Arkaiya SA

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Foundation of microbiome balance

Revolutionizing Diagnostics with *M. smithii* PCR Test

EPFL Pharmaceutical Biotechnology class presentation

Dr. Duncan Sutherland, Founder & CEO

25.09.2024

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Overview

- Founded in 2023, at EPFL Innovation Park
- Specializes in microbiome diagnostics for toddlers.
- Flagship product: PCR test for *Methanobrevibacter smithii* (M. smithii), a critical gut archaea.

Foundation of Microbiome Balance

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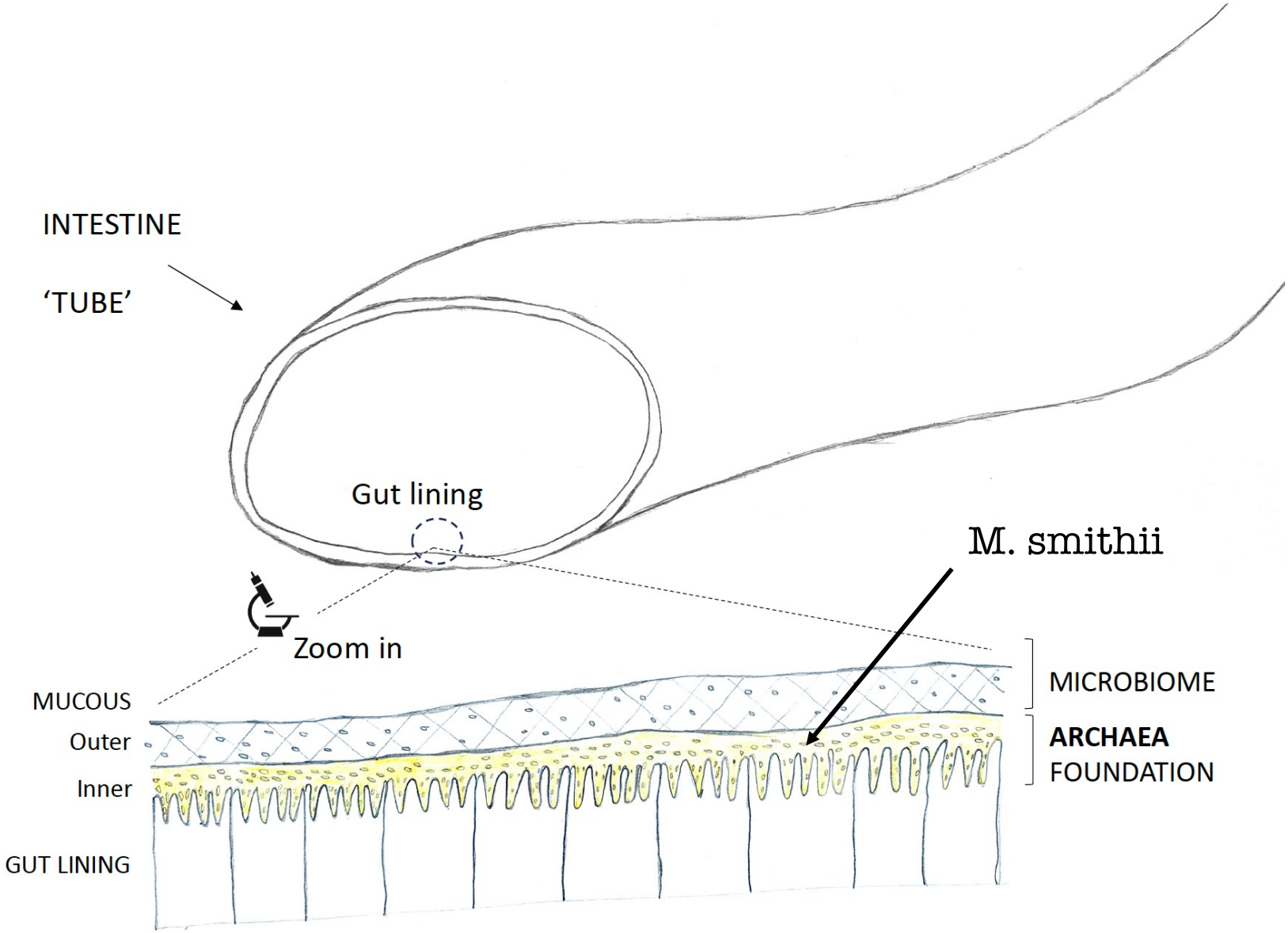

Why *M. smithii* is a Game Changer

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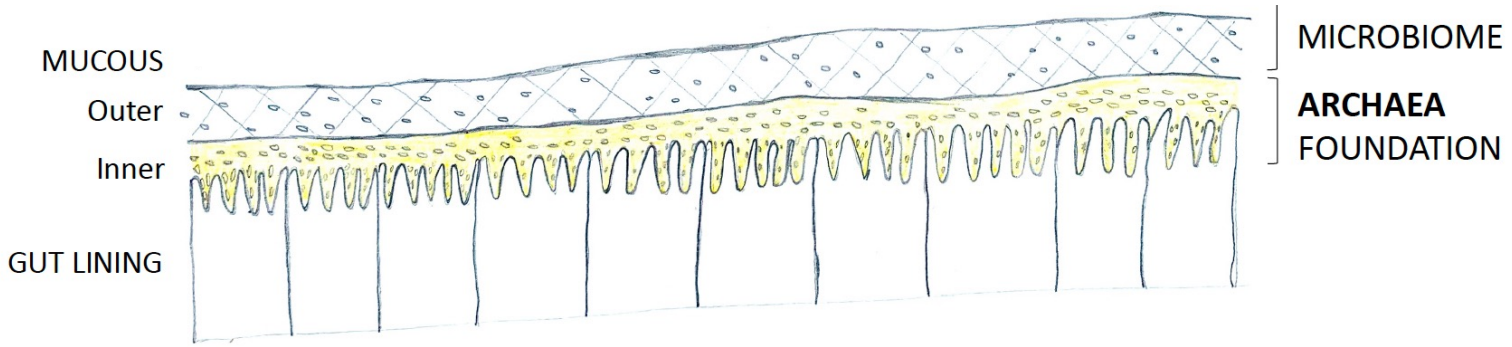

1

Neglected

M. smithii has been largely neglected in microbiome research due to its challenging detection and cultivation, but it plays a pivotal role in gut health

2

Foundational Layer

M. smithii forms the foundational layer of the gut mucous and microbiome, which is essential for proper immune system development and the formation of a healthy microbiome.

3

Critical Biomarker

It is potentially the most relevant biomarker for mucosal health in early life, with significant implications for long-term health.

The Problem

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Impact

- An estimated 1 in 5 toddlers may be deficient in *M. smithii*, affecting their overall health and development.

Market Need

- Microbiome deficiencies in toddlers are linked to various health issues, including compromised mucosal integrity and inflammation.
- Current diagnostic methods are either costly or unreliable.

Our Solution

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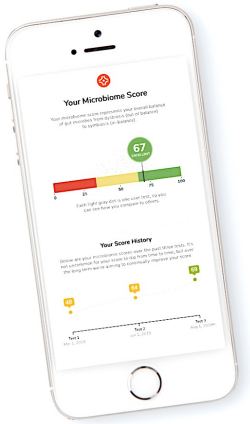
PCR Test

Product

- Arkaiya SA's semi-quantitative PCR test detects *M. smithii* early, enabling timely intervention.



Web App

Patented

Invisible Yet Foundational

- *M. smithii* has long been "invisible" due to its unusual hard cell wall, making it difficult to detect with standard analytics. Additionally, its anaerobic cultivation is highly challenging, leading to its neglect in mainstream research.

Unique Biomarker

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☑ Breakthrough Innovation

- Arkaiya SA, in collaboration with our partners, has pioneered methods that successfully detects and cultivates *M. smithii*, opening new avenues in health diagnostics and therapeutics.

☑ Foundational Layer of the Microbiome

- *M. smithii* forms a foundational layer in the human microbiome, becoming the most dominant species of the colon in healthy adults, with up to 10% relative abundance.

☑ Critical Biomarker

- Toddlers with low levels of *M. smithii* may be advised to take supplements like HMOs (human milk oligosaccharides) to promote this foundational layer, enhancing mucosal health and overall microbiome formation.

Market Opportunity

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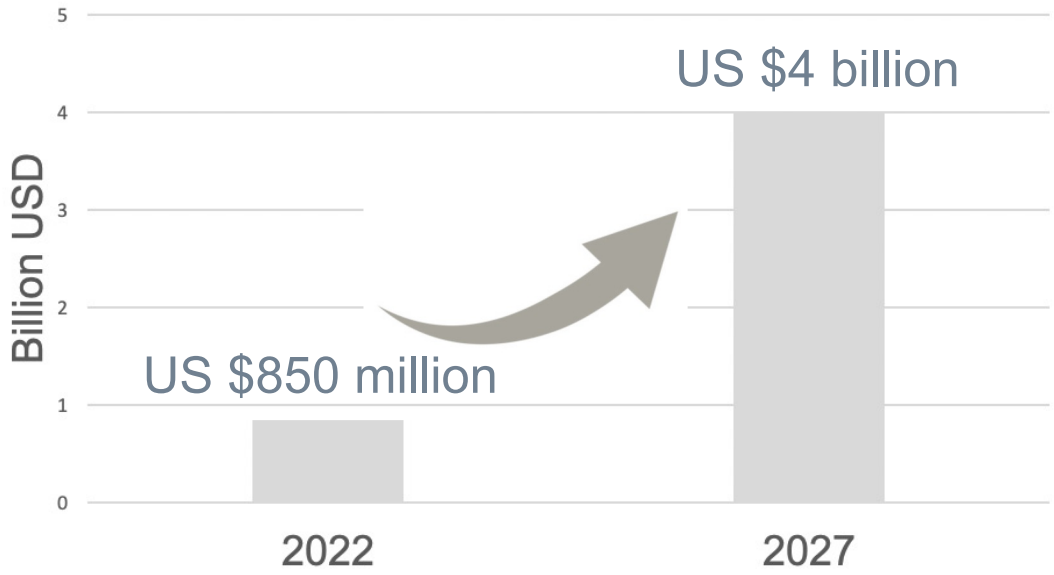
Microbiome Diagnostic Market Projection



Target Customers

Competitive Landscape

=> none focus specifically on *M. smithii*.

VIOME

synlogic

SECOND GENOME

Technology & Innovation

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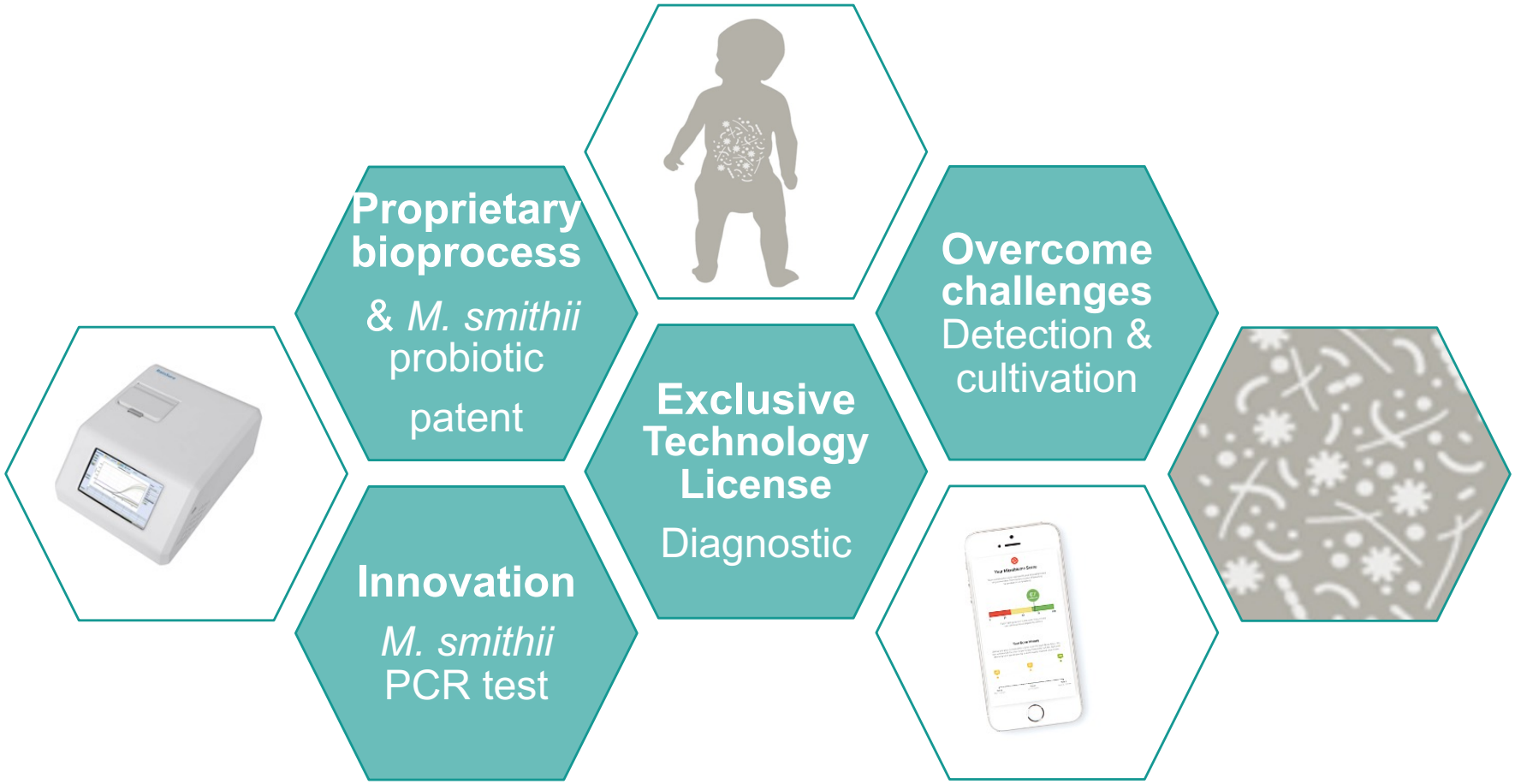

Business & Revenue Model

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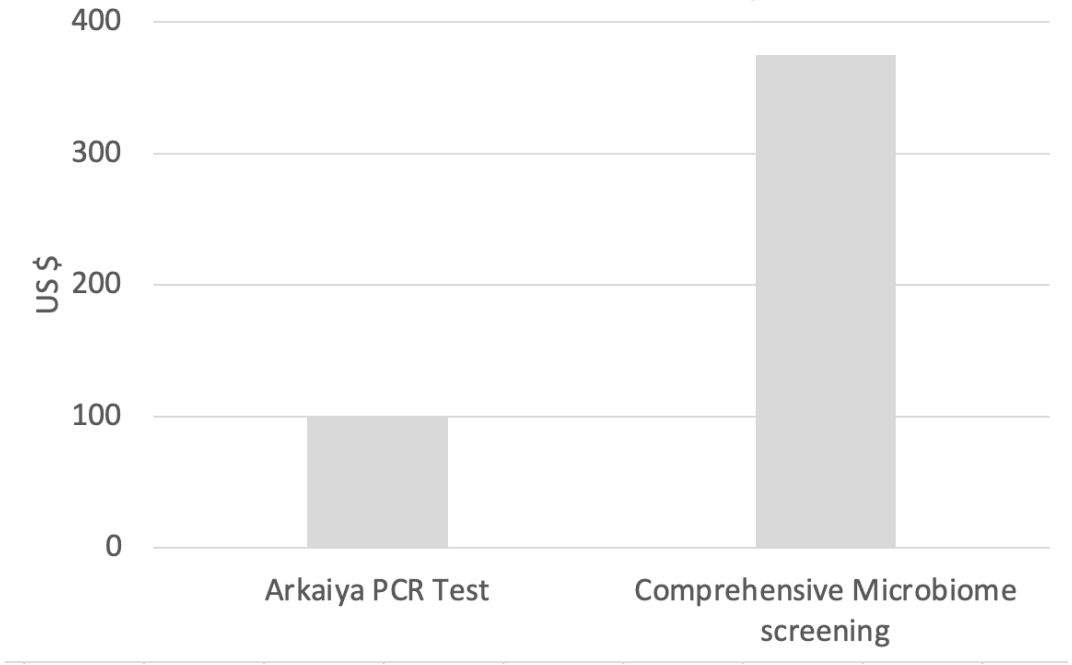
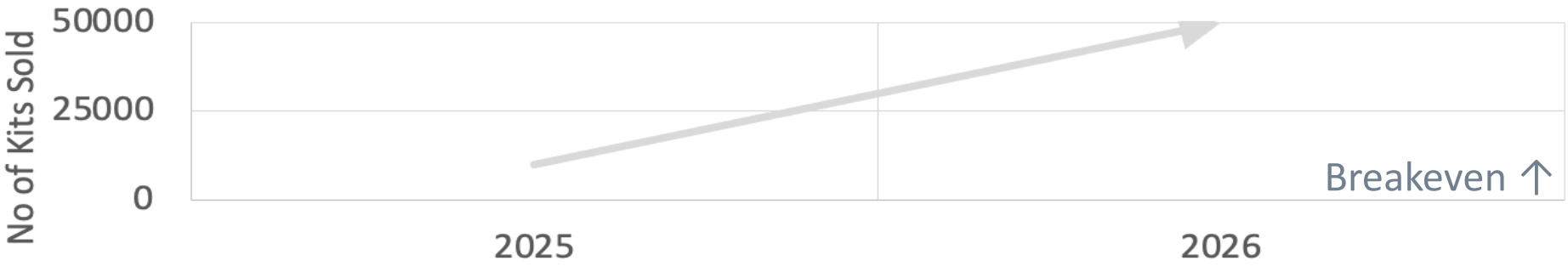
Price Point Advantage



Profitability

CHF 100.- per kit

Sales Targets



Funding Strategy

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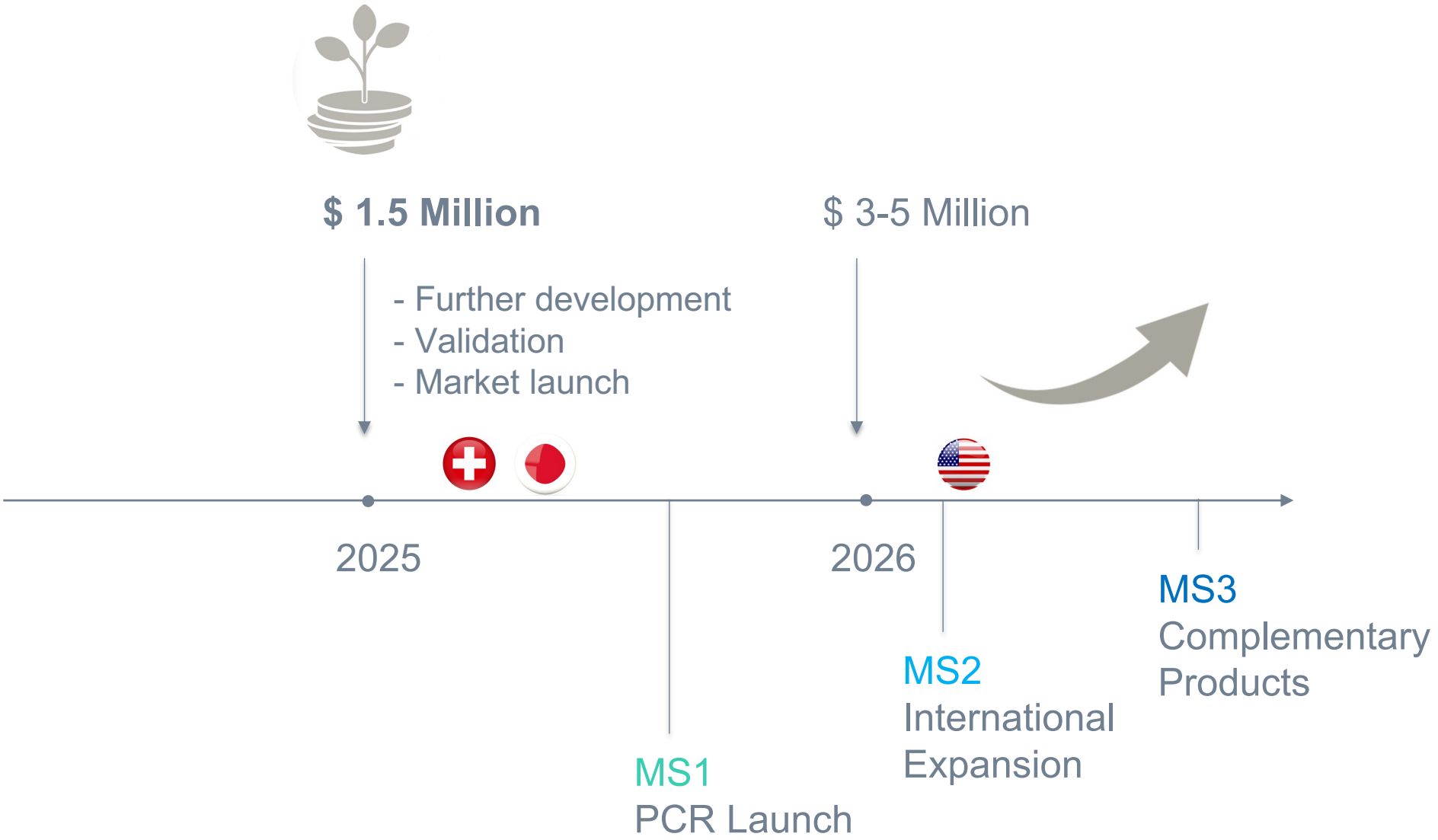

Milestones & Achievements

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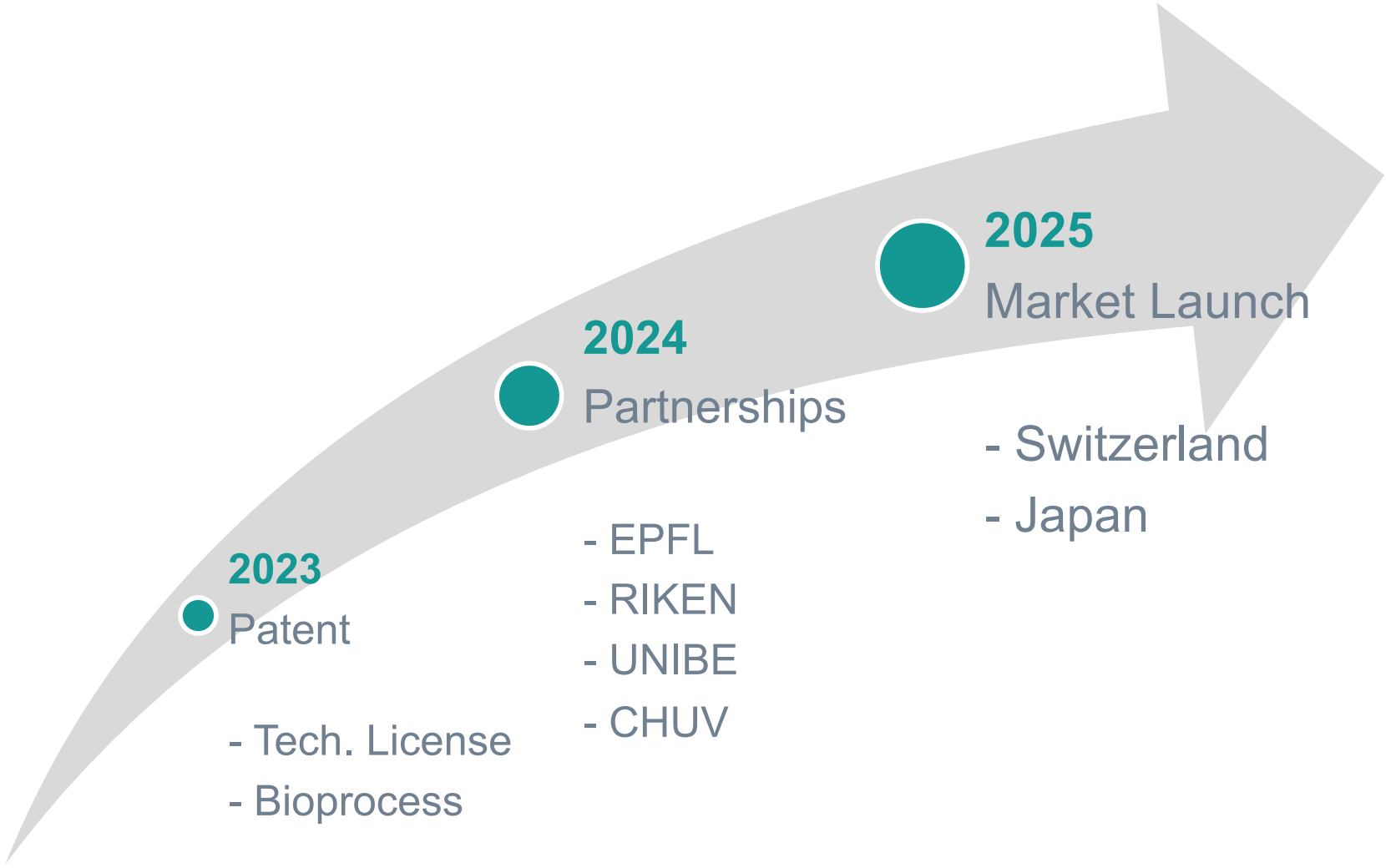

Executive Team

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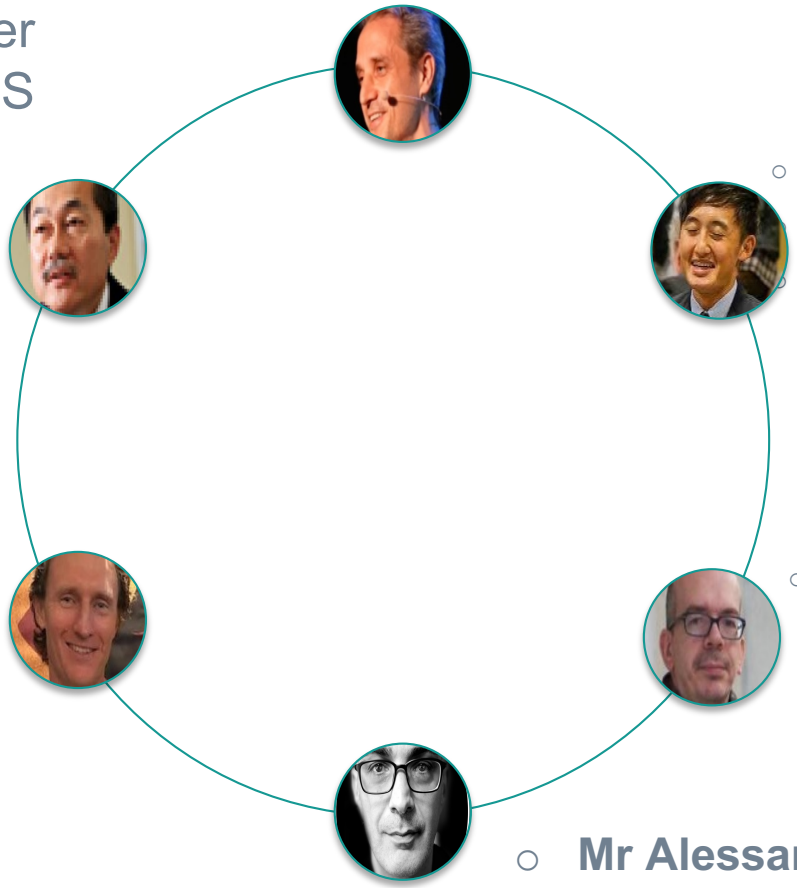
- **Dr. Duncan Sutherland CEO**
  10+ years in gastro immunology R&D,
  5+ years in entrepreneurship, inventor of 6 patents.

- **Prof. Hiroshi Ohno**
  Board Member
  Dep. Director RIKEN IMS



- **Dr. Shohei Asami**
  Microbiome scientist,
  PCR diagnostics expert.

- **Mr Swithun Still**
  Board Member
  (former GAFTA President)

- **Dr. Axel Martinelli**
  Molecular biologist,
  scientific advisor.

- **Mr Alessandro Mavilio**
  Software engineer,
  Web platform manager.

Why Arkaiya?

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Arkaiya is set to transform early childhood microbiome health

‘Arkaiya SA, is pioneering in its field but is also poised to revolutionize early childhood microbiome health.

Join us in revolutionizing microbiome health.’

TEDx Ecublens 2024

Hidden role of archaea in the gut microbiome

Question & Answers

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Follow-up questions:

Dr. Duncan Sutherland, duncan@arkaiya.com

Appendices

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Additional information

A-1. Human milk oligosaccharides (HMO) ↑ archaea

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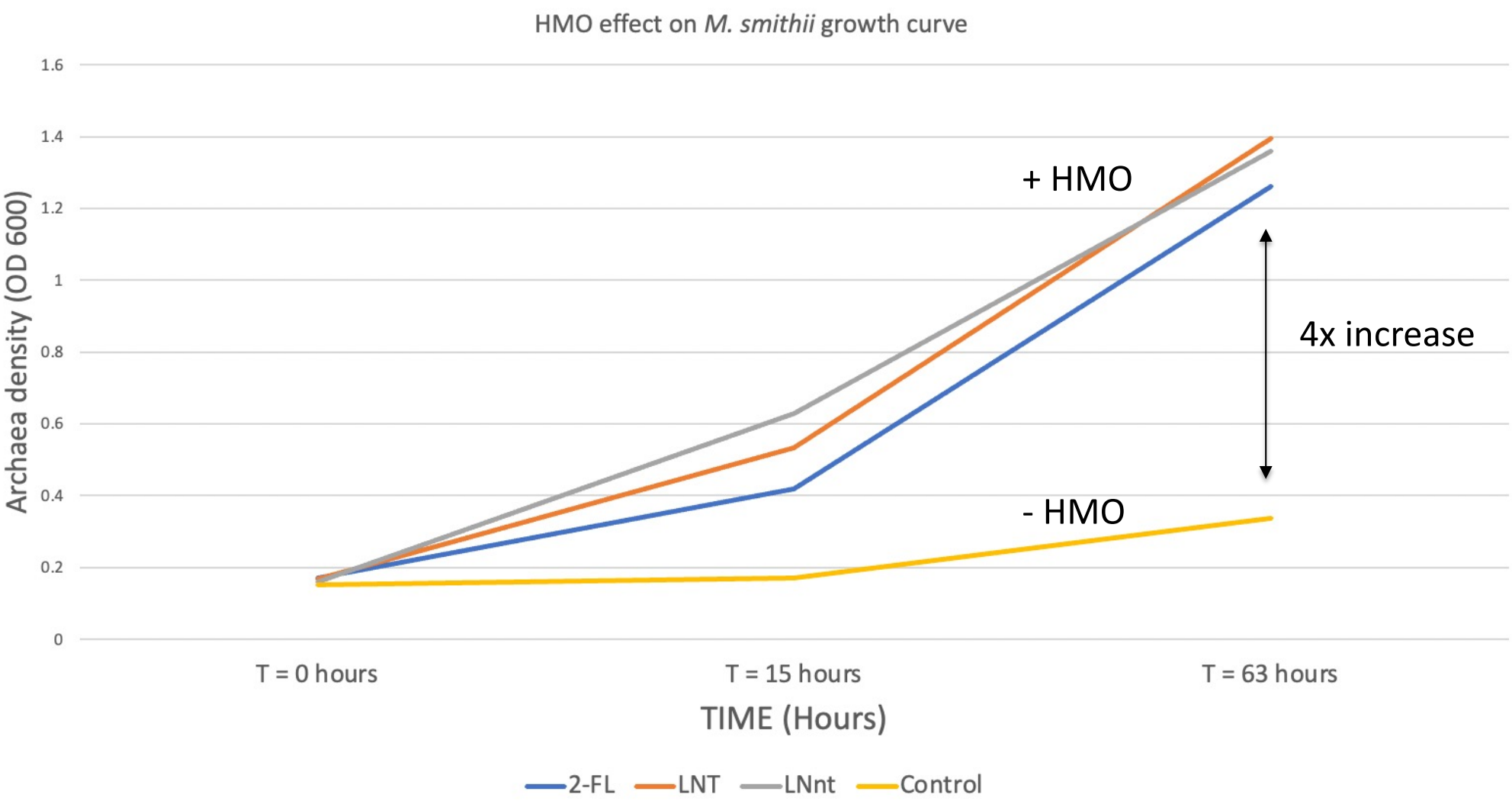

Arkaiya SA collaboration with DSM & HES-SO Sion, 2023

A-2. Archaea missing in malnourished infants

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M. smithii archaea levels in microbiome
(qPCR *M. smithii* abundance relative to total bacteria)

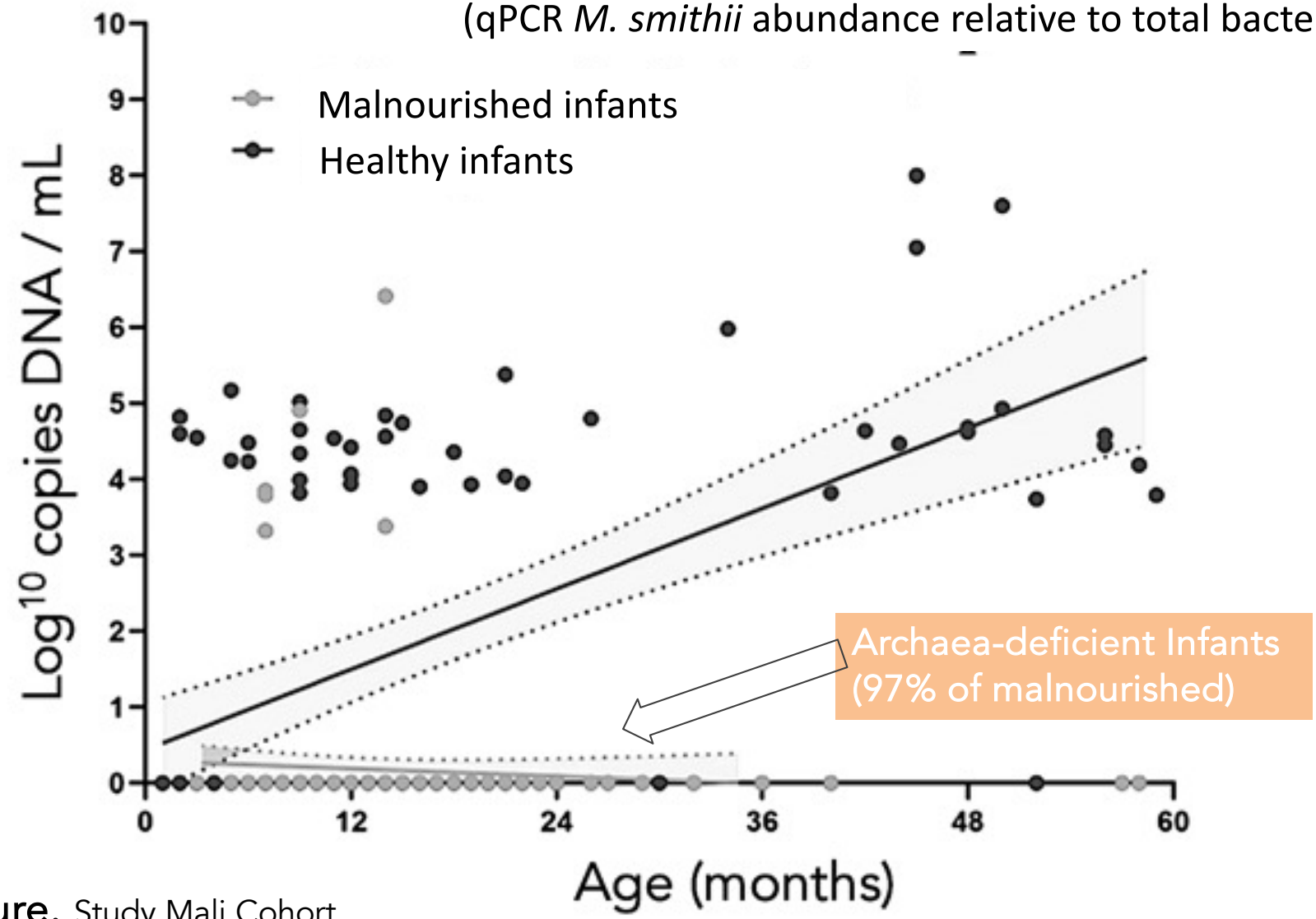

Figure. Study Mali Cohort
110 healthy, 143 malnourished

Camara *et al*, Article 5426, **Nature** Scientific Reports, 2021

A-3.Archaea supports mucosal defense

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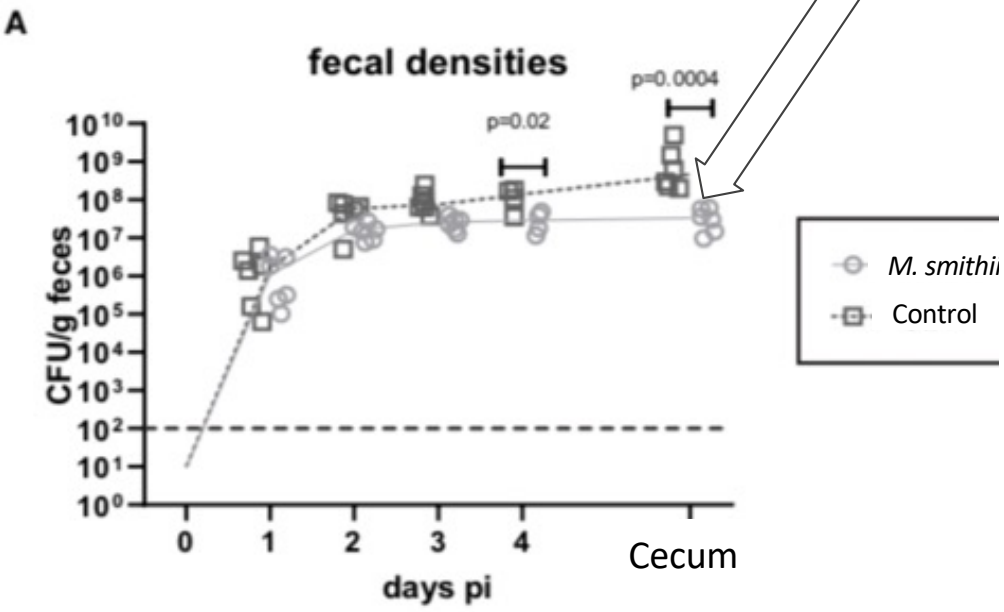
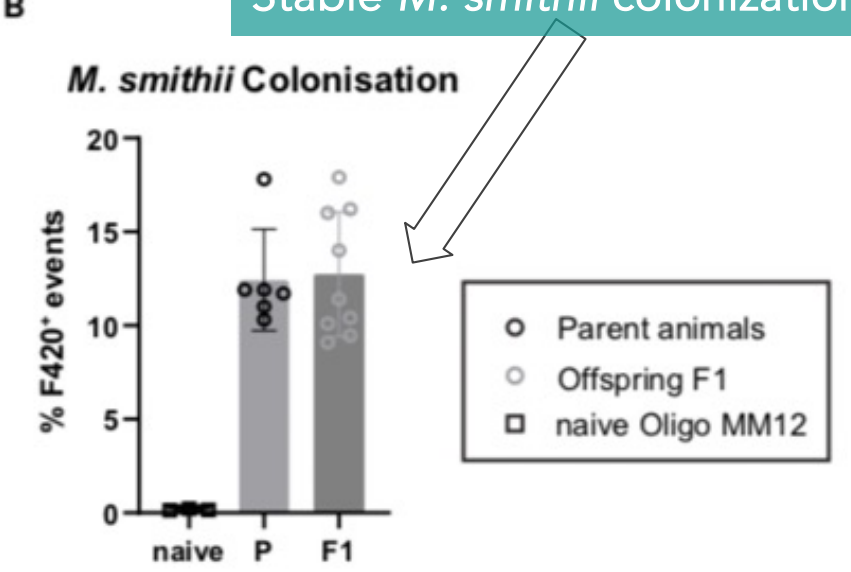
100x reduction of pathogen
In *M. smithii* colonized mice



Colonization resistance
Salmonella Typhimurium
(strain SL1344 ΛinvC ΛssaV)

Stable *M. smithii* colonization



***In vivo* mouse model**
Gnotobiotic mice
12 bacteria + *M. smithii*

UNIBE_Prof Hapfelmeier Lab, Publication in preparation 2022

A-4. Patent portfolio

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Category	Description	ID	Status	Regions.
Probiotic	Use of archaea in human food	US20180193390A1	Granted 2019	Worldwide
Postbiotic	Use of inactivated archaea for immune regulation	WO2020002543A1	Granted 2023	US EU JP
Diagnostic	Archaea as a biomarker and therapeutic for immune health in early life	WO/2023/170262	Filed 2023	US EU JP CH

A-5. OlogioMM12 gnotobiotic mice (preclinical)

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Acutalibacter muris	KB18
Akkermansia muciniphila	YL44
Bacteroides caecimuris	I48
Bifidobacterium animalis	YL2
Blautia coccoides	YL58
Clostridium innocuum	I46
Enterocloster clostridioformis	YL32
Enterococcus faecalis	KB1
Flavonifractor plautii	YL31
Limosilactobacillus reuteri	I49
Muribaculum intestinale	YL27
Turicimonas muris	YL45
Methanobrevibacter smithii	DSM861

A-6. *M. smithii* archaea promotes beneficial bacteria

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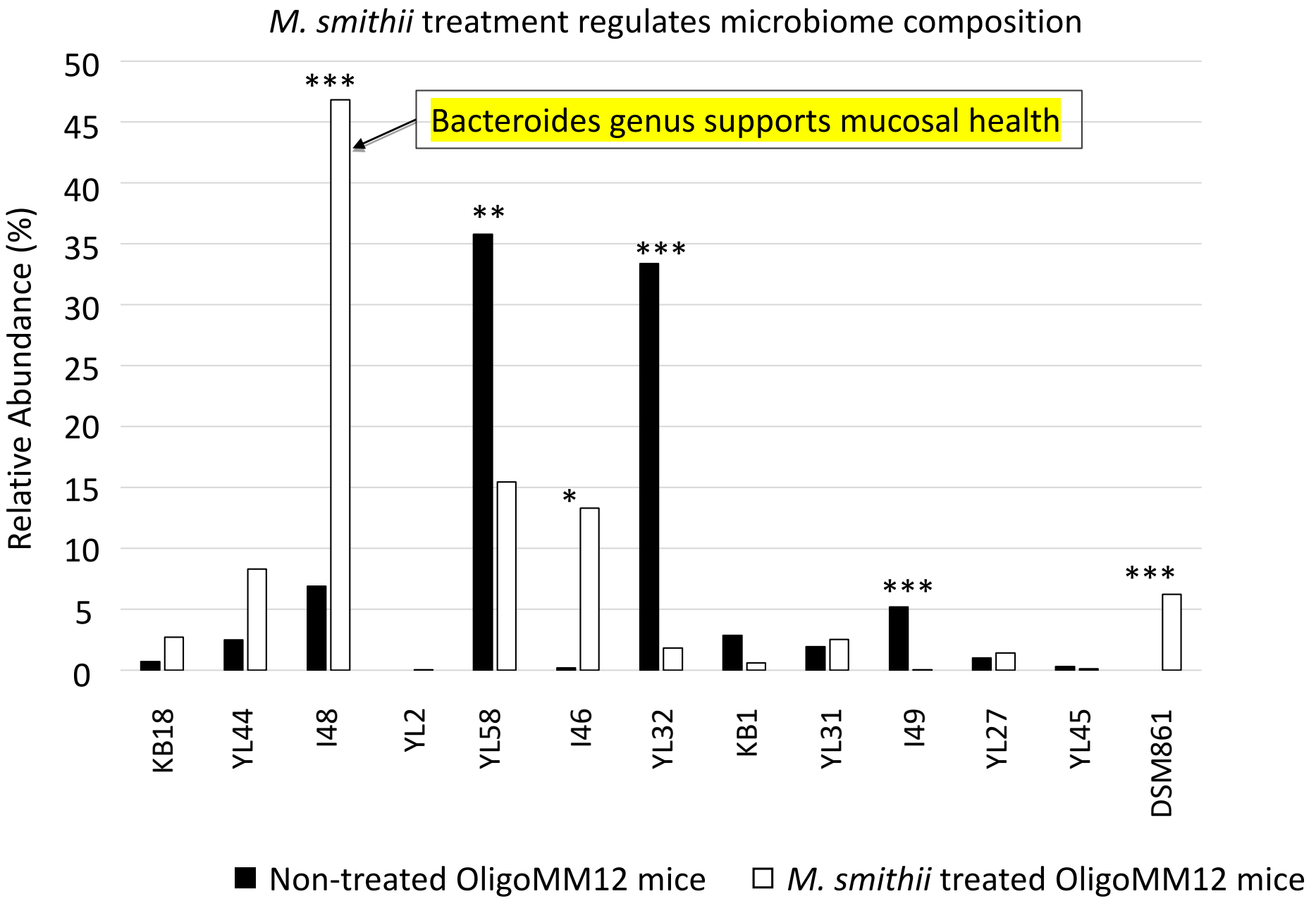
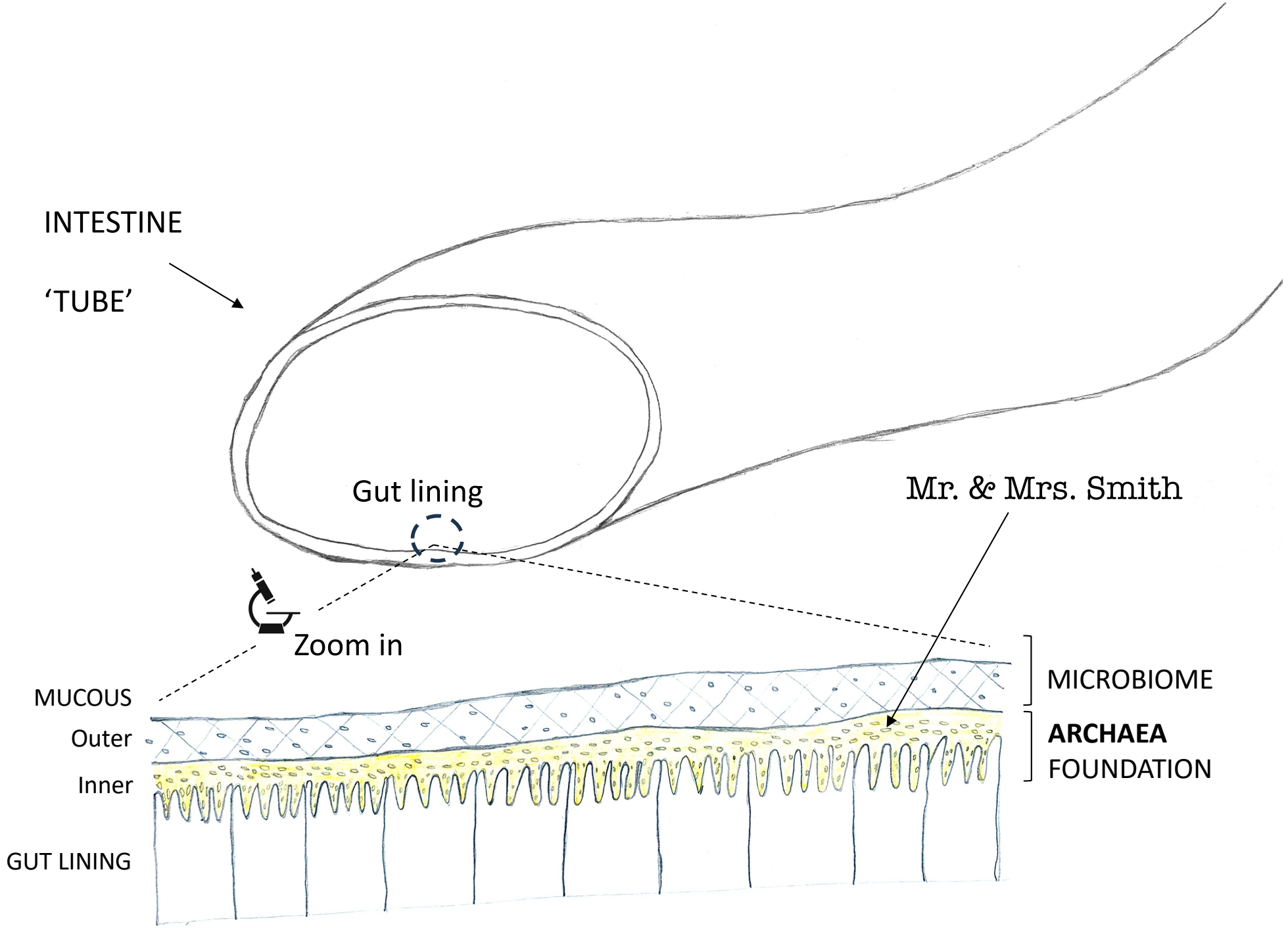
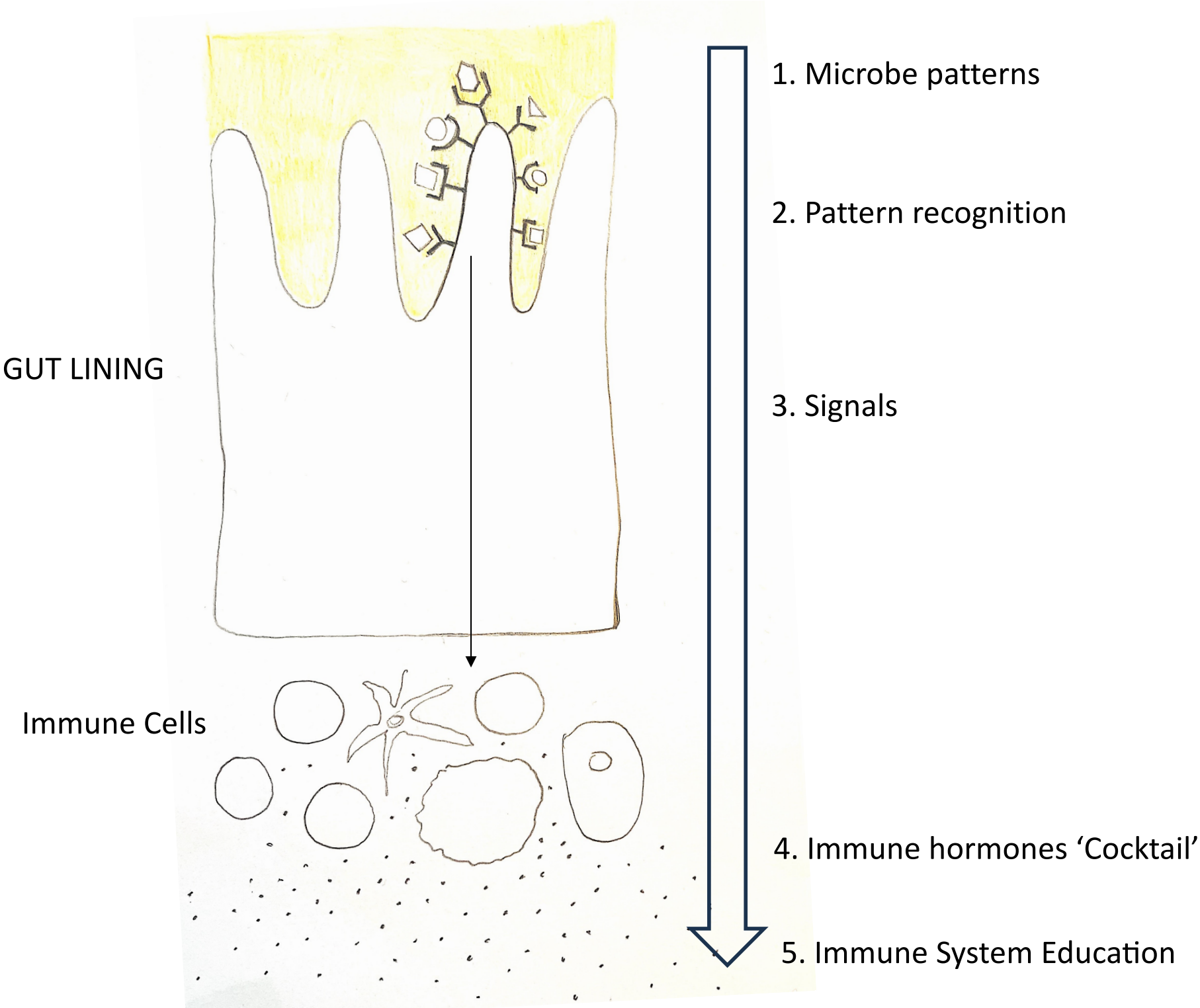
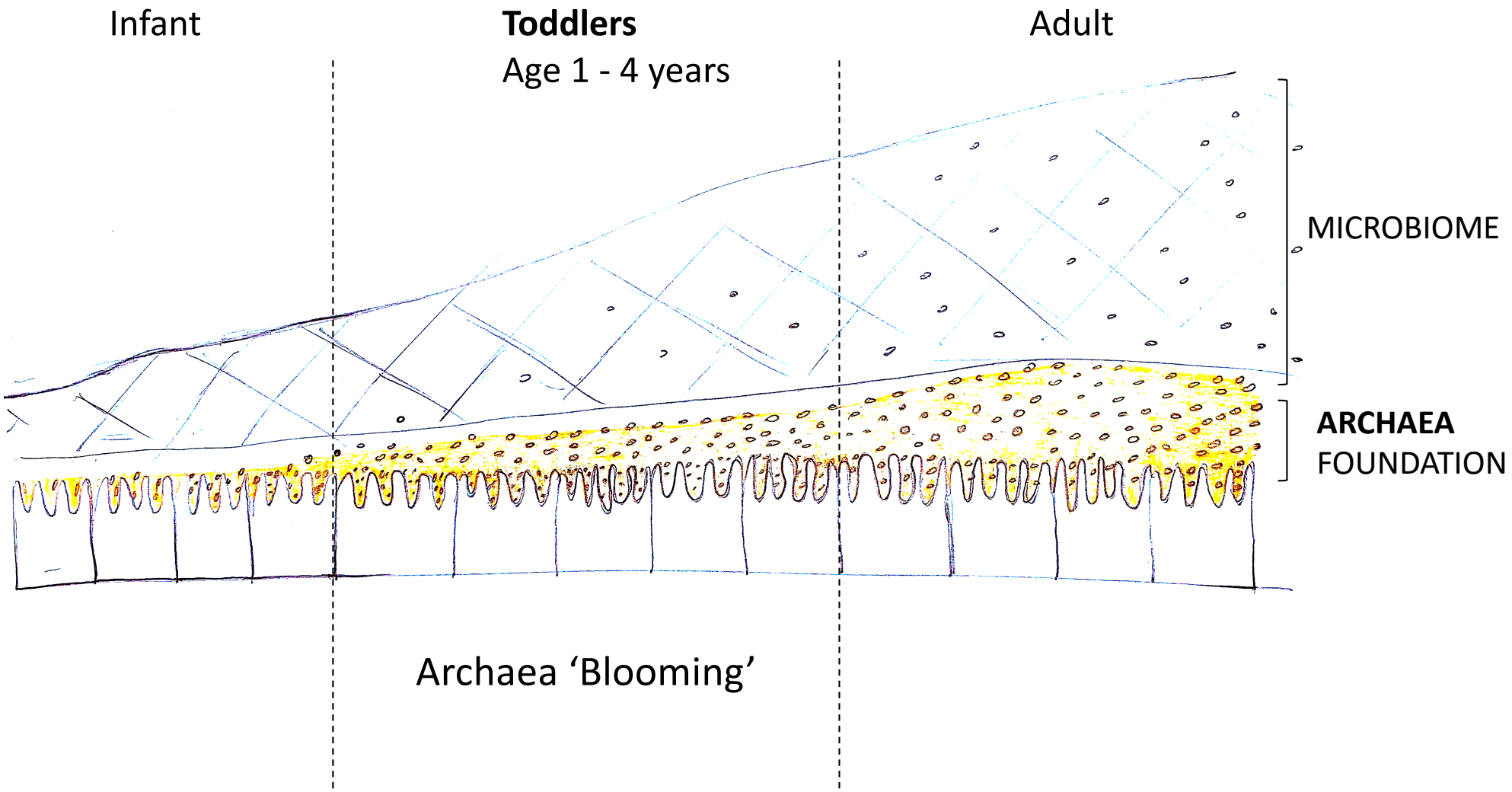
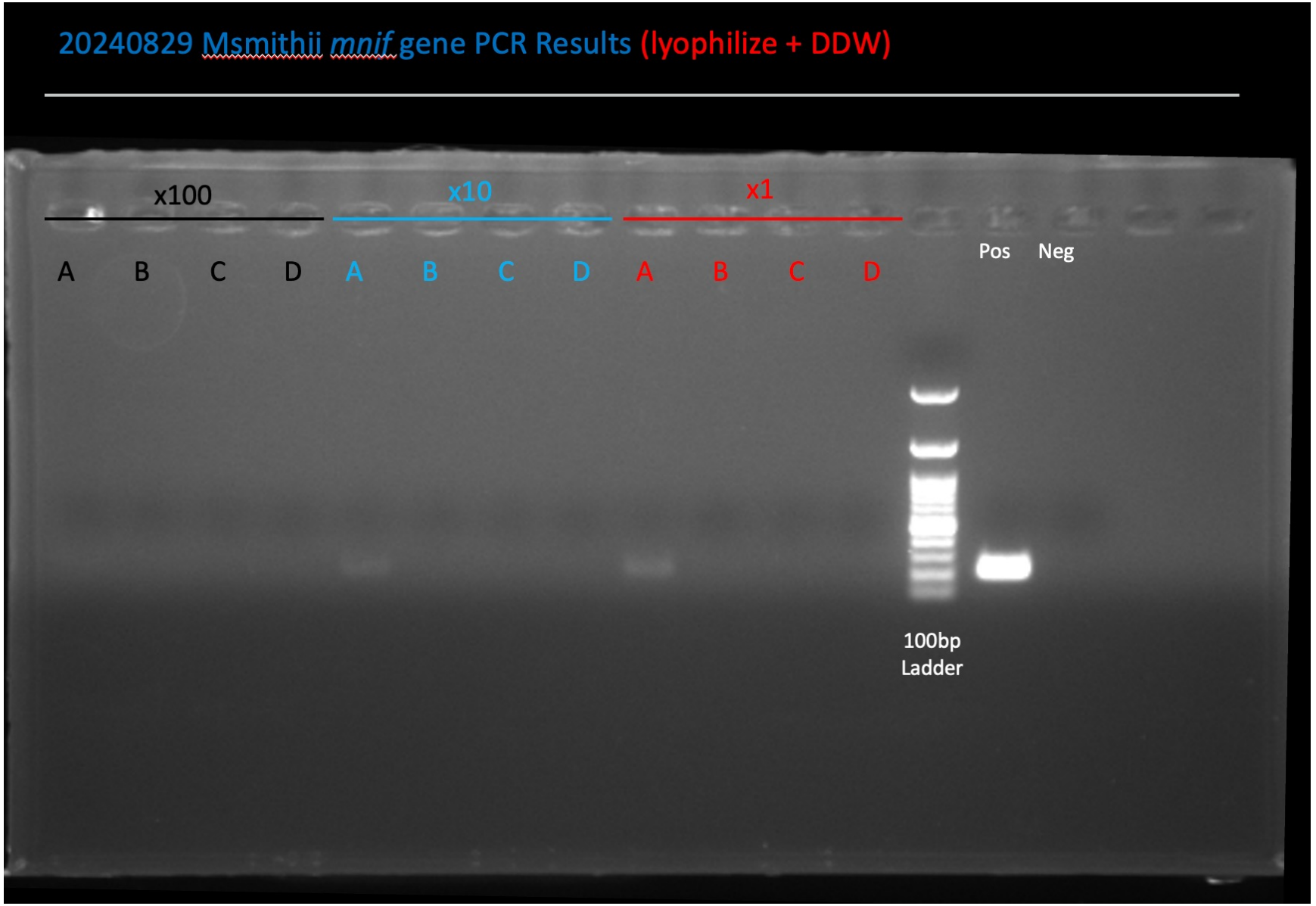



INTESTINE
'TUBE'
Gut lining
Mr. & Mrs. Smith
Zoom in
MUCOUS
Outer
Inner
GUT LINING
MICROBIOME
ARCHAEA
FOUNDATION


GUT LINING
Immune Cells
1. Microbe patterns
2. Pattern recognition
3. Signals
4. Immune hormones ‘Cocktail’
5. Immune System Education


Infant
Toddlers
Age 1 - 4 years
Adult
MICROBIOME
ARCHAEA
FOUNDATION
Archaea ‘Blooming’

20240703 Msmithii *mnif* gene PCR Results (non-freeze dried)


20240829 Msmithii mnif gene PCR Results (lyophilize + DDW)
x100
x10
x1
A
B
C
D
A
B
C
D
A
B
C
D
Pos
Neg
100bp
Ladder

A-7. Literature

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- Archaea inversely associated with childhood asthma (n = 496)

Barnett et al, Intestinal archaea inversely associated with childhood asthma, **J Allergy & Clin Immunology**, 2019

- Archaea inversely associated with inflammatory bowel disease

Ghavami et al, Alterations of the human gut *Methanobrevibacter smith*ii as a biomarker for inflammatory bowel diseases, **Microb Pathog**, 2018

- Archaea inversely associated with colorectal cancer in aged 50+

Coker et al, Altered gut archaea composition and interaction with bacteria are associated with colorectal cancer, **Gastroenterology**, 2019

- Archaea inversely associated with atopic dermatitis

Melli et al, Gut microbiota of children with atopic dermatitis: Controlled study in the metropolitan region of Sao Paulo, Brazil, **Allergy & Immunopathology**, 2020

- Keystone archaea species are in mother's milk and essential to baby's health

Togo et al, Culture of Methanogenic Archaea from Human Colostrum and Milk, **Scientific Reports**, 2019

- Keystone archaea species in newborn gastric juices

Grine et al, *Methanobrevibacter smithii*, a methanogen consistently colonising the newborn stomach, **European J of Clinical Microbiology & Inf. Diseases**, 2017

- Archaea colonization associated with organic dairy milk consumption

Van de Pol et al, Gut colonization by methanogenic archaea is associated with organic dairy consumption in children, Frontiers in Microbiology, 2017

- Archaea colonization inversely associated with obese-associated microbiota (inflamed phenotype)

Million *et al*, Obesity-associated gut microbiota is enriched in Lactobacillus reuteri and depleted in Bifidobacterium animalis and *M. smithii*. Int J of Obesity, 2012