# Using mRNA Technology to Improve T1D Patient Care

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The Biotech Enterprise
(BIOT5219, SEC04)

04-17-2024

(Janež et.al, 2020)

# UNMET NEED

**Bolus injections**

1-2 injections of basal insulin per day

**Expenses**

Average cost of $100-300 per insulin vial

**CSII**

Used for severe hypoglycemia

Continuous subcutaneous insulin infusion

**Reduced cost**

Lessen cost of manufacturing

Fewer doses needed

**Patient care**

Fewer injections needed

Longer-lasting effect

Less side effects



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# OUR SOLUTION

## An mRNA-based insulin therapy

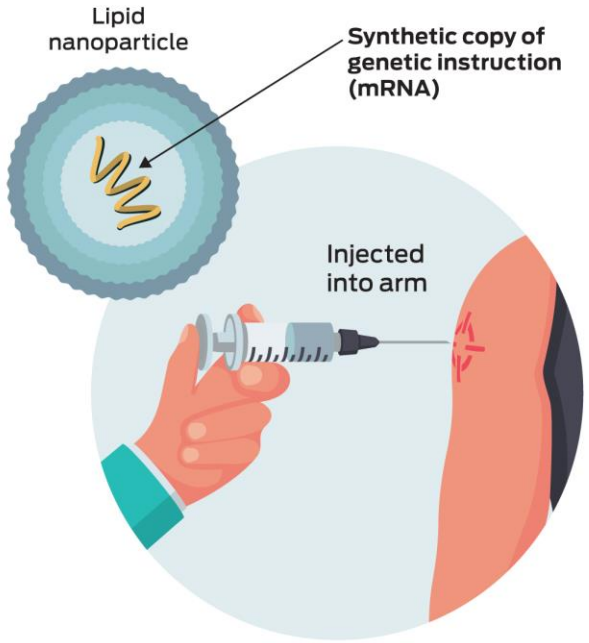
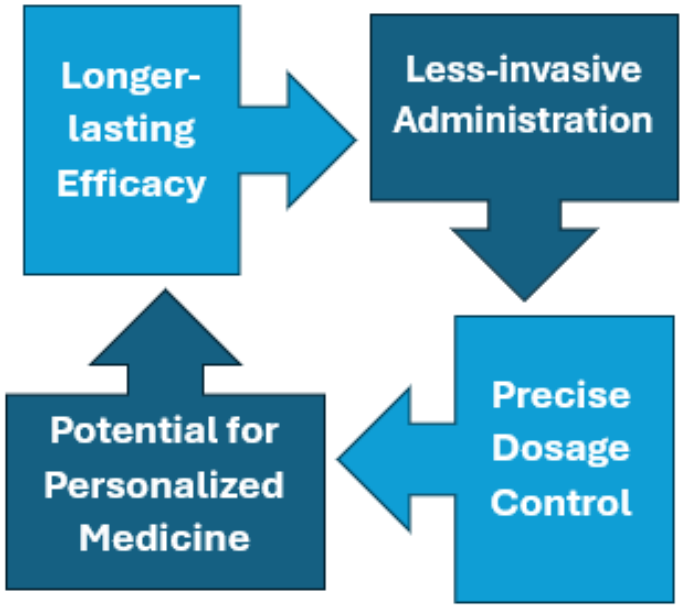



Figure 1. GlucoScript Administration Route (Ho & Trumbull, 2021)




**Phase I data showed that GlucoScript was safe and well tolerated in 88% of subjects**

| Insulin Type | Duration |
|---|---|
| Short-Acting (Humulin R, Novolin R, Afrezza) | 3-6 hours |
| Intermediate-Acting (Novolin N, Humulin N) | 12-18 hours |
| Long & Ultra-Long Acting (Glargine, Detemir, Degludec) | 12-36 hours |
| Insulin mRNA | 3-5 days |

**3X Longer**

Figure 2. Action of Duration for Various Insulin Types - Based on Multiple Dose PK Study Data (GlucoScript, 2024)

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# WE ARE…

## Chief Executive Officer

Ana Sordo Garcia, M.B.A.

Harvard Business School

AstraZeneca

Lilly

## Chief Medical Officer

Dr. Devya Krishnarajah, MD, PhD

Stanford Medicine

GlucoScript

## Chief Scientific Officer

Dr. Baba Mohammad, PhD

Johns Hopkins University

AMGEN

## Chief Commercial Officer

Nikhil Mamidi, M.B.A

Northeastern University

AstraZeneca

## Chief Finance Officer

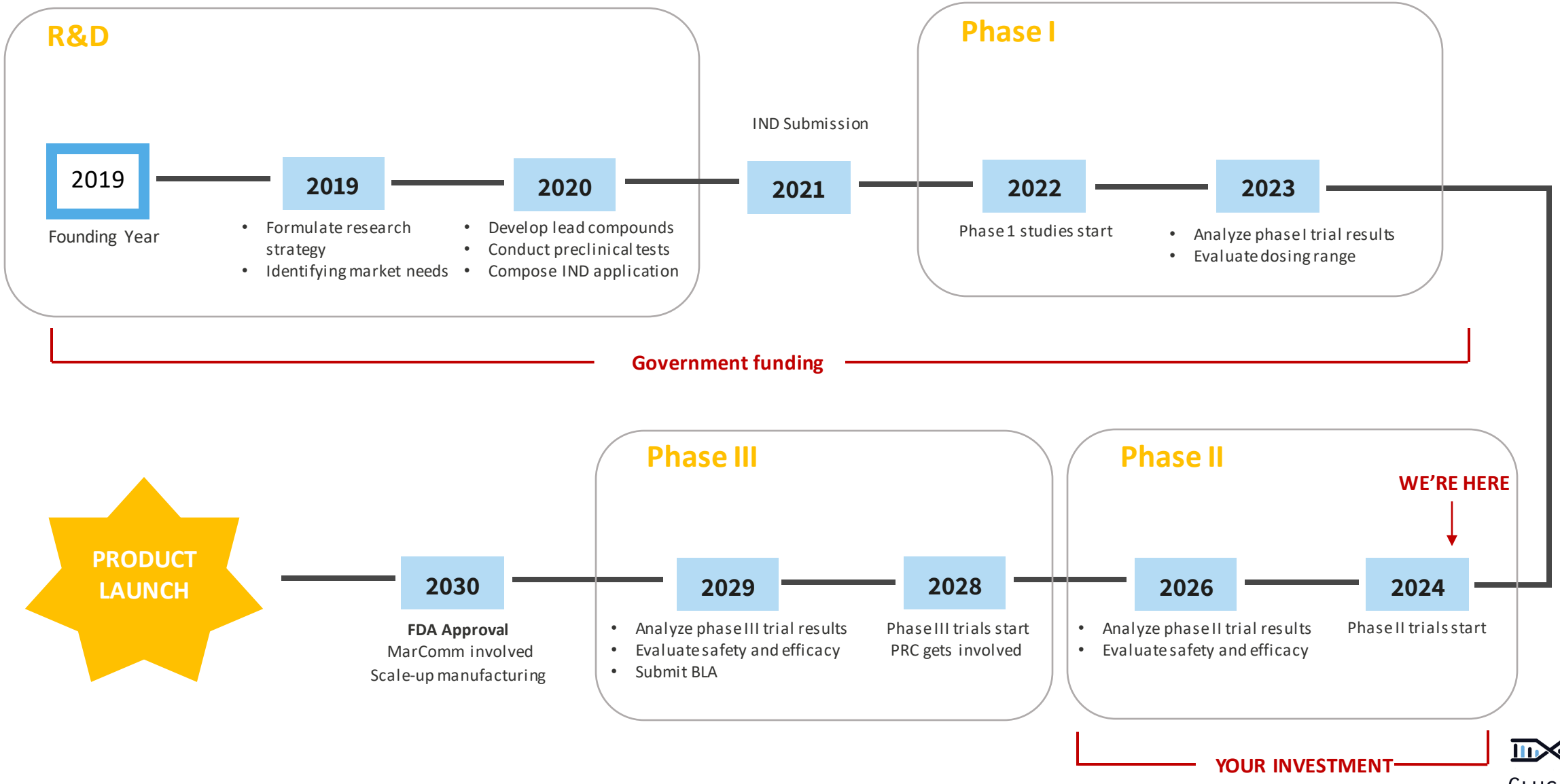
Vaishali Jain, M.B.A

Northeastern University

NOVARTIS

GlucoScript

# TIMELINE

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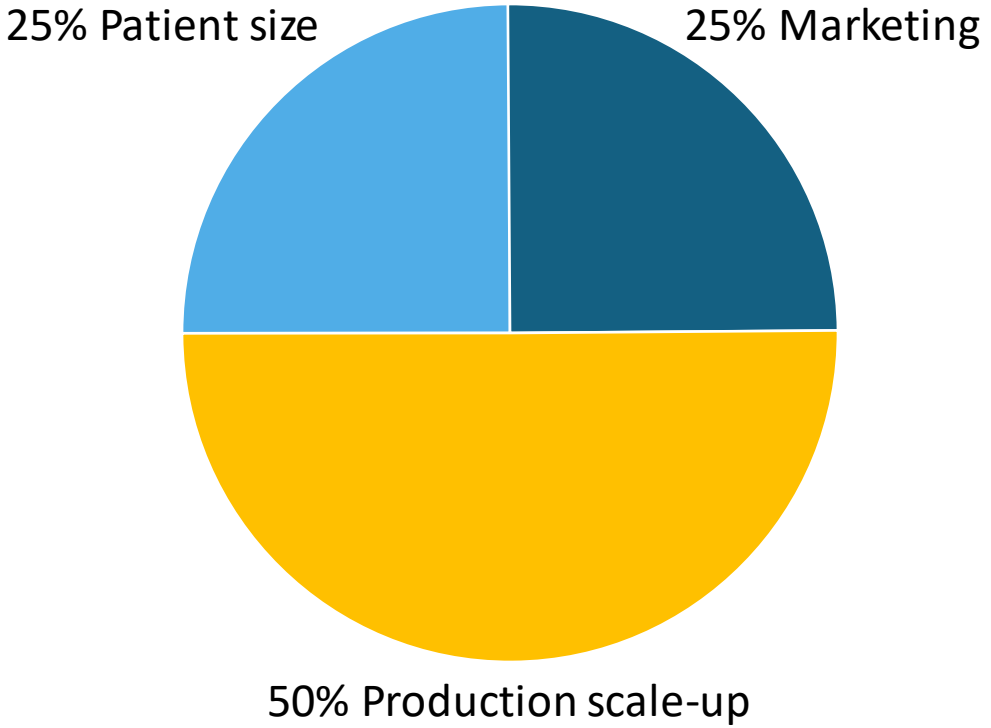
# FUNDING

**Patient size**
*(25M USD)*
50 → 100 patients

**Production scale-up**
*(50M USD)*
1L → 3L reactions

**Early-stage marketing**
*(25M USD)*
Market research and promotional material construction




**TOTAL ASK: 100M USD**



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# SUMMARY

Patients currently need multiple, expensive insulin injections to manage their T1D.

Reactions to current insulin treatments may occur due to non-human cell production.

GlucoScript has a better safety profile than conventional insulin therapies

Patients may experience more stable blood glucose levels throughout the day thanks to GlucoScript's longer-lasting effects.

GlucoScript, which is presently undergoing phase 2 trials, demonstrated encouraging outcomes in phase 1 trials, exhibiting an 88 percent success rate.

With your help, we hope to bring GlucoScript to market in about 6 years.



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# Q&A

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# References


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# TEAM REFLECTION

## Where We Were

At the beginning of our journey, we were 5 individuals with diverse backgrounds who shared vision for revolutionizing type 1 diabetes treatment options. Our earliest stages were characterized by several brainstorming sessions, hours in the lab, and constant trial and error – most importantly it was fueled by passion and determination!

## Where We Are

Today, we look back on the significant progress we have made – what was once just an idea for an mRNA-based insulin therapy, now shows promising efficacy and safety profiles, and the potential to be the new gold standard for treating type 1 diabetes. We started as an unknown team, but have gained the support of fellow researchers, physicians, and business leaders from around the country.

# INDIVIDUAL REFLECTIONS

| | |
|---|---|
| Module 7: Med Affairs & Compliance | **Ana**: It was astounding to learn how legal, medical, and regulatory all needed to be involved in PRC when marketing a product and planning its launch. |
| Module 8: Patient Access & Alliance (or Collaboration) Management | **Nikhil**: Reflecting on this module, I was particularly struck by the pivotal role alliance managers and KOLs play in shaping market access, promoting collaboration, and defining healthcare strategies and innovations. |
| Module 9: Submission and Commercial Prep | **Devya**: I was surprised to learn about how rigorous and extensive the training is for the Sales Force team of a biotech company. |
| Module 10 : Supply chain, Quality & Manufacturing | **Baba**: I was amazed to know about that the supply chain management extensive responsibilities, spanning from raw material procurement to final product distribution. |
| Module 11: Ethics & Investor Relations | **Vaishali:** I found it fascinating how pharmaceutical companies strike a balance in their communication strategies between ethical and regulatory requirements. |
| Module 12: Organizational Growth: Leadership, Culture and Effectiveness | **Vaishali:** In my opinion, a good leader is someone who fosters peace and harmony within the company while promoting a healthy work environment. |

# Thank You

Ana Sordo Garcia
Baba Mohammad
Devya Krishnarajah
Nikhil Mamidi
Vaishali Jain

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# PHASE 1 CLINICAL TRIAL

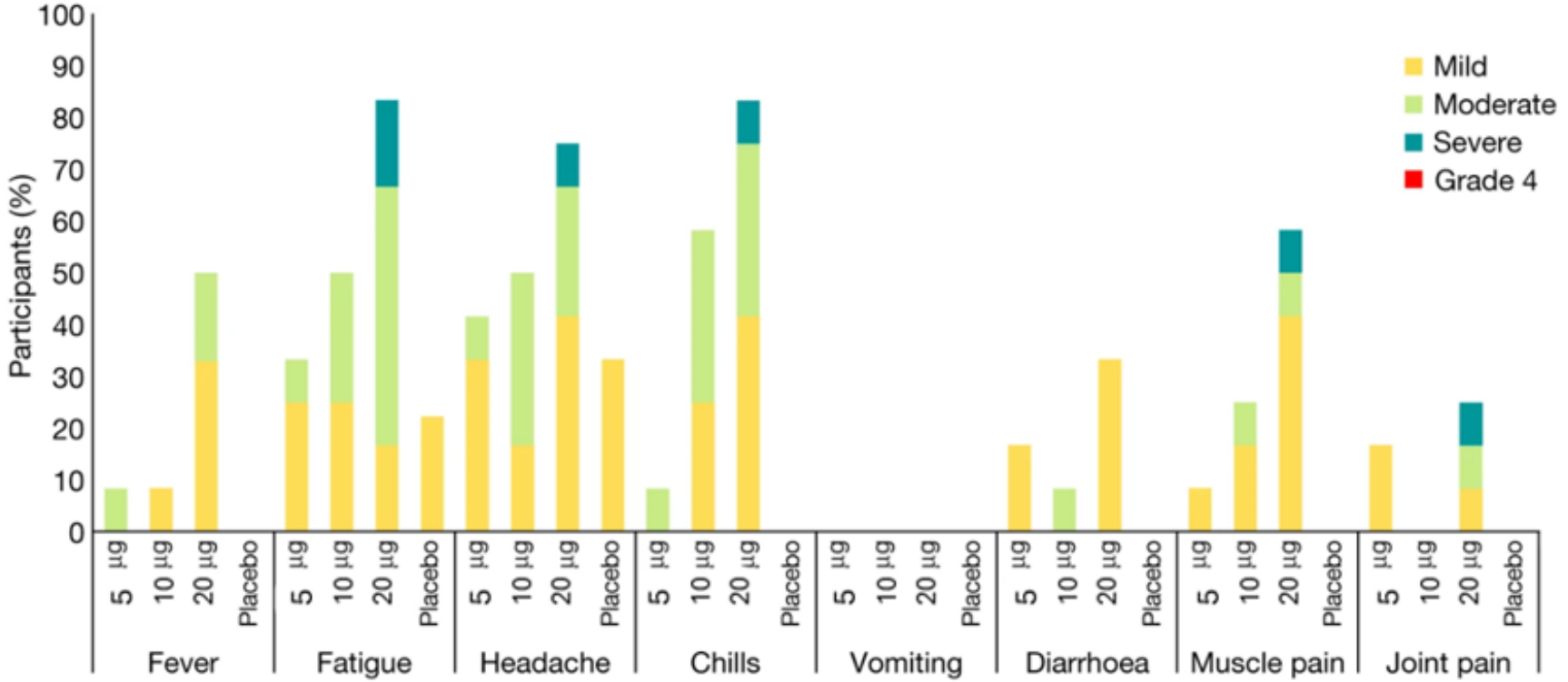


Figure 4. Systemic Events Reported Within 7 days of Injection of GlucoScript (adapted from Mulligan et al., 2020)

**Primary endpoints:**

1. Assess adverse reactions, side effects, overall, safety of the injection in humans.
2. Evaluate the vaccines tolerability by assessing systemic reactions, and any other discomfort or adverse events reported by subjects.