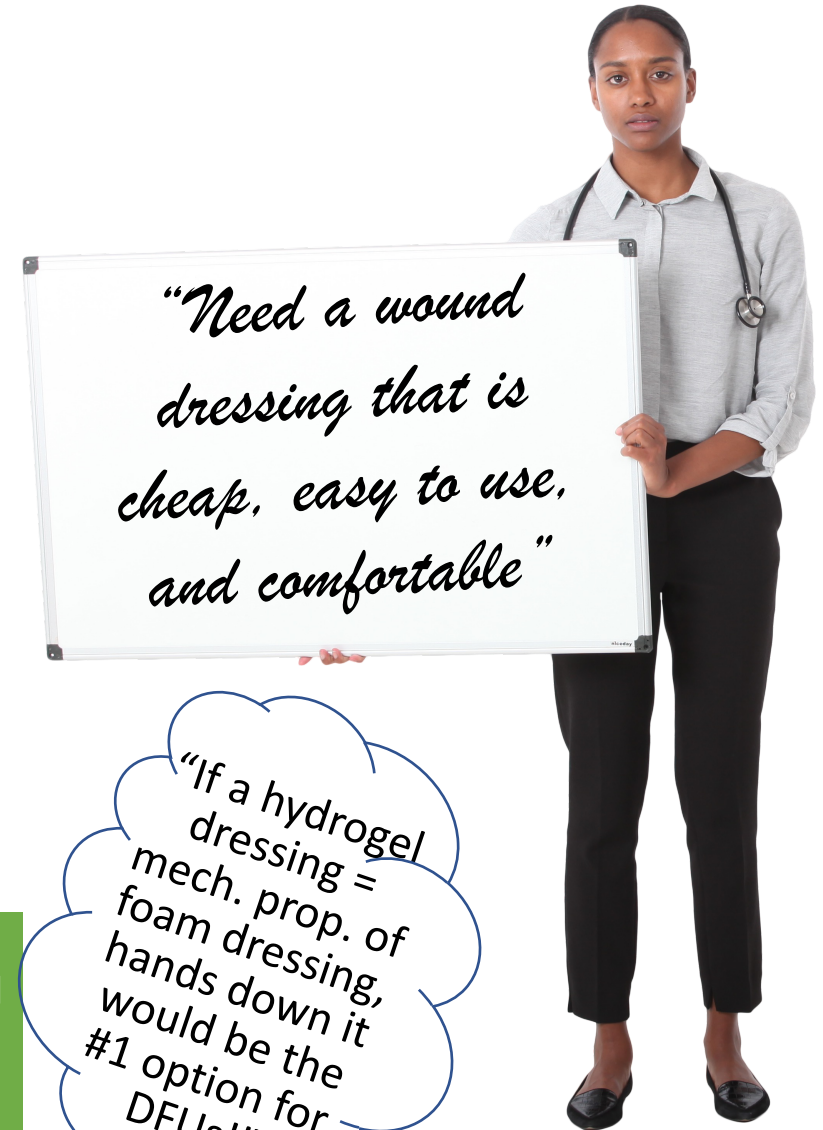
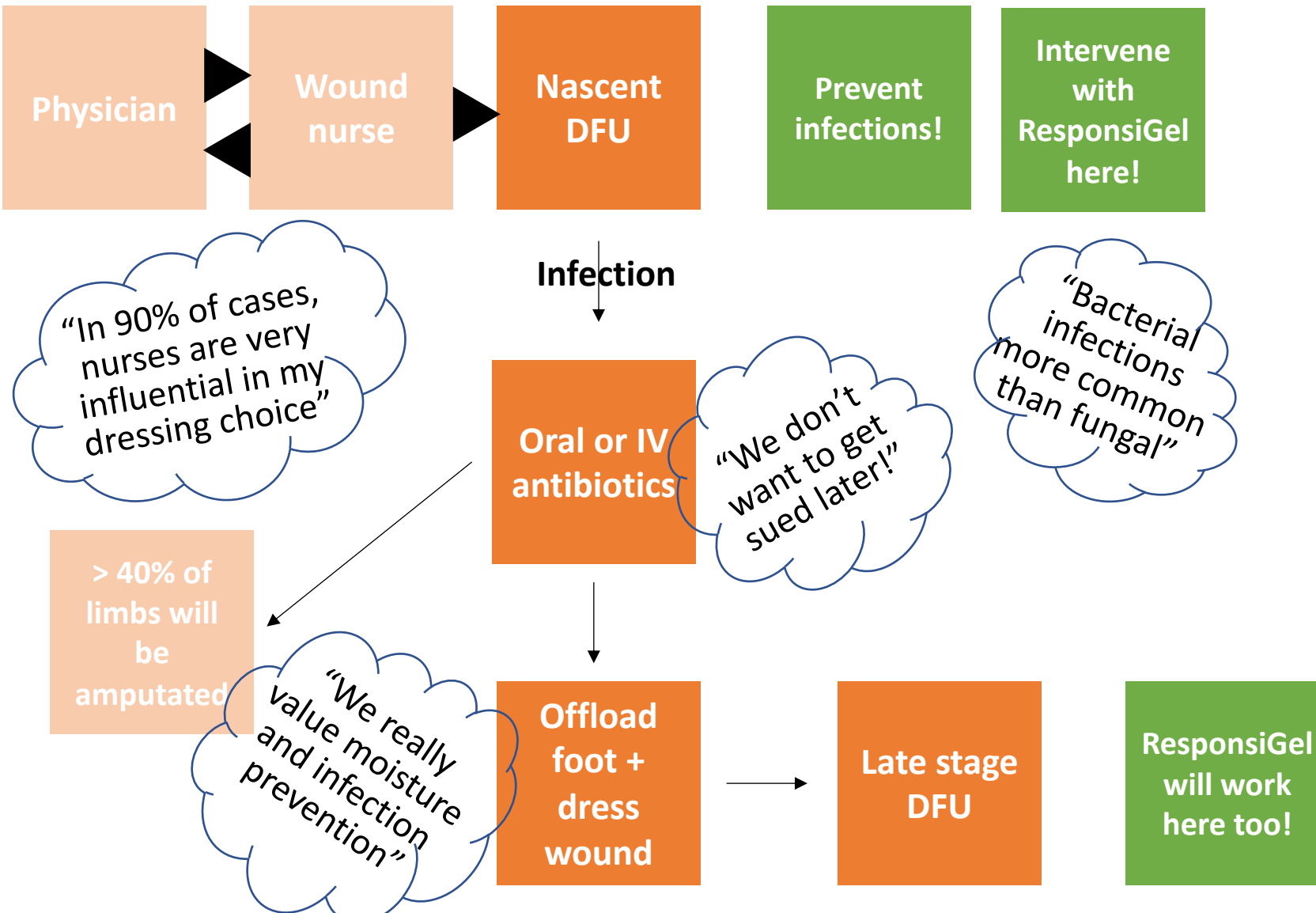
*“The dressing I currently use is too dry and uncomfortable”* The patient received 2 weeks worth of Aquacel Ag dressing at a wound clinic



*“Changing wound dressings daily is extremely painful, the adhesive rips my skin off”*

*“Nothing seems to ever work; it has been years and I still have a persistent fungal infection”* The patient had been on numerous oral and topical antifungals in the course of over 5 years

# What practitioners had to say

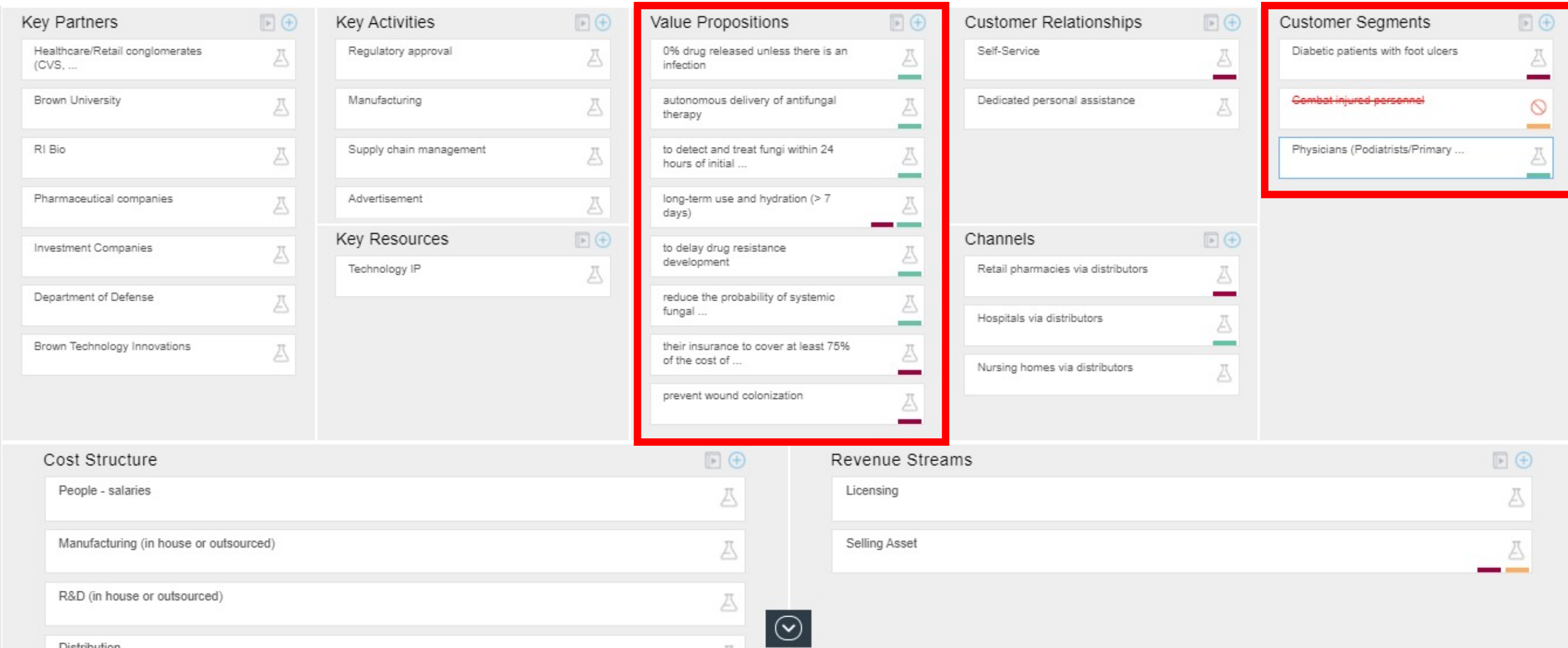


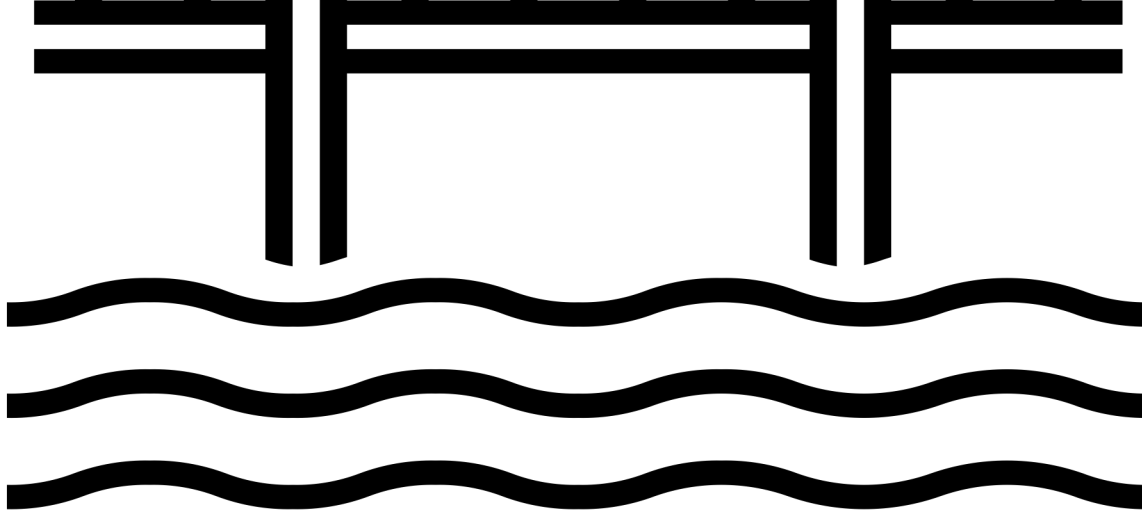
# What we were testing up to this point

Diabetic foot ulcer patients want an easily accessible long-term use dressing that keeps the ulcer hydrated and prevents infections

| Value Propositions   | Physicians/<br>Nurses | Patients | Industry<br>experts |
|--|-----------------------|----------|---------------------|
| <b>0% drug released</b> unless there is an infection   | ✓                     |          |                     |
| <b>autonomous</b> delivery of antifungal therapy   | ✓                     |          | ✓                   |
| to <b>detect and treat fungi</b> within 24 hours of initial wound colonization   | ✓                     |          | ✓                   |
| <b>long-term</b> use and <b>hydration</b> (> 7 days)   | ✓                     | ✓        |                     |
| to <b>delay drug resistance</b> development  | ✓                     |          | ✓                   |
| <b>reduce</b> the probability of <b>systemic fungal infection</b> development by over 25% (with current treatments ~20% reduction) | ✓                     |          | ✓                   |
| <b>prevent</b> wound <b>colonization</b>   | ✓                     | ✓        |                     |

# Halfway point canvas

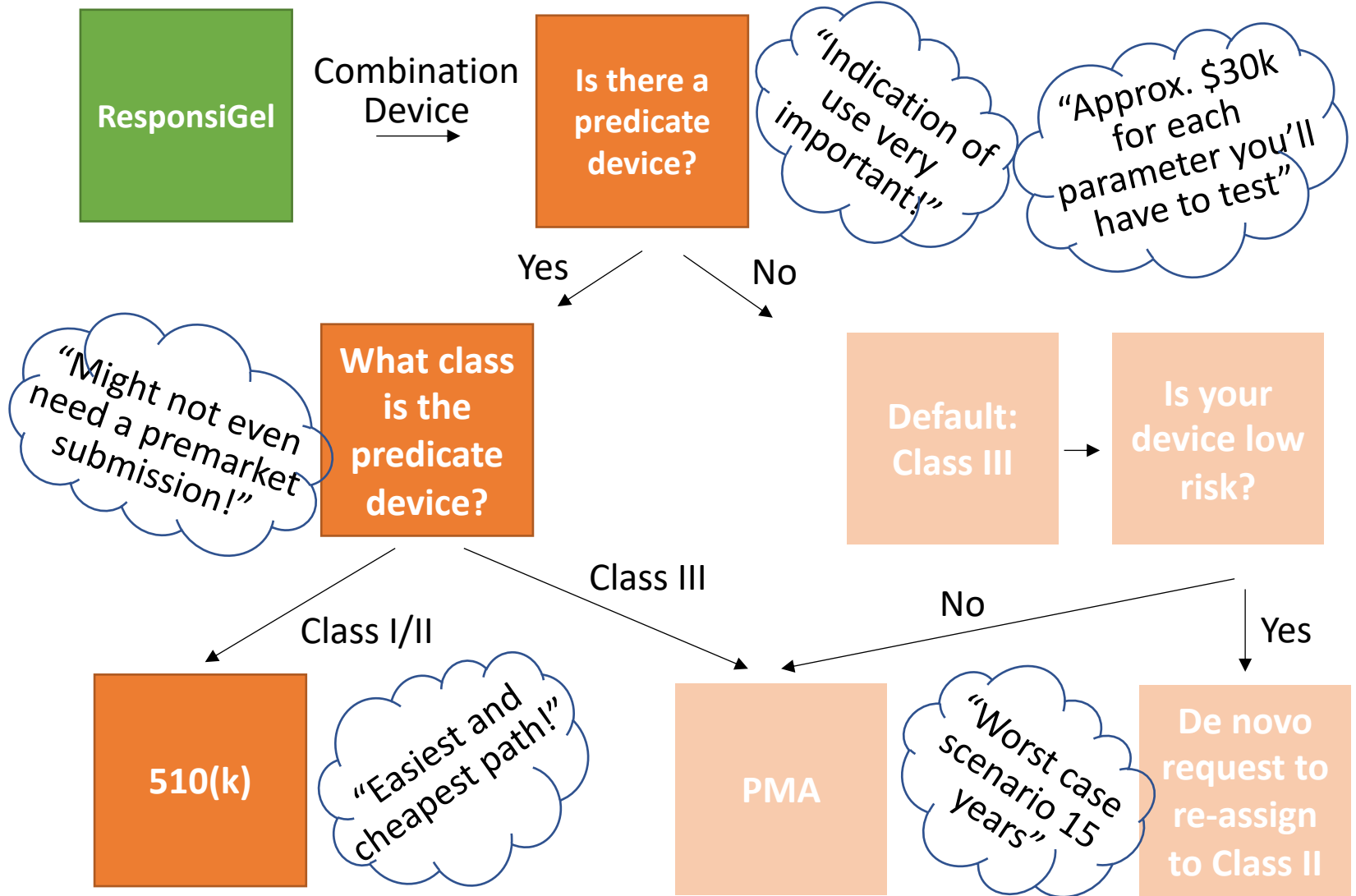




ResponsiGel

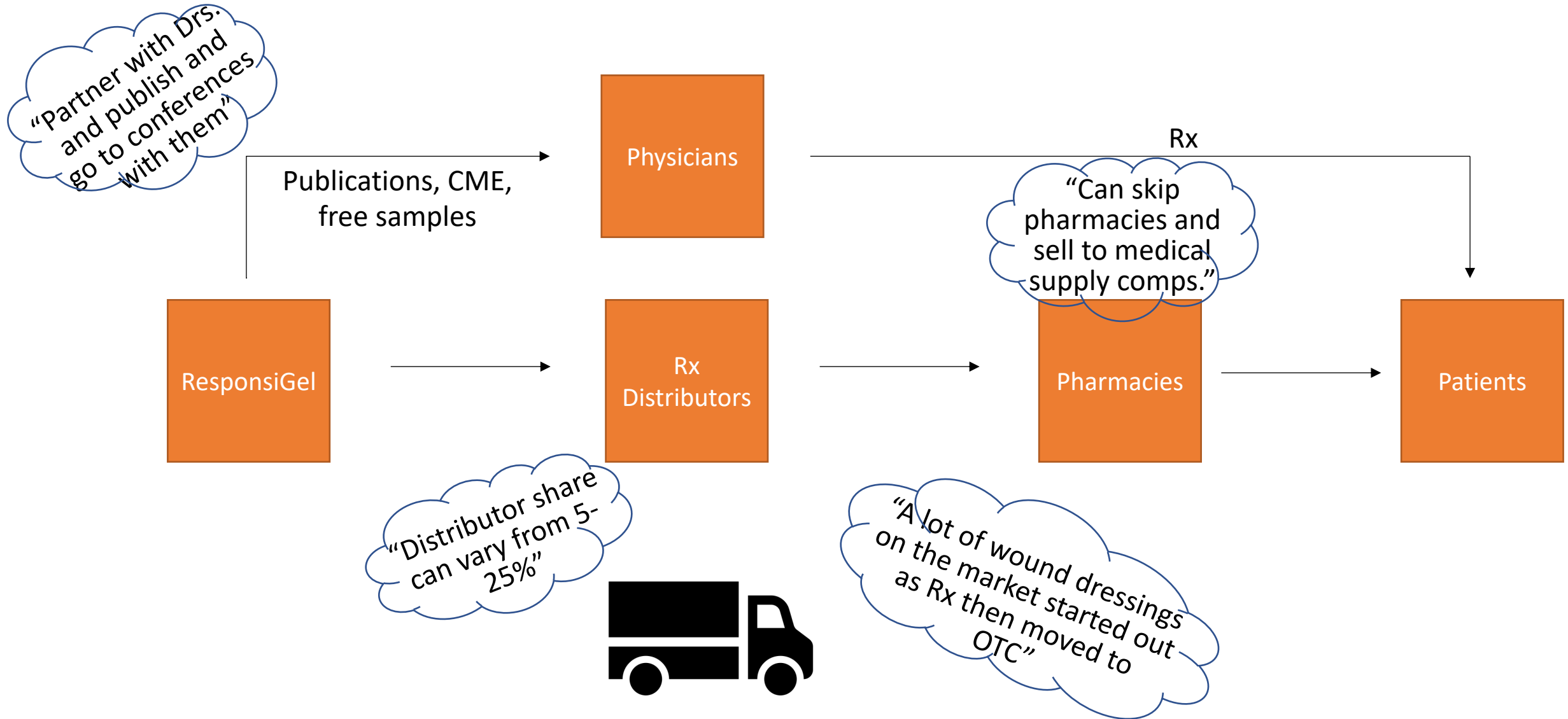


# Insight into the regulatory process



“Five years of market exclusivity to devices/drugs that combat bacterial and fungal infections.”

# Insight into distribution and marketing



# What we were testing up to this point

We need to partner with a pharmaceutical company that produces antifungals.

## Final value propositions

Provides **7 days** of hydration → **~\$1,500 in savings** to the patient per wound

**Prevents** wound microbial **colonization** reducing **healing times and costs by ~50%**

**Reduce** the probability of **systemic fungal infections** by over 25% (with current treatments ~20% reduction) **saving ~\$20,000**

**Mechanical** properties **similar to foam** dressings aiding ulcer protection and allowing patients to wear shoes and **move normally**

## Final key partners

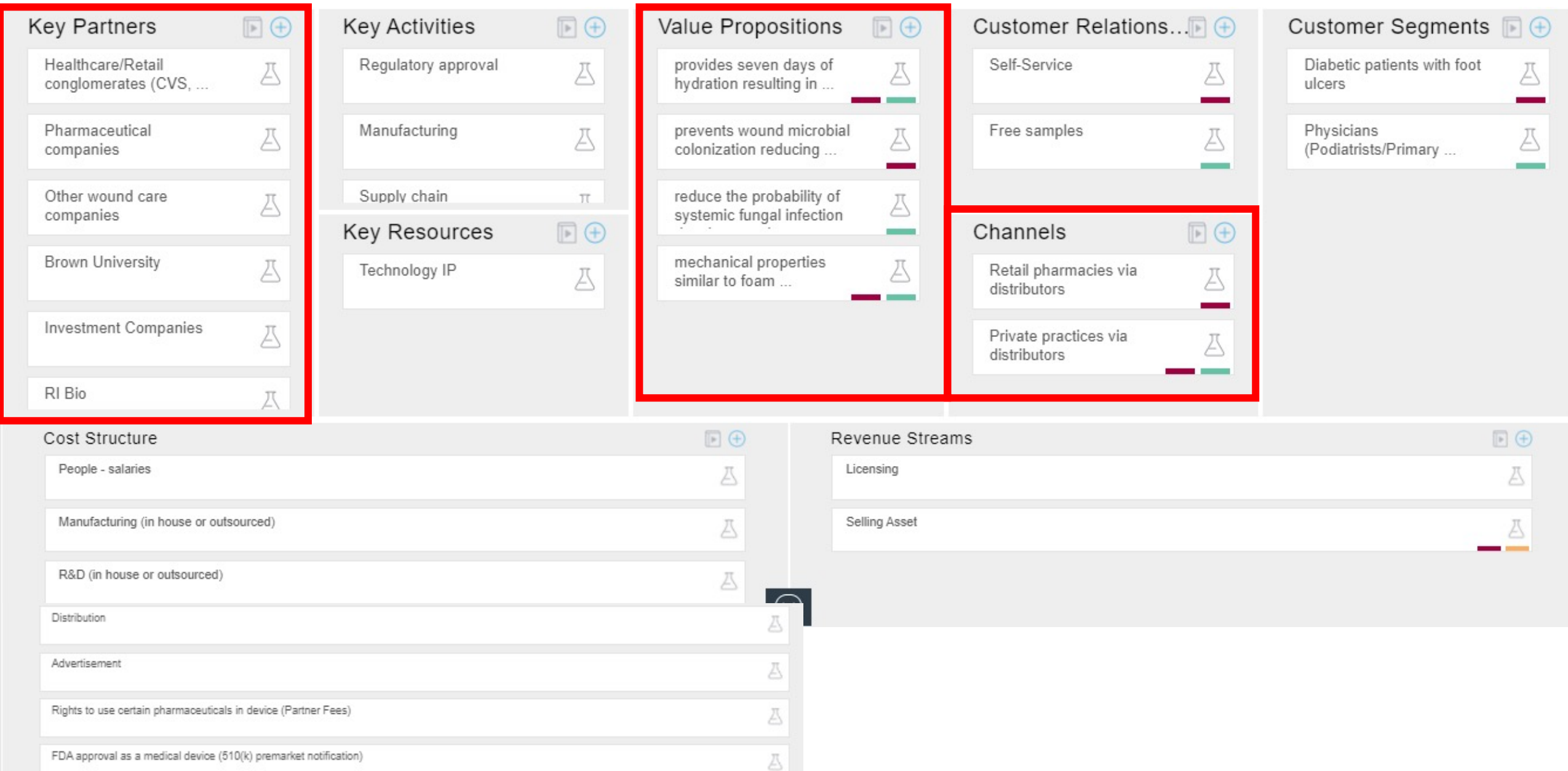
Pharmaceutical companies

Other wound care companies

Healthcare/Retail conglomerates (CVS)

Brown University

# Final business model canvas



# Product-Market Fit

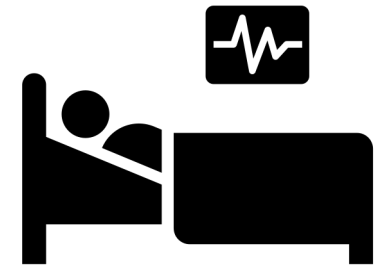
Not quite there yet:

- DFUs seem to be **too small** a market when the **incidence of fungal** infections is taken to account
- Need to explore **widening** the market by **including pressure ulcers**
- **Add antibacterial properties** to our technology to capture more of the DFU market

~4 million serviceable DFU patients

Realistically going to reach ~75% of all patients

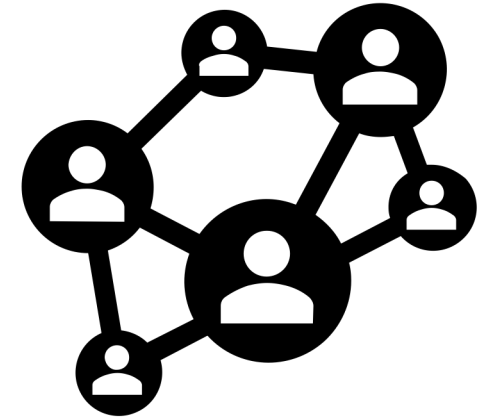
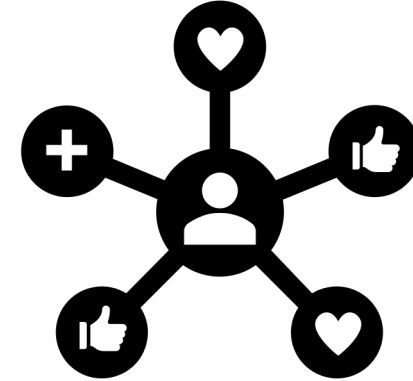
→ ~3 million, 1-5% fungal infection → 30,000



# Next Steps – Discovery and Tech Research

Now

Continue the **customer discovery** process and **cultivate relationships** with wound clinics, physicians, and industry network



2021

**Further develop technology** in the University setting and conduct **pre-clinical** studies with input from new network



Health Resources in Action  
*Advancing Public Health and Medical Research*

Winter 21

Launch and apply for **SBIR/STTR** funding to study product stability and scale up



**SBIR · STTR**  
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