BRIGHT

Business Plan

iGEM TU/e 2025

Eindhoven, Oktober 8, 2025

1 | Executive Summary

Bile Acid Malabsorption (BAM) is a significantly underdiagnosed condition that affects millions of patients around the world suffering from chronic diarrhea. Despite its high prevalence, BAM often remains undetected for years due to the lack of accessible and reliable diagnostic tools. This diagnostic gap leads to prolonged patient suffering, inefficient use of healthcare resources, and increased costs across the system.

BRIGHT introduces a novel solution: a synthetically engineered, bioluminescent protein sensor that detects bile acids in stool samples. Upon binding, the sensor undergoes a conformational change that triggers a visible color shift, which can be captured using a smartphone camera. This makes the test simple, non-invasive, and accessible for both patients and healthcare professionals.

Extensive interviews with clinicians, patients, insurers, pharmacies, and business developers confirm the urgent need for improved diagnostics in this field. Patients expressed a strong preference for private, at-home testing due to stigma and discomfort, while clinicians emphasized the importance of scientific validation and integration into existing workflows. Stakeholders agreed that a home-based point-of-care test (POCT) aligns well with user needs but acknowledged that technical, regulatory, and awareness barriers make a direct-to-home launch challenging.

As a result, BRIGHT will follow a phased rollout strategy, starting with a laboratory-based test in secondary care settings. This approach enables clinical validation, supports reimbursement potential, and builds trust among healthcare providers. Once established, BRIGHT will transition toward a home-based POCT, expanding access and empowering patients to seek diagnosis earlier and more comfortably.

This business plan demonstrates not only the desirability of BRIGHT's solution but also its feasibility and viability as a scalable diagnostic innovation with the potential to transform care for BAM and related conditions.

BRIGHT is more than a diagnostic tool; it represents a shift in how BAM is identified, understood, and managed. By combining cutting-edge innovation with accessibility and patient empowerment, BRIGHT strives to illuminate a path forward for millions of patients who have long been left in the dark. With the right support, BRIGHT has the potential to reshape healthcare delivery, accelerate early detection, and ensure that BAM patients receive the timely, accurate care they deserve.

2 | Meet the Team Behind BRIGHT

BRIGHT is driven by a highly motivated and enthusiastic team of two master's students and one bachelor's student from Eindhoven University of Technology (TU/e). Our initiative is strengthened by the support of four additional master's students, one bachelor's student, three professors, and two PhD candidates. We also collaborate closely with several industrial stakeholders who share our vision.

Our mission is to revolutionize the diagnosis and treatment of chronic diarrhea, with a particular focus on BAM. This journey began with a collaboration with Dr. Daniel Keszthelyi, a gastroenterologist at Maastricht University Medical Center (MUMC). During the ideation phase for an iGEM project, Dr. Keszthelyi approached us with a challenge: Could we develop a more accessible and accurate method to detect BAM?

As we delved into the problem, we were struck by the scale of the issue, and even more so by the lack of awareness surrounding it. Our literature review revealed a significant knowledge gap, while interviews with patients and clinicians highlighted the real-world impact and the urgent need for better diagnostic tools. This inspired us to take action and develop an innovative, user-friendly solution to improve BAM detection and ultimately enhance patient care.

Contents

1 | Problem Statement

Around 1 in 20 individuals suffers from chronic diarrhea, and in roughly one third of these cases ***Bile Acid Malabsorption (BAM)*** *is the underlying cause. Despite this high prevalence, BAM often remains undiagnosed for over five years due to limited awareness and the lack of accessible diagnostic tools. This delay not only prolongs patient suffering but also places additional strain on specialized healthcare services and contributes to rising healthcare costs. Insights from healthcare professionals and patients consistently highlight the urgent need for a more practical and accessible diagnostic solution.*

Millions of people worldwide suffer from chronic diarrhea, affecting approximately 3–5% of the world population, which accounts for more than 250 million individuals (1; 2). Among adults with obesity, prevalence even rises to approximately 8.2% (3). With global obesity rates having more than doubled since 1990, the burden of chronic diarrhea is expected to continue rising (4). Although not life-threatening, chronic diarrhea significantly disrupts patients' quality of life, impacting social interactions, work, and mental health. Despite its widespread impact, awareness of this condition remains low, and there is a significant shortage of accessible diagnostic tools.

One major, yet frequently overlooked cause for chronic diarrhea is bile acid malabsorption (BAM), a common but significantly underdiagnosed gastrointestinal disorder. BAM affects millions of patients worldwide and is estimated to be responsible for up to 30% of chronic diarrhea cases, equating to approximately 1–2% of the global population (5; 6). In the Netherlands, this translates to an estimated 160,000–300,000 patients. Although official national figures are lacking, interviews with healthcare professionals suggest that only a few thousand cases are diagnosed each year. This diagnostic gap has profound consequences for patients, healthcare systems, and society at large.

Unnecessary Patient Suffering Currently, patients endure years of medical diagnostics before receiving effective treatment. This unnecessary suffering is reflected in patients' experiences. Many initially receive incorrect diagnoses, such as irritable bowel syndrome (IBS) or functional diarrhea, eventually resulting in repeated tests and trial-and-error treatments, where clinicians and patients try multiple therapies in the hope that something works. Consequently, BAM goes undetected for an average of over five years. During this time, symptoms, delays in correct diagnosis, and repeated hospital visits severely interfere with social life, work, and physical activities. In conducted interviews, patients frequently mentioned suffering from isolation, anxiety, and depression as a result. Additionally, patients shared that feelings of embarrassment prevented them from visiting a general practitioner (GP), leaving them without support at home. Some even resort to self-diagnosis through online research when healthcare providers fail to offer answers. Beyond the psychological toll and disruption to daily life, BAM also poses direct physiological risks such as bile acid deficiency. This deficiency can result in fat malabsorption and impaired absorption of fat-soluble vitamins A, D, E, and K, nutrients essential for bone health, vision, and immune function (7; 8).

Absence of diagnostic tools Despite its impact, current diagnostic methods are impractical, unreliable, or inaccessible, leaving many patients without a viable option, or leading doctors and patients to avoid certain tests (6; 7; 9; 10; 11). This, in turn, causes further diagnostic delays, prolonging patient suffering. Discussions with gastroenterologists and patients have emphasized the urgent need for a diagnostic tool that is simple, affordable, non-invasive, and accessible, preferably at the comfort of their own home.

Overburdened Clinicians The issue of long diagnostic delays not only impacts patients but also places additional strain on clinicians who are already facing high workloads. Across the globe, healthcare systems are struggling with growing waiting lists. In the United Kingdom (UK), the National Health Service (NHS) reported that nearly 3 million individuals are waiting over 18 weeks for treatment, double the number compared to pre-COVID levels (12). Similarly, the Organisation for Economic Cooperation and Development (OECD) highlighted that waiting times for elective procedures in almost all member states have significantly worsened in recent years (13).

In the Netherlands, the average waiting time to see a medical specialist has increased dramatically, particularly for a gastroenterologist. In 2016, the average wait time for a gastroenterologist was 6.2 weeks;

today, it has risen to 17.2 weeks. This trend has prompted Dutch healthcare authorities to raise concerns and urge governmental intervention (14; 15; 16).

Lack of Awareness Despite BAM's significant prevalence in chronic diarrhea, awareness among clinicians and researchers remains limited. Conducted interviews with Dutch GPs revealed a significant knowledge gap within the healthcare system: most only recall BAM from their medical training and rarely consider it in daily practice. Even several gastroenterologists admitted in interviews that BAM is often overlooked as a diagnostic option. Additionally, a comprehensive literature search revealed that fewer than 300 studies on BAM were published on PubMed in the last decade, while oncology-related publications exceeded 150,000(!) in 2025 alone. This stark contrast illustrates the substantial knowledge gap and lack of research focus on BAM.

Economic Consequences Besides its clinical impact, the economic burden of undiagnosed BAM is considerable. Although no direct cost-of-illness studies exist for BAM, evidence from chronic diarrhea indicates substantial productivity losses. Studies estimated indirect costs of approximately €2,100 per employed patient per year, suggesting that BAM alone could plausibly account for hundreds of millions of dollars in lost productivity annually. In the Netherlands, for example, assuming a population of 18 million, an employment rate of 73%, and a chronic diarrhea prevalence of 3–5% (of which 30% is attributable to BAM), the implied indirect costs range between €248 and €413 million per year (17; 18; 19). These figures are illustrative, yet they highlight how the underdiagnosis of BAM translates into a meaningful economic burden for society.

The direct healthcare costs are equally significant. In the United States (US), chronic gastrointestinal disorders, including chronic diarrhea, account for an estimated €300 million annually (20; 21). Given that BAM is responsible for roughly 30% of chronic diarrhea cases, a substantial share of these expenditures can be attributed to delayed or missed BAM diagnoses. Similar patterns have been reported elsewhere: a UK analysis showed that earlier recognition of BAM could save more than €15.5 million annually in diagnostic package-of-care costs alone, excluding the expenses of unnecessary treatments given before the correct diagnosis (6). Together, these findings underline that missed or delayed BAM diagnoses not only prolong patient suffering, but also place a preventable and avoidable financial strain on healthcare systems

In Summary, BAM affects approximately 80 million individuals around the world, yet remains largely overlooked in clinical practice. The absence of accessible diagnostic tools and limited awareness among clinicians and researchers results in diagnostic delays averaging over five years. This results in unnecessary patient suffering and hundreds of millions in avoidable healthcare costs. Insights from interviews with patients and gastroenterologists reinforce the pressing need for a simple, affordable, and accessible diagnostic solution, one that can accelerate diagnosis, improve outcomes, and reduce the economic burden on healthcare systems.

2 | Market Analysis

Market analysis was conducted using the framework outlined in Disciplined Entrepreneurship by Bill Aulet. This approach begins with a broad market scan and gradually narrows to a clearly defined beachhead market. Potential markets were first identified through brainstorming, after which several were selected for deeper investigation and hypothesis generation. These hypotheses were tested through a combination of secondary and primary market research. Based on these insights, a beachhead market was chosen, the total addressable market (TAM) was calculated, and a user persona was developed to capture the needs and context of the target user. Additionally, a comprehensive competitor analysis was conducted to map the current diagnostic landscape and identify strategic positioning opportunities. Although the process is extensive, it provides a comprehensive understanding of both the end user and the market landscape, forming a solid foundation for subsequent steps.

2.1 | Potential Markets

Potential markets were initially identified through brainstorming sessions, followed by exploratory research including literature reviews and interviews with healthcare professionals and business developers. These efforts led to the development of Table 2.1, which outlines 11 distinct market opportunities spanning patient diagnostics, research applications, and adjacent sectors.

A key strategic dimension in this analysis was the distinction between laboratory-based and home-based diagnostic approaches. Laboratory-based tests require clinical infrastructure, professional sample handling, and integration into existing hospital workflows, positioning hospitals and gastroenterologists as primary customers. In contrast, home-based tests enable patients to collect samples independently, offering convenience and accessibility while targeting patients directly as end users. This distinction fundamentally shapes product development, regulatory pathways, reimbursement strategies, and go-to-market approaches. Consequently, markets were evaluated across both modalities where applicable, resulting in distinct customer profiles for each approach.

Table 2.1: Overview of Potential Markets and Customer Segments

Market	Customers
Chronic diarrhea patients (home-based test)	Patients
Gastroenterologists treating patients with chronic diarrhea (laboratory-based test)	Hospitals
Patients living with Crohn's disease	Hospitals/Patients
Fundamental liver research	Universities, Academic Hospitals
Drug screen anti FXR drugs	Pharma companies
Organ on a chip platforms	Universities, Academic Hospitals
Pets with surgeries (Dogs have similar bile acids)	Pet owners
Microbiome classification add on	Viome
Field diagnostics	Remote villages in developing nations
Water quality testing	Remote villages in developing nations
Livestock diagnostics, liver health	Farmers who want to check the liver health of their livestock
Check population health based on sewers	National Institutes of Public Health and Environment (E.g., RIVM)

2.2 | Secondary market research

From this initial list of 11 potential markets, two were prioritized for deeper analysis: chronic diarrhea patients and Gastroenterologists treating patients with chronic diarrhea. This selection was guided by several strategic considerations. First, the team's core mission centers on alleviating patient suffering from chronic diarrhea, directing focus toward diagnostic applications rather than research or veterinary

uses. Since patients living with Crohn's disease can also suffer from chronic diarrhea, this market segment is encompassed within the broader chronic diarrhea patient population and does not require separate prioritization at this stage. Second, practical factors such as geographical proximity, language accessibility, existing relationships with healthcare professionals, and the presence of diagnostic infrastructure influenced feasibility assessments.

2.2.1 | Geographical Market Assessment

With these 2 markets prioritized, it needed to be decided where the beachhead market would be. Since we are entering a relatively unknown market, we looked at countries within the OECD. While OECD countries collectively represent a substantial market for BAM diagnostics, the diversity across 38 member states presented significant operational complexity. Healthcare systems, reimbursement mechanisms, regulatory frameworks, and clinical practice patterns vary considerably across jurisdictions. Navigating this heterogeneity would require extensive resources, localized partnerships, and prolonged timelines for market entry. Given the team's current resource constraints and the need for a focused, executable strategy, the OECD-wide approach was deemed too broad and ambitious for the initial commercialization phase. Instead, the team elected to concentrate on specific countries where impact could be more immediately realized and market learning could inform future expansion. For this, we looked at 4 options based on awareness of BAM and geographical proximity:

- The Netherlands
- Germany
- Denmark
- The UK

The Netherlands and Germany present particularly compelling opportunities. In both countries, awareness of BAM among healthcare professionals remains limited, and existing diagnostic practices are often under-utilized or impractical. This gap represents both a challenge and an opportunity: while market education will be required, there is significant room for a novel diagnostic solution to gain traction. In these healthcare contexts, both laboratory-based and home-based approaches appear relevant. A laboratory-based test could integrate into existing hospital workflows and referral pathways, while a home-based option would cater to patient preferences for convenience and help relieve pressure on overstretched gastroenterology departments. Although Germany represents the larger market, our lack of direct connections with German healthcare professionals limits near-term opportunities. In contrast, our established contacts within the Netherlands provide a stronger starting point, enabling earlier market education and adoption of a new diagnostic tool. Given this, BRIGHT will initially focus on exploring and evaluating both pathways in the Dutch market to determine the most effective route to adoption, while keeping Germany in view as a longer-term opportunity.

Denmark and the UK were prioritized due to their high clinical awareness of BAM and well-established diagnostic pathways, which show evidence of validated market need. However, this market maturity presents a paradox: while demand is confirmed, the laboratory-based testing segment is already saturated. Incumbent solutions are deeply embedded in hospital workflows, creating significant barriers to entry that would demand substantial resources and differentiation to overcome. The home-based diagnostic segment tells a different story. Despite growing patient preference for convenient, accessible testing, no dominant home-based solution has emerged in either market. This underserved segment represents BRIGHT's most viable entry point, offering a differentiation opportunity that sidesteps direct competition with established laboratory providers. This was confirmed by talks with a Danish GP. Therefore, BRIGHT will pursue home-based diagnostics exclusively in Denmark and the UK.

2.2.2 | Final Market Selection

Based on this analysis, BRIGHT identified four priority market segments for initial commercialization focus:

- Laboratory-based test in the Netherlands
- Home-based test in the Netherlands

- Home-based test in Denmark
- Home-based test in the UK

These four segments balance market opportunity with feasibility of entry, align with the team's mission to support chronic diarrhea patients, and provide a strategic foundation for disciplined market entry and future expansion. The data presented in the following sections are based on secondary market research and informed estimates, intended to support strategic decision-making by generating hypotheses and highlighting potential opportunities across these segments. The table below presents an overview of our findings.

Table 2.2: Market segment analysis for BRIGHT.

Market segment name	**Laboratory-based test in the Netherlands**	**Home-based test in the Netherlands**	**Home-based test in Denmark**	**Home-based test in the UK**
End User	Gastroenterologists	Chronic Diarrhea patients	Chronic Diarrhea patients	Chronic Diarrhea patients
Task	Assess suitability for bile acid sequestrant therapy without trial-and-error.	Assess suitability for bile acid sequestrant therapy without trial-and-error and reducing the barrier of going to the GP.	Assess suitability for bile acid sequestrant therapy without trial-and-error and reducing the barrier of going to the GP.	Assess suitability for bile acid sequestrant therapy without trial-and-error and reducing the barrier of going to the GP.
Key Benefit	More accessible than current methods; improves patient experience and recognition through accurate diagnosis.	Less cumbersome for the patients and more accessible than current methods.	Less cumbersome for the patients and more accessible than current methods.	Less cumbersome for the patients and more accessible than current methods.
Urgency of Need	Medium: BAM is often overlooked, making the product less urgent. However, some gastroenterologists have indicated the need for new diagnostics.	Low: There is little awareness of BAM among patients.	Medium: there is little awareness of BAM among patients, but higher than in NL.	Medium: there is little awareness of BAM among patients, but higher than in NL.
Lead Customer	Gastroenterologist specialized in chronic diarrhea.	Patients with chronic diarrhea.	Patients with chronic diarrhea.	Patients with chronic diarrhea.
Willingness to Change	Medium: Some see a need, while others are unaware of the issue.	High: the patients are suffering, and the alternatives are impractical.	Medium: there are SehCAT tests.	Medium: there are SeHCAT tests.
Purchase Frequency	10–20 tests per week.	1–2 tests per patient.	1–2 tests per patient.	1–2 tests per patient.
Customer Concentration	High: specialists are networked and attend conventions.	Low: stigma and normalization limit patient interaction.	Low: stigma and normalization limit patient interaction.	Low: stigma and normalization limit patient interaction.

Market Size (# of End Users)	686 gastroenterologists (22)	~200,000 patients	~60,000 patients.	~700,000 patients.
Estimated Value per User	€100 per test.	€40 per test.	€40 per test.	€40per test.
Competition Alternatives	Fecal bile acid analysis, trial and error treatment.	Fecal bile acid analysis, trial and error treatment.	SehCAT, fecal bile acid analysis, trial and error treatment.	SehCAT, fecal bile acid analysis, quantitative fecal bile acids assay, trial and error treatment.
Required Components	Stool sample collection method, camera/plate reader.	Packaging, self-test cassettes, stool sample collection method, phone camera software, portable light-controlled measurement chamber.	Packaging, self-test cassettes, stool sample collection method, phone camera software, portable light-controlled measurement chamber.	Packaging, self-test cassettes, stool sample collection method, phone camera software, portable light-controlled measurement chamber.
Other Market Considerations	Covered by insurance; part of clinical workflow.	Home-based tests may not be reimbursed or part of the clinical workflow.	Home-based tests may not be reimbursed or part of the clinical workflow.	Home-based tests may not be reimbursed or part of the clinical workflow.
Personal Considerations	Domestic market, close proximity.	Domestic market, close proximity.	Within EU, there is regulatory alignment.	Outside EU, requiring additional regulatory steps.

The market segmentation matrix, shown in Figure 2.1, illustrates both significant overlap and key differences across the three patient markets. Overall, the urgency of need is relatively low, as BAM is not life-threatening. However, the challenges and diagnostic practices vary by country.

In the Netherlands, BAM is often underdiagnosed and underexposed due to the lack of reliable diagnostic alternatives. The most common approach is trial-and-error medication, which can be ineffective and may cause side effects. Interviews with Dutch gastroenterologists and patients confirmed a moderate perceived urgency to improve current practices. However, the NVMDL, the Dutch National Association for Gastroenterology, has expressed full support for our study (See Appendix A), signaling a recognized need and strong potential for adoption in the Netherlands.

In contrast, the UK and Denmark already address the issue using a more costly diagnostic method: the SeHCAT test. Public and clinical awareness of bile acid malabsorption is also higher in these countries, which could facilitate the adoption of new diagnostic markers. Nevertheless, both face significant limitations with the current standard. In the UK, the National Institute for Health and Care Excellence (NICE) has questioned the cost-effectiveness of SeHCAT, while in Denmark, socioeconomic factors limit access to the test (23; 10). Discussions with a Danish GP further revealed that initial diagnostic testing typically occurs in primary care, whereas SeHCAT is reserved for secondary care and often considered a last resort. This practice contributes to additional diagnostic delays. These challenges indicate that both markets may be highly receptive to a more affordable and accessible alternative.

From a development and market entry perspective, however, the Netherlands presents the most favorable starting point. The endorsement from the NVMDL and close contact with gastroenterologists provide credibility, facilitating early adoption, while the lack of competitors leaves a significant market gap. Denmark is a logical second step: although the market is smaller than the UK, the need for improved diagnostics is clear, and EU membership simplifies regulatory approval and certification. Expansion into

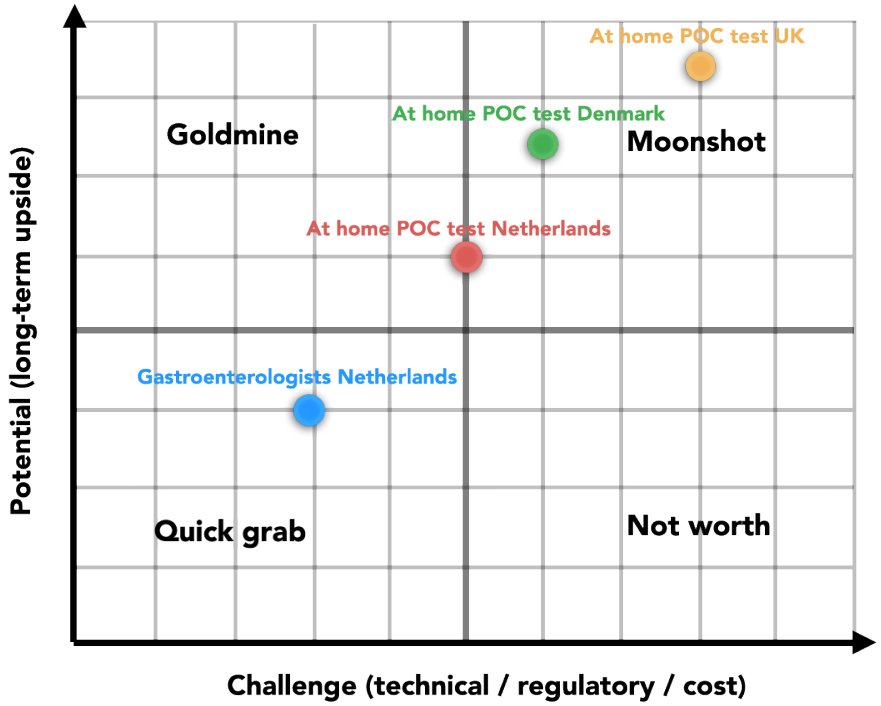

Figure 2.1: BRIGHT market segmentation showing potential versus challenge for various opportunities in the MDL domain.

the UK will be more complex due to differing regulatory requirements and the presence of established alternatives, making it a longer-term opportunity. Implementation into the rest of the OECD completes the longer-term expansion landscape.

2.3 | Primary Market Research

BRIGHT has conducted an extensive primary market study to evaluate whether its diagnostic sensor addresses a genuine need among patients, clinicians, and industry stakeholders. Through a series of interviews with gastroenterologists, GPs, patients, and business experts, we gathered valuable insights into the current diagnostic challenges and expectations for innovation. Across all groups, there was a strong consensus that improved diagnostics are urgently needed, not only to enhance patient well-being but also to reduce inefficiencies within the healthcare system. These findings formed a phased development strategy for BRIGHT.

2.3.1 | User Research

To discover what requirements a new diagnostic device for BAM should have, several clinicians and patients were interviewed. The most relevant results can be found below.

Healthcare professionals play a central role in the diagnostic pathway of chronic diarrhea. GPs serve as the first point of contact for most patients, responsible for initial assessment and referral, while gastroenterologists provide specialized follow-up diagnosis and treatment. Their daily experience, medical expertise, and practical insights are indispensable for evaluating the clinical value, safety, and feasibility of BRIGHT.

The key findings from clinician interviews are summarized below:

- **Main Requirements:** High accuracy, high sensitivity, clear and easy-to-understand results, low costs and simple instructions.

- **Main Advantages:** Faster and more confident decision-making, fewer unnecessary specialist referrals, increased awareness, and standardization in diagnosing BAM.
- **Main Concerns:** Risk of wrong interpretation without proper guidance, combined with potential overreliance on the test as a substitute for comprehensive diagnostics.

Clinicians consistently emphasized the need for robust scientific validation and strict adherence to quality standards. While the test should enable faster and more confident clinical decision-making, they cautioned that it must not replace comprehensive diagnostic approaches. Overreliance on the test could lead to missed diagnoses of other conditions, such as IBS and Crohn's disease.

Patients with chronic diarrhea and suspected or confirmed BAM are at the center of the diagnostic pathway. They experience the full burden of symptoms daily, including social, professional, and mental health impacts. Their lived experience provides unique insights into delays, misdiagnoses, and the practical challenges of managing symptoms. Understanding patients' perspectives is essential to evaluating the clinical utility, accessibility, and usability of BRIGHT. Patients can identify unmet needs, highlight barriers in current diagnostic approaches, and provide guidance on how a rapid, non-invasive test could improve quality of life and reduce diagnostic uncertainty.

Key findings from patient interviews include:

- **Main Requirements:** Simplicity, affordability, non-invasiveness, and accessibility. Several patients further expressed a strong preference for a home-based test, but not all patients shared this opinion.
- **Main Advantages:** Faster diagnosis could reduce years of uncertainty, improve quality of life, and alleviate frustration and anxiety.
- **Main Concerns:** False reassurance or unnecessary worry if the test gives invalid outcomes or is indecisive.

Patients consistently highlighted the value of early and accurate diagnosis. While a majority preferred the convenience of home testing, others felt more reassured by in-clinic testing, suggesting that offering both options could enhance adoption. Their main concern was an invalid or indecisive test.

2.3.2 | User Needs

Table 2.3 summarizes the key requirements identified by clinicians and patients during user research. Based on these insights, a new diagnostic device for BAM should prioritize delivering accurate results and ensuring ease of use, while accelerating clinical decision-making. Accessibility and affordability are considered important by both groups, though these should not have the highest priority. Clinicians are generally flexible regarding the test setting, acknowledging both the benefits and limitations of laboratory-based and home-based testing. Most patients expressed a preference for home-based testing due to its convenience and privacy, although some favored in-clinic testing for reassurance and support. A home-based point-of-care test (POCT) could effectively meet the needs of both patients and clinicians, offering patients the comfort of testing at home while maintaining clinical involvement to ensure proper interpretation and follow-up. It is therefore important to note that a positive test result for BAM should not exclude other gastrointestinal conditions, such as IBS or Crohn's disease, underscoring the need for comprehensive diagnostic oversight.

2.3.3 | Stakeholder Feedback

To get a clear view of how a test can be implemented into current healthcare systems with these requirements, we have conducted several interviews with other stakeholders, such as pharmacies, insurers, and business developers. Key findings from these talks are represented below.

Pharmacy A pharmacy staff member at City Pharma was interviewed to explore what role pharmacies could play in the communication and distribution of a diagnostic tool such as BRIGHT. She explained the limits of pharmacy practice in the Netherlands, as pharmacists cannot prescribe medication themselves. All treatment pathways for specialized products require a referral or prescription from a GP. Over-the-counter sales are possible for common products, but these are also widely available at drugstores or grocery stores.

Table 2.3: Requirements Tests

Needs	Clinicians	Patients
Trustworthy	High	High
Ease of Use	High	High
Faster Diagnosis	High	High
Accessible	Medium	High
Affordable	Medium	Medium
Home-Based Test	Medium	Medium
Laboratory-based Test	Medium	Low

Government We further interviewed a representative from VGZ, a major Dutch health insurance provider. Our goal was to understand how diagnostic innovations, such as a laboratory-based test and home-based POCT, could potentially be reimbursed within the healthcare system to improve market feasibility. The representative explained that reimbursement in the Netherlands depends strongly on the position of a diagnostic test within the care pathway. Tools introduced directly at the GP or first-line care are more difficult to get reimbursed, as insurers require strong evidence of clinical utility and cost-effectiveness. By contrast, introducing a new diagnostic test first in academic hospitals, then regional hospitals, and only later in primary care is a more realistic trajectory for achieving coverage.

Industry To assess the commercial viability and market entry strategy for BRIGHT, we interviewed several business developers from organizations including The Gate (the TU/e start-up and technology transfer office), Unitron, Duofor, Spotlight, and an independent regulatory expert specialized in healthcare innovation. Although each expert brought a unique perspective, their views on market dynamics were largely aligned. The consensus was that launching BRIGHT directly as a home-based POCT would face significant challenges. Technical and regulatory barriers are considerably higher for home-based diagnostics compared to laboratory-based solutions, as further discussed in Section 6. Additionally, awareness of BAM among GPs and patients is low within the Netherlands, as highlighted in Section 1, which could hinder early adoption. Introducing a laboratory-based test within clinical settings before moving on to a home-based POCT could offer the solution. This approach should allow for scientific validation, build credibility among healthcare professionals, and lay the groundwork for broader awareness. Once this is established, BRIGHT can gradually transition towards a home-based POCT, aligning with patient preferences while maintaining clinical oversight.

To summarize, the insights gathered from clinicians, patients, insurers, pharmacies, and business developers all point to a strong need for improved diagnostics in the field of chronic diarrhea, particularly for conditions like BAM. While a home-based POCT aligns more closely with patient preferences, stakeholder feedback and system constraints indicate that a phased rollout, starting with a laboratory-based test in secondary care, is the most feasible and desirable path forward. This strategy ensures clinical validation, supports reimbursement potential, and builds the foundation for future expansion into primary care and home settings.

2.4 | End User Persona

A user persona for the beachhead market was developed based on interviews with gastroenterologists to gain deeper insight into their needs and behaviors (see Table 2.4). Since the gastroenterologist segment was selected through the market segmentation matrix, the persona focuses on a clinician who is experienced in the field and receptive to innovative techniques and solutions that can enhance patient care.

Table 2.4: User Profile for Beachhead Market

Category	Description
Demographics	Works in an academic hospital in the Netherlands. Highly educated, generally conservative in clinical practice but open to innovative solutions that demonstrate clear value. Annual income is approximately €100,000.
Psychographics	Deeply motivated by improving patient outcomes, though often overwhelmed by administrative burdens and long working hours. Experiences stress due to high responsibility and fears of clinical errors. Prefers actionable solutions over theoretical discussions and values efficiency in clinical workflows.
Proxy Products	Commonly uses calprotectin tests for inflammation, psychotherapy for IBS management, surgical tools when necessary, and occasionally prescribes bile acid sequestrants.
Watering Holes	Engages with peers and experts through hospital networks, medical congresses, and professional consultations.
Day in the Life	The day begins early with coffee and breakfast, followed by hospital rounds, patient consultations, and team check-ins. Lunch is typically brief. Afternoons are spent on administrative tasks and follow-ups. Evenings are reserved for family time, household responsibilities, and relaxation (E.g., watching Netflix).
Priorities	■ Curing patients (Weighting: 35%) ■ Enhancing patient wellbeing (Weighting: 25%) ■ Maintaining work-life balance (Weighting: 20%) ■ Efficient time management (Weighting: 10%) ■ Controlling costs (Weighting: 10%)

2.5 | SOM, SAM, TAM

SOM The Serviceable Obtainable Market (SOM) is calculated based on the persona described in Section 2.4, as these are most likely to adopt innovative diagnostic tools. According to the Dutch National Association for Gastroenterologists, there are 686 registered gastroenterologists in the Netherlands, of which 133 are affiliated with academic hospitals (22; 24). Each gastroenterologist sees approximately 150 patients per week, with an estimated 10 suffering from chronic diarrhea (25). This results in a weekly demand of around 1,330 tests. However, considering that only about 25% of these patients are new cases, the realistic weekly demand is closer to 333 tests (26). Assuming a price of €100 per test (see Section 4), the annual SOM is estimated at approximately €1.7 million.

SAM The Serviceable Available Market (SAM) includes all chronic diarrhea patients treated by gastroenterologists across the Netherlands. With 686 active specialists and using the same patient estimates, the total weekly demand would be around 3,430 tests. This translates to an annual SAM of approximately €9 million. Furthermore, according to the Dutch 'Capaciteitsorgaan', the number of gastroenterologists is expected to grow: while 125 are projected to retire over the next six years, 200 new specialists are anticipated to enter the field within the next two years (27). Along with the growing population, this trend suggests a growing SAM in the near future.

TAM The Total Addressable Market (TAM) considers all individuals in the Netherlands suffering from chronic diarrhea, regardless of whether they seek specialist care. As outlined in Section 1, this group represents approximately 3–5% of the population, equating to 540,000–900,000 individuals (28). For broader accessibility, such as availability in drugstores, we assume a lower price point of €40 per test.

This results in a TAM ranging from €21 million to €36 million.

We have chosen to primarily focus on the Dutch market for now, as this is the most feasible and realistic approach for our team. International expansion will result in a significantly larger market, with the TAM in the OECD countries estimated to be over €2 billion.

2.6 | Competitors

Despite limited awareness of BAM among healthcare professionals, several diagnostic approaches exist within the current landscape. However, each faces significant barriers related to accessibility, practicality, or regulatory approval, creating substantial gaps in the diagnostic pathway that many patients experience. The following sections outline the established methods, emerging solutions, and the clinical reality that unfolds when adequate diagnostics are unavailable.

2.6.1 | Established Methods

Currently, there are two main methods for diagnosing BAM, though both face considerable practical limitations that restrict their widespread use.

SeHCAT Test The SeHCAT test is widely regarded as the gold standard for BAM diagnosis in Europe. The test uses a radiolabeled bile acid analog (selenium-75-labeled homocholic acid taurine) measured through gamma camera scans to assess bile acid retention over seven days. The procedure requires patients to ingest a capsule, followed by two hospital visits: one scan three hours post-ingestion and another seven days later. The test demonstrates strong diagnostic performance, with sensitivity of approximately 87% and specificity of approximately 93%, and can classify disease severity based on retention levels. However, several factors severely limit the SeHCAT test's accessibility. The procedure requires specialized nuclear medicine facilities, exposes patients to radiation, necessitates multiple hospital visits over a week, and involves substantial costs. Most critically, SeHCAT is only widely available in the UK and Denmark. It has not been approved in many other global markets, such as the US and Japan, leaving a significant diagnostic gap in these regions that BRIGHT could address (7; 11).

Fecal Bile Acid Analysis Fecal bile acid analysis involves collecting stool samples over 48 hours while maintaining a fat-rich diet. Samples are then analyzed for bile acid content using liquid chromatography-mass spectrometry (LC-MS) or enzymatic assays. While the test can provide clinically useful information and is relatively inexpensive from a materials perspective, it suffers from lower accuracy compared to SeHCAT and presents significant practical challenges (9; 11). The requirement for a 48-hour stool collection under dietary restrictions creates a substantial patient burden. Interviews with gastroenterologists in the Netherlands revealed that clinicians consider this test impractical and even inhumane for patients, leading them to rarely prescribe it. Patients confirmed this, describing the test as highly impractical and distressing, with many expressing strong reluctance to undergo the procedure. Additionally, the test lacks standardization across laboratories, with varying cutoff values that complicate result interpretation and clinical decision-making.

2.6.2 | Emerging Solutions

Quantitative Fecal Bile Acids Assay A more recent entry to the market is the quantitative fecal bile acids assay, which represents a significant improvement in convenience over the 48-hour collection method. This approach requires only a single stool sample from patients, measuring total bile acid content in that specimen. The test is performed in laboratory settings and can deliver results within approximately 9 minutes, offering a rapid turnaround that could support clinical decision-making (29; 30). Despite these advantages, the quantitative assay faces a critical barrier: extremely limited market availability. The test is currently available only in the UK and has not yet secured the regulatory certifications necessary for marketing in other countries, including the US and Europe. This geographic restriction severely limits its potential to address the global diagnostic gap for BAM. Additionally, the test is not suitable for a home-based test, leaving most patients and clinicians without access to this more convenient testing option.

2.6.3 | Current Clinical Practice

The limitations of existing diagnostic methods, whether due to unavailability, impracticality, or patient burden, create a significant gap in the clinical pathway for BAM. This results in clinicians often resorting to an alternative approach that bypasses definitive diagnosis.

Trial and Error Medication Discussions with gastroenterologists in the Netherlands revealed a common practice: initiating empirical treatment without a confirmed diagnosis, with the hope of relieving symptoms through sequential medication trials. This trial-and-error approach involves prescribing bile acid sequestrants or other therapies and observing patient response over several months before switching to alternative medications if symptoms persist. While this strategy occasionally achieves symptom relief relatively quickly, it more often results in prolonged periods of uncertainty for patients. During these trials, patients are exposed to multiple unnecessary medications, each carrying potential side effects. Incorrect dosing can also lead to complications such as constipation, adding to the patient's burden. Beyond the physical health risks, patients described this process as mentally challenging, characterized by frustration, anxiety, and a sense of abandonment by the healthcare system. From an economic perspective, while individual medications may appear inexpensive, the cumulative costs of trial-and-error treatment escalate over time as patients cycle through multiple therapies. Moreover, this approach fails to provide the diagnostic certainty that could enable targeted, efficient treatment from the outset. The prevalence of trial-and-error medication as a clinical practice underscores the severity of the diagnostic gap. It reflects not a preferred clinical strategy, but rather a workaround born from the absence of accessible, practical diagnostic tools, precisely the unmet need that forms the basis for BRIGHT's value proposition.

To summarize, the current competitive landscape for BAM diagnostics is characterized by fragmented availability, practical barriers, and significant unmet need. Established methods like SeHCAT and 48-hour fecal bile acid analysis offer diagnostic value but remain inaccessible or impractical for most patients globally. Emerging solutions such as the single-sample quantitative assay show promise but face regulatory and geographic constraints, along with the requirement for specialized laboratory equipment that fundamentally prevents its evolution into a patient-administered self-test. In the absence of viable diagnostic options, clinicians resort to empirical treatment approaches that prolong patient suffering and increase healthcare costs. This landscape creates a clear opportunity for an accessible, accurate, and patient-friendly diagnostic solution that can address the substantial gaps left by existing methods.

3 | Value Proposition

BAM is currently underdiagnosed due to the limited awareness, high costs, and logistical challenges of existing diagnostic methods, such as the SeHCAT test and fecal bile acid analysis. This leaves many patients with chronic diarrhea untreated or misdiagnosed, leading to reduced quality of life and increased healthcare costs.

BRIGHT proposes a new detection method: a synthetically engineered, bioluminescent, protein sensor. By binding to bile acids within a person's stool sample, a conformational change will take place within the protein, triggering a color change. This approach requires only a single stool sample, and the color change can be easily captured using modern smartphone cameras, making our product simple and accessible for both patients and healthcare professionals. Our goal is to develop this sensor initially into a **laboratory-based test** to validate clinical performance and build credibility within the healthcare system, before advancing it into a **home-based point-of-care test (POCT)**. Discussions with industrial stakeholders confirmed that this phased pathway is the most technically and commercially feasible route to market. Simultaneously, patient and clinical interviews revealed that a home-based POCT represents the most desirable solution, addressing critical barriers in the current diagnostic landscape.

By enabling private, at-home screening, BRIGHT not only empowers individuals to seek diagnosis without discomfort or stigma but also accelerates access to care and improves early detection across the healthcare system. Conversations with gastroenterologists confirmed this, emphasizing that a home-based POCT would reach significantly more patients, and do so faster, as it bypasses the current lengthy diagnostic trajectory. The clinical relevance and potential impact of this innovation have been recognized by the NVMDL, which has openly declared its support with an official letter of support (see Appendix A).

Compared to current methods, BRIGHT offers the following unique selling points:

- **Accessibility:** The BRIGHT home-based POCT can be implemented in standard healthcare systems without the need for specialized nuclear imaging or advanced chromatography. It will also lower patient boundaries for testing, increasing the diagnostic reach. By streamlining the diagnostic process and reducing unnecessary referrals, BRIGHT will alleviate the pressure on the healthcare system, particularly on overburdened gastroenterologists.
- **Affordability:** BRIGHT's home-based POCT is expected to cost approximately €40, a significant reduction compared to other alternatives. This lower cost makes BAM diagnostics more accessible to a broader range of healthcare providers, including hospitals, general practitioners, and drugstores.
- **Economic impact:**
- **Economic impact:** Studies have shown that earlier diagnosis could save €248–413 million per year in lost productivity costs in the Netherlands alone. Additional savings would accrue from avoided healthcare costs, including unnecessary treatments, repeated diagnostic procedures, and specialist referrals.
- **Scalability:** The simplicity of the BRIGHT sensor makes it relatively easy to produce and implement it at a large scale. No special equipment is necessary, which simplifies the production process.

By lowering diagnostic barriers, BRIGHT enables earlier and more accurate identification of BAM, improving patient outcomes while reducing costs for healthcare providers and insurers. The technology opens the door to home-based diagnostics, aligning with the healthcare system's shift toward decentralization and patient empowerment.

> ***BRIGHT is not just introducing a new diagnostic tool, we're redefining how gut health is approached, diagnosed, and managed.***

4 | Marketing Strategy

The previous sections have outlined the key requirements for successful market implementation of BRIGHT's home-based POCT, including clinical validation, reimbursement potential, and ease of use. BRIGHT's market entry strategy is designed to align with these factors, beginning with a laboratory-based diagnostic test and evolving into a widely accessible home-based POCT.

To facilitate smooth market adoption, it is essential to build awareness among patients, clinicians, and relevant governmental bodies. Recognizing this, BRIGHT has already initiated targeted awareness campaigns and plans to expand these efforts throughout the development process. These campaigns aim to highlight the clinical relevance of BAM, the limitations of current diagnostic approaches, and the value of BRIGHT's solution in improving patient outcomes.

4.1 | Market Position

In the Dutch healthcare system, as in many OECD countries, patients typically consult a GP before being referred to a specialist (13). This gatekeeping model creates a bottleneck for conditions like BAM, where awareness is low and accessible diagnostic tools are limited. Stakeholder feedback confirmed that a direct rollout as a home-based POCT would face significant barriers as a result of this system. To address this, BRIGHT will first introduce a laboratory-based test in academic and regional hospitals. Once clinical utility is established and awareness increases, BRIGHT will transition toward a home-based POCT.

The laboratory-based test will be sold to hospitals, where gastroenterologists can prescribe it to chronic diarrhea patients who have reached second-line care. The expected price point is €100, which, based on discussions with gastroenterologists and a representative from VGZ, is considered acceptable within hospital budgets. Inclusion in health insurance packages will be pursued to encourage adoption.

The home-based POCT will be available both by prescription from general practitioners and over-the-counter in pharmacies and drugstores. A lower price point of €40 will be targeted to ensure affordability and broad access, especially for patients who may not yet have reached specialist care.

Together, this will make diagnostics more accessible and faster for patients, reduce unnecessary referrals, and improve access to care. Educational outreach and pilot studies will support this transition and ensure safe and effective use in primary care settings.

This approach allows for:

- **Controlled** clinical validation and data collection.
- **Easier integration** into existing laboratory infrastructure.
- **Increased awareness** among clinicians and patients.
- **Stronger positioning** for reimbursement and regulatory approval.

Although the initial hospital-based phase may generate less revenue, the long-term potential of a home-based POCT offers broader market reach and increased income opportunities, as shown in Section 2.

4.2 | Adoptation strategy

As discussed in Sections 1 and 2, awareness of BAM is essential for successful adoption. Patients, general practitioners, and gastroenterologists must recognize BAM as a serious and underdiagnosed condition. To support this, BRIGHT is actively engaging with healthcare professionals to raise awareness about BAM, its prevalence, and the limitations of current diagnostic methods.

Initial outreach includes conversations with both general practitioners and gastroenterologists. Additionally, an article about BAM and BRIGHT has been published in the magazine of Crohn&Colitis NL, the Dutch patient association for digestive diseases, representing over 90,000 patients. BRIGHT plans to maintain close collaboration with the association and publish additional articles throughout the

development process. Additionally, this work has been presented at startup competitions and industry networking sessions.

To reach a broader patient network, BRIGHT will explore additional outreach channels. Through our connection with the NVMDL, we aim to generate enthusiasm among gastroenterologists for our diagnostic solution. Engagement with the Dutch national associations for GPs (NHG and LHV) has been initiated to advocate for BAM's inclusion in standard diagnostic guidelines in first-line healthcare. BRIGHT's solution will be promoted at medical congresses to further build clinical support.

Beyond clinical awareness, it is equally important that healthcare providers and governmental bodies, such as the National Institute for Public Health and the Environment and Municipal Health Service (RIVM and GGD in the Netherlands), recognize BAM as a significant public health issue. By clearly communicating the economic burden of undiagnosed BAM, we aim to demonstrate the value of early and accurate diagnosis and secure recognition and support from these stakeholders. We plan to initiate these conversations early in the development process.

Communication strategies will be tailored to different stakeholder groups, including clinicians, hospitals, pharmacies, and patients, to ensure relevance and impact. Messaging will highlight the current gaps in the diagnostic market and value BRIGHT's ease of use, affordability, and potential to improve patient outcomes.

5 | SWOT Analysis

A SWOT analysis was done in order to outline internal strengths and weaknesses, as well as external opportunities and threats that may influence the development and market adoption of BRIGHT's diagnostic solution. Table 5.1 presents a strategic overview of BRIGHT's current position. Each element is briefly discussed below and further elaborated in the relevant sections of this business plan.

Table 5.1: SWOT analysis for BRIGHT's bile acid sensor

Strengths	**Weaknesses**
• Innovative bioluminescent sensor technology • Widely accessible and user-friendly • Cost-effective alternative to competitors • Strong academic and clinical partnerships • Intellectual property protection secured through provisional patent filing	• Early-stage development with no clinical validation • Regulatory approval pending • Limited funding and financial resources • Gaps in business and regulatory expertise
Opportunities	**Threats**
• Gap in market • Rising demand for home-based diagnostics • Potential expansion to other diagnostic devices	• Low awareness of BAM among clinicians and patients • Risk of limited market adoption • Emerging competitors with similar technologies

Strengths BRIGHT introduces an innovative bioluminescent sensor designed to improve BAM diagnostics. As discussed in Section 3, this technology will significantly improve accessibility and user-friendliness compared to existing methods. Additionally, it will offer a cost-effective alternative to current competitors, addressing key barriers in the diagnostic landscape. Our strong academic and clinical partnerships, detailed in Section 8, further provide a solid foundation for development and validation, while helping mitigate current gaps within the team's capabilities. Intellectual property protection has also been secured through a provisional patent filing, providing a twelve-month window to refine the technology before submitting a full patent application.

Weaknesses Since BRIGHT is in the early stages of development, the sensor still requires optimization and clinical validation. We are confident in the feasibility of successful development as a result of our feasibility study (see Section 6). Regulatory approval is another hurdle as BRIGHT has no EU In Vitro Diagnostic Regulation (IVDR) certification yet. The regulatory landscape is complex and demanding, which could delay market entry or increase costs. In particular, the fabrication and approval process of the home-based POCT presents unique challenges that could complicate compliance with medical device regulations. However, our team has initiated contact with regulatory experts to map out the necessary steps, which are discussed in Sections 6 and 9. This should prepare us and prevent potential regulatory delays. Funding is currently also limited. While we have sufficient resources for initial development, we lack the capital to launch a full-scale startup. We are actively seeking funding opportunities, as described in Section 11, and are confident that through existing partnerships and future funding rounds, enough money will be obtained for market entry. Lastly, our team is currently focused on technical development and lacks expertise in business and financial strategy. We are addressing this by planning to extend our team and leveraging external support from stakeholders, as noted in Section 8.

Opportunities As mentioned in Sections 1 and 2.6, there is a lack of accessible diagnostic tools for BAM on the market. This clear market gap presents a perfect opportunity for BRIGHT to address with its home-based POCT. This opportunity is further amplified by the growing demand for home-based diagnostics, driven by healthcare workforce shortages and a shift towards patient-centered care (31; 32). The market for at-home testing is projected to grow at a Compound Annual Growth Rate (CAGR) of 4.8% over the next decade, underscoring the potential for BRIGHT to make a significant impact (33; 34). Interviews with patients and clinicians complemented this market growth. Beyond BAM, our sensor

platform also holds promise for broader diagnostic applications. While these are not part of our initial focus, they represent a promising avenue for future expansion and academic collaboration.

Threats A major threat to BRIGHT is the current awareness of BAM, as low awareness among both patients and healthcare professionals could hinder market adoption. This challenge is addressed in our market strategy and outreach plans (see Sections 4 and 6). Moreover, BRIGHT faces competition from existing diagnostic methods as well as emerging research looking into new diagnostic pathways for BAM, as discussed in Section 2.6. While these existing methods have notable limitations, such as high costs, limited accessibility, or discomfort for patients, our solution must demonstrate clear advantages in accuracy, user convenience, and affordability to differentiate ourselves.

6 | Feasibility

The feasibility of BRIGHT's test is assessed across two distinct phases: an initial laboratory-based test and a future home-based POCT. Each phase is evaluated for technical feasibility, adaptability within the healthcare system, and regulatory compliance. This phased approach allows BRIGHT to first build a strong scientific and operational foundation before scaling to a consumer-facing solution.

6.1 | Laboratory-Based Test

The first phase focuses on diagnosing in clinical laboratories, conducted in collaboration with the NVMDL and academic hospitals. During the first phase, BRIGHT aims to produce a laboratory-based diagnostic test for BAM that offers improved ease of use and accessibility compared to existing alternatives. The test will be introduced through gastroenterology clinics, leveraging the fact that gastroenterologists are already familiar with BAM and frequently encounter affected patients. Through interviews with gastroenterologists and a site visit to the Star-SHL laboratory, we gained practical insights into clinical workflows and laboratory integration requirements..

6.1.1 | Technical Feasibility

The BRIGHT sensor is based on previous literature that explores the use of the FXR bile acids receptor, which is a nuclear receptor that regulates bile acid synthesis and triglyceride levels in the body. In this study, a modified version of the FXR receptor was combined with 2 fluorescent domains to track bile acids in cells (35). While effective for research purposes, this approach uses fluorescent proteins, which need excitation in order to fluoresce. Still, the altered FXR domain was a solid foundation for our sensor as the receptor undergoes conformational change when binding to bile acids, creating a secondary binding pocket. This binding pocket, which binds a specific protein domain, can be used to modulate affinity interactions by shifting the balance of a system.

Additionally, over the past decade, extensive research has been conducted on NanoLuc luciferase and its split variants. These systems enable the dynamic activation and deactivation of sensor constructs through affinity-based interactions (36). Building on these two principles, BRIGHT has developed a novel system utilizing three distinct split-NanoLuc components to create an affinity-driven switching mechanism, triggered by bile acid binding to the FXR receptor.

Upon ligand binding, the FXR receptor undergoes conformational changes that activate the split-NanoLuc system, resulting in a detectable color change. This visual output can currently be measured with a plate reader or a phone camera and serves as a reliable indicator of the biological interaction. The technique has been successfully validated in proof-of-concept studies, demonstrating its potential for diagnostic applications.

These concepts have currently only been tested in scientific research, resulting in limited data. This means that most data will need to be gathered during initial lab tests in cooperation with clinical tests. Ongoing experiments with the BRIGHT sensor show measurable stool bile acid concentrations as low as 10-30 µM. Chronic diarrhea patients are expected to have bile acid concentrations in the low mM range, which currently corresponds to where the sensor switches color. Compared to healthy patients, this is estimated to be around 10 times more, depending on the severity of BAM. Titration experiments have allowed us to determine the sensor's limit of detection and dynamic range (8; 9). The current limit of detection of the sensor is between 1 and 10 µM, which is a thousand times lower than where we need to measure. Determination of the overall sensitivity and specificity will require patient data, but this does not represent a major barrier. Collaborations with Dr. Daniel Keszthelyi, a gastroenterologist from Maastricht University Medical Center (MUMC), have already been set up to obtain clinical samples, with a call for healthy controls being prepared in due time. Altogether, these findings demonstrate a strong scientific basis for the feasibility of the laboratory-based test.

6.1.2 | Operational Adaptability

Having established the technical basis, we evaluated the feasibility for implementation in clinical laboratories. For our test, stool samples have to be diluted and processed using standard pipetting techniques. *E. coli* is used to produce the bioluminescent protein sensor, which can be grown and harvested under

standard laboratory conditions. No complex coupling reactions are necessary in this process. At a small scale, the process is straightforward for trained staff and well-suited to clinical testing phases. Scaling up may require additional equipment, but because *E. coli* can produce high protein yields, much of the production can still be managed at a smaller scale while meeting increased demand. The main requirements for this entire process are the presence of a plate-reader for luminescence measurements and properly trained employees. Proper freezing capacity is also essential to ensure sample integrity, since bile acids are not very stable at room temperature, where they can be converted to secondary bile acids or broken down after several hours. They remain stable only for several days at 2–8 °C, for a few months at –20 °C, and require –80 °C storage for long-term preservation (37; 38). These requirements are all standard in clinical laboratories, making transfer from the research setting to clinical practice highly feasible.
For production, E.Coli bacteria are used for creating the bioluminescent protein sensor, which can be grown and harvested in a biochemical laboratory. The production process at a smaller scale is very straightforward and easy to perform when done by trained employees, which is good for the feasibility in the phase of clinical tests. For larger-scale production, some extra equipment might be necessary, but a large part of production can be done at a small scale, even with higher demand, since high yields of protein expression can lead to high amounts of tests produced.

6.1.3 | Regulatory Feasibility

To bring the BRIGHT sensor to the European market as a laboratory test, compliance with the EU's IVDR is required (39; 40; 41). This process involves proper device classification and implementation of a certified Quality Management System (QMS). The laboratory-based test is expected to be classified under Class B risk level, which would require certification according to ISO 13485, as well as performance evaluation studies to demonstrate safety, reliability, and clinical effectiveness. Following these certifications and evaluations, BRIGHT will obtain CE marking to enable market authorization (42; 43).

To ensure full regulatory compliance, we are already engaging with experienced regulatory advisors who will be guiding us through the documentation and certification procedures. With their support, BRIGHT is confident in its ability to obtain all necessary certifications and meet the regulatory standards required for market entry without delay.

6.2 | Home-Based POCT

The second phase aims to broaden BRIGHT's reach by targeting patients suffering from chronic diarrhea who may not yet have access to specialized diagnostics. By introducing a clinically validated home-based POCT, we seek to significantly reduce the time to diagnosis and empower patients to take the first step toward treatment without needing immediate specialist referral.

The BRIGHT home-based POCT is designed for direct application to stool samples, delivering a clear and interpretable result. This result will be securely transmitted to the patient's GP, who will assess the outcome and determine appropriate follow-up care. It is important to emphasize that a positive result for BAM does not exclude other gastrointestinal conditions. Therefore, GPs should continue to conduct standard diagnostic procedures to rule out other gastrointestinal conditions such as Crohn's disease and IBS. In the meantime, however, BAM symptoms can be treated empirically.

6.2.1 | Technical Feasibility

For a home-based POCT, results must be robust, even under imperfect user handling conditions. This requires miniaturizing the test to eliminate the need for specialized laboratory equipment and minimizing sample preparation steps. User instructions must be intuitive to reduce error rates, while results should be measurable using a standard smartphone camera to maximize accessibility. To achieve these objectives, BRIGHT will collaborate with pharmacies and companies experienced in developing home-based tests to ensure technical feasibility. Throughout development, usability testing with laypeople will be conducted to validate whether the device meets the requirements for a reliable home-based test. Furthermore, a compact, smartphone-compatible measurement box is needed to eliminate background light interference and ensure accurate colorimetric readings across different phone models. BRIGHT is already exploring this solution as part of its development efforts. Bringing the full vision to life will require a new comprehensive engineering cycle with iterative design, testing, and refinement.

6.2.2 | Operational Adaptability

Recognizing that a POCT can be challenging for some patients, BRIGHT aims to simplify the process by developing a smartphone application that provides step-by-step guidance. This app will use the phone's camera to quantify test results and securely transmit them to the patient's GP, who can then determine the appropriate follow-up. Although development of the app has yet to begin, BRIGHT believes it will significantly enhance the overall value of its diagnostic solution.

The goal is to incorporate the home-based POCT into sustainably disposable kits that can be distributed through pharmacies and general drugstores such as the Etos in the Netherlands. To enable broad adoption, the home-based POCT must be compact, portable, and compatible with modern smartphones. Packaging should be optimized for shelf placement and designed to ensure a long shelf life. To proactively address these challenges, BRIGHT plans to initiate early discussions with Ahold Delhaize, the parent company of Etos.

6.2.3 | Regulatory Feasibility

Lastly, home-based POCTs are subject to stricter diagnostic regulations under the EU's IVDR. Unlike the laboratory-based test, a home-based POCT is classified as a Class C device. This higher classification entails not only ISO 13485 certification for a QMS, but also more rigorous clinical validation. Specifically, manufacturers must demonstrate that untrained users can safely and effectively operate the test through comprehensive usability studies. In addition, Class C devices are subject to enhanced scrutiny by a Notified Body, resulting in longer approval timelines, increased development costs, and stricter post-market surveillance obligations (42).

To conclude, the current feasibility for launching a laboratory-based test is relatively high. BRIGHT is confident in its ability to bring such a test to market within a reasonable timeframe (see Section 9). The test builds on established literature, and initial proof-of-concept studies have validated the underlying technique. Since no specialized equipment is required, integration into clinical laboratories is expected to be straightforward. In parallel, BRIGHT has initiated discussions with regulatory advisors to ensure a timely preparation and submission of the necessary documentation.

While the home-based POCT presents additional challenges, such as a more complex technical basis and stricter regulatory requirements, BRIGHT remains confident in the long-term feasibility of a home-based POCT for BAM, both technically and commercially. The phased development strategy provides a solid foundation for this future expansion, enabling a more gradual and manageable entry into the home-testing market.

7 | Economic Viability

To successfully enter and grow within the market, it is essential to scale up production. The overarching objective is to make this test accessible to all patients suffering from chronic diarrhea, including those with IBS, Crohn's disease, post-surgical intestinal complications, and BAM. BRIGHT's economic viability rests on two pillars: Immediate profitability through the laboratory-based test and a future growth opportunity with the home-based POCT. We first evaluate the laboratory-based test as the foundation for short-term revenue, and then outline the potential of the home-based POCT to demonstrate long-term scalability.

7.1 | Laboratory-Based Test

As outlined in Section 2, the beachhead market focuses on patients who have reached second-line care at gastroenterologists in the Netherlands, as they demonstrate the highest awareness of the problem.

To estimate production costs, we analyzed a techno-economic study on large-scale enzyme production in *E. coli* and incorporated stakeholder feedback (44). Our sensor proteins can be expressed in *E. coli* without complex coupling reactions, keeping production relatively straightforward. Ferreira et al. (2018) reported a production cost of approximately €269 per kilogram of enzyme at high-throughput scale. At the minimum required working concentration of 5 nM, one kilogram of protein dissolved in assay buffer yields over two million milliliters of sensor solution, sufficient for approximately two million tests (1 mL per test, including allowance for spillage). This translates to an enzyme cost per test of less than €0.0001.

Protein costs represent only a fraction of total costs, though. Approximately 50% of overall production costs arise from labor and facility overhead (44). While smaller production runs result in higher per-unit costs, our process requires limited specialized equipment, so we expect the cost per test to remain below €1. Given the relatively small initial market and the fact that clinical tests priced around €100 are often reimbursed, a selling price around €75–100 for the laboratory-based test would be reasonable. This pricing would yield a profit margin of approximately €74 to €99 per test, corresponding to a profit of over €1–1.5 million per year for the SOM, and over €10–15 million per year for the SAM.

In the first few years, such profits are necessary to cover laboratory and office equipment, repay external investments, and reinvest in further development. The profit margin further ensures that BRIGHT remains economically viable in the first phase.

7.2 | Home-Based Test

The second phase focuses on scaling to home-based POCTs. While protein production costs remain the same, additional costs arise from packaging and the compact, smartphone-compatible measurement chamber. As these can be produced using inexpensive materials such as cardboard and dark plastic, total production costs are not expected to exceed €10 per test.

The selling price must be adjusted for the consumer market, as individuals are unlikely to pay €100 for a diagnostic test at the pharmacy. Based on discussions with stakeholders and patients, a price point of approximately €40 appears feasible, corresponding to a profit margin of €30 per test. With a TAM of 540,000–900,000 home-based POCTs, the resulting profit potential lies between €15 million and €27 million, similar to the SAM.

Home-based POCTs, however, enable international commercialization, which could significantly enhance profitability and ensure long-term viability. Additionally, BRIGHT plans to launch a companion smartphone application to guide users, as mentioned in Section 6.2.2, providing opportunities for subscription and advertisement revenue. However, as this phase is far in the future (see Section 9), precise economic estimates remain challenging.

In summary, BRIGHT demonstrates economic viability. The laboratory-based test provides immediate revenue with profitable margins, ensuring short-term sustainability and the ability to fund further development. The home-based POCT represents a long-term growth opportunity, with the potential for large-scale adoption, international expansion, and additional revenue streams through a companion

smartphone application. Together, these phases illustrate both the immediate and future financial potential of BRIGHT, making it an attractive and scalable investment opportunity.

8 | Team, Skills and Stakeholders

BRIGHT is built on a multidisciplinary foundation, combining expertise in bio-organic chemistry, molecular diagnostics, and biochemical modeling. This unique blend enables us to drive both the scientific development of the BRIGHT sensor and its clinical translation. Through strategic collaborations with academic, clinical, and industrial stakeholders, we've expanded our capabilities and gained valuable insights into regulatory, technical, and market-related challenges. While our team has some shortcomings, our industrial partners have helped bridge these gaps by offering guidance in business development, regulatory compliance, and funding strategies.

8.1 | The Team

Currently, BRIGHT is developed by a team of eight TU/e students who combine their technical expertise with a strong entrepreneurial drive. While each member contributes unique skills ranging from wet lab research to modeling and design, three team members have taken a deep dive into Entrepreneurship and startup development. This team consists of two Master's students and 1 bachelor student from TU/e: all from either Medical Engineering or from Biomedical Engineering. Our work is further strengthened by the support of three professors and two PhD candidates. In addition, we collaborate closely with several industrial stakeholders who share our vision and help shape BRIGHT into a solution with real-world relevance.

Each member brings a distinct specialization:

- **Jelmer Pieters (CEO):** Leads the business strategy, fundraising, stakeholder engagement, and regulatory preparation. Jelmer also oversees the integration of synthetic biology into the BRIGHT sensor.
- **Janneke van de Ven (CTO):** Specialized in protein engineering, Janneke drives the technical development and optimization of the sensor. She further manages lab logistics and operational planning.
- **Kady Hoogenboom (Clinical Liaison):** Ensures clinical relevance by incorporating feedback from healthcare professionals and patients, and oversees clinical validation efforts.

Our entrepreneurial focus allows us to go beyond the purely scientific aspect of BRIGHT. We actively explore how our solution can be translated into real-world applications, considering market needs, business models, and scalability from the start. By combining innovation in synthetic biology with insights from the start-up world, we aim to create a project that is not only scientifically sound but also impactful and feasible outside the lab.

Our journey began with a call from Dr. Daniel Keszthelyi, who highlighted the lack of accessible diagnostic tools for BAM within the Dutch healthcare system. His challenge sparked our commitment to develop a novel solution. Together, we have successfully built a first proof-of-concept and are actively optimizing the system in the lab.

Beyond our technical capabilities, we possess a foundational understanding of regulatory pathways, access to advanced laboratory infrastructure, and initial insights into market needs. At the same time, we recognize the areas where additional expertise and resources will be essential as we move forward.

8.2 | Current Shortcomings

Despite our strong technical foundation, we recognize several gaps that must be addressed:

- **Business & Commercialization Expertise:** With a shared background in (Bio)Medical engineering, we recognize that our team has a limited range of expertise. No one has had formal training or expertise in finance, marketing, or entrepreneurship. We aim to onboard individuals with experience in health-tech startups and commercialization.
- **Industry Experience:** With an average age of 23, our team lacks direct experience in the healthcare industry and startup environments. We are actively seeking advisors or team members with backgrounds in medical device companies or biotech ventures.

- **Legal & Intellectual Property (IP) Strategy:** We currently lack in-house expertise in intellectual property (IP) protection and legal strategy. Legal guidance will be essential as we move toward product development and potential licensing.
- **Quality Assurance & Regulatory Affairs:** While we've begun exploring regulatory pathways, we need deeper expertise in CE marking, ISO standards, and clinical trial design.
- **Infrastructure & Facilities:** We currently rely on TU/e's lab facilities. For future development and scale-up, we will need access to dedicated lab space and office infrastructure.
- **Manufacturing & Supply Chain:** We have no in-house capabilities for large-scale production or supply chain management. Partnerships with manufacturing experts will be crucial.

8.3 | Stakeholders

To address these gaps and guide our development, we collaborate with a diverse group of stakeholders:

- **Academic Advisors:** Professors and PhD candidates at the TU/e provide scientific mentorship, review experimental work, and support technical development. The TU/e also provides advanced laboratory infrastructure and hardware needed for production.
- **Clinical Advisors :** Dr. Daniel Keszthelyi, along with several other gastroenterologists, advises us on diagnostic pathways and patient needs. Support from the NVMDL strengthens our clinical network and credibility. Discussions with GPs, along with the NHG and LHV, will facilitate implementation into primary care settings.
- **Industrial Partners:** Partners from The Gate, Unitron, Duofor, and an independent regulatory expert specialized in healthcare innovation offer guidance on business development, patenting, regulatory compliance, and funding. Claire Michielsen, an iGEM alumna currently launching her own startup, Spotlight, provides peer mentorship and startup insights.
- **Patient Input:** Interviews with patients ensure our solution aligns with real-world needs and expectations (see Section 2).
- **Future Manufacturing Partners:** We aim to expand our existing relationships with Unitron and Lonza to support industrial-scale production and distribution.

Together with these stakeholders, BRIGHT is confident in its ability to overcome current gaps and build a successful, impactful startup.

9 | Development Plan

Together with business accelerators and domain experts, BRIGHT has developed a detailed development plan for the coming years. Through a two-phase development strategy, the goal is to bring a fully developed home-based POCT for BAM to market within 15 years (see figure 9.1). This approach aims to bring healthcare closer to the patient and significantly reduce diagnostic delays.

The current timeline and strategy are based on extensive interviews with gastroenterologists, general practitioners, patients, and industrial stakeholders, ensuring both a smooth market entry and robust safety measures. As of October 8, 2025, BRIGHT successfully surpassed its first milestone: participation in the TU/e Contest. The next major milestone is the iGEM Grand Jamboree, where BRIGHT will publicly present its concept to a broader international audience.

Following this, BRIGHT will focus on further optimization of the test until 2028, with clinical validation planned through 2030. The team aims to obtain IVDR certification by 2032, enabling market entry as a laboratory-based diagnostic test. In parallel, BRIGHT will initiate the design cycle for the home-based POCT, targeting market launch by 2040.

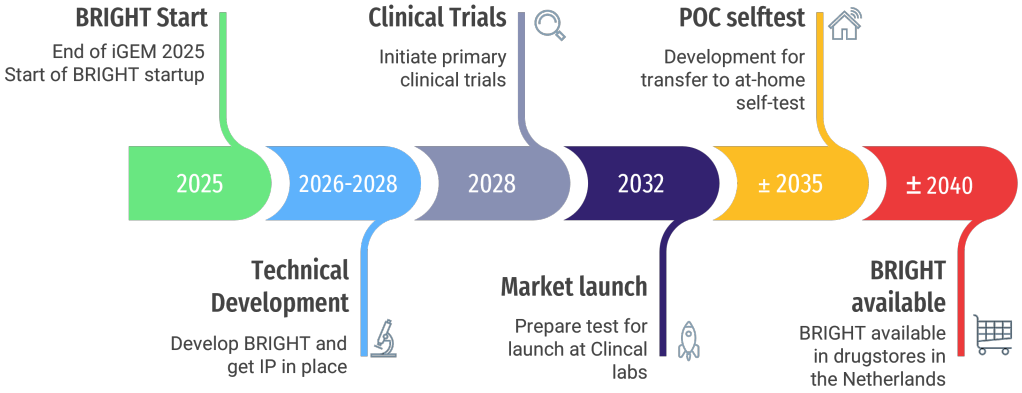

Figure 9.1: Roadmap for the development of BRIGHT.

As of October 8, 2025, BRIGHT has been actively developing its diagnostic sensor for nine months. During this initial phase, a proof-of-concept has been established, key stakeholders have been identified, and the target market has been outlined. A successful first funding round has been completed, and valuable input has been gathered from both stakeholders and patients. BRIGHT also participated in the TU/e Contest, where students pitch innovative ideas and present their business plans. Out of nearly 60 teams, BRIGHT placed as second runner-up and received critical feedback to refine its concept. Additionally, the first awareness campaign for BAM was launched in collaboration with Crohn & Colitis NL.

By the end of October 2025, BRIGHT will present its concept to a broader international audience at the iGEM Grand Jamboree, a global synthetic biology competition featuring over 400 teams from more than 60 countries. Each team competes within one of 17 categories, such as agriculture, therapeutics, oncology, and biomanufacturing. BRIGHT will participate in the diagnostics category. This event offers a valuable opportunity to gain new insights, skills, and international exposure.

From 2026 to 2028, the focus will be on improving our sensor through intensive laboratory studies. This work is planned to be carried out through a Master's graduation project, followed by a PhD trajectory at TU/e. Janneke, our current operations manager, will lead the laboratory development, and together with Jelmer and Kady, they will focus on the entrepreneurial and business development aspects. The collaboration with TU/e provides access to laboratory and office space, shared equipment, and special software packages such as Matlab, significantly reducing early-stage costs. The technical goal during this phase is to match the sensitivity and specificity of existing diagnostic alternatives. A SMART (specific, measurable, achievable, relevant, and time-bound) one-year plan has been made to complete the necessary experiments and data collection over the first period. Through a PDCA (plan-do-check-act) cycle, the team will continuously refine the sensor based on experimental results and feedback from

stakeholders.[1] Through a PDCA (plan-do-check-act) cycle, the team will continuously refine the sensor based on experimental results and feedback from stakeholders. Once a laboratory-validated prototype is achieved, BRIGHT plans to file a provisional patent. Full IP filing will be postponed until after clinical validation, due to anticipated refinements to the technology. In parallel, BRIGHT plans to expand its team to include expertise in business development and financial strategy (see Section 8). A second funding round will be launched, targeting current partners and public funding opportunities from the EU and Dutch government, such as the Biotech Booster program, with which BRIGHT is already in contact.

In early 2028, we plan to initiate clinical validation at the MUMC, in close collaboration with Dr. Daniël Keszthelyi. Based on interviews with gastroenterologists and the analysis of the current Dutch healthcare system, clinical validation will involve comparing healthy individuals with diagnosed BAM patients, as no alternative diagnostic tests are currently used in the Netherlands. With support from the Dutch national gastroenterologist association, we aim to expand validation to additional University Medical Centers (UMCs) in the Netherlands. UMCs are targeted due to their greater financial and regulatory flexibility in testing new medical treatments and diagnostic devices. Simultaneously, a second awareness campaign targeting general practitioners and patients will be launched to increase understanding of BAM. This will all be carried out as part of the ongoing PhD trajectory. Ethical approval and GDPR-compliant data management will be ensured for all studies.

Following one year of clinical validation, BRIGHT will prepare the dossier required for CE marking under the EU's IVDR for class B diagnostic devices (42; 41; 43). Support from The Gate accelerator program will help establish the foundational elements of the startup, including implementation of the ISO 13485 quality management system in collaboration with an independent regulatory expert. Our goal is to complete CE marking by 2032. During this period, the team will continue refining the test based on clinical and laboratory findings, while formally transitioning into a startup and filing a full patent to secure its intellectual property.

After obtaining certification, BRIGHT will introduce the laboratory-based diagnostic test to academic hospitals across the Netherlands. We aim to make the test eligible for hospital reimbursement, significantly improving accessibility and adoption.

The next phase involves expanding to all Dutch hospitals. In parallel, BRIGHT will begin development of a home-based POCT for BAM. This will require a new design and testing cycle, followed by usability and risk-assessment studies in compliance with IVDR requirements. As home-based tests fall under Class C diagnostic devices, stricter safety documentation will be required as discussed in Section 6.

By 2040, BRIGHT aims to commercialize a home-based POCT for BAM in the Netherlands, making it available in general drugstores to maximize accessibility. The long-term goal is to expand availability to other OECD countries and eventually to global markets.

9.1 | IP Strategy

From the beginning, BRIGHT's team recognized that protecting and managing intellectual property (IP) is essential for turning a scientific concept into a sustainable innovation. To support this, we received guidance from Sebastiaan Huntjens, Bart Grevenhof, and Nataša Maršić, both from the Gate, who advised on IP strategy and long-term patent planning.

Our operations manager, Janneke van de Ven, completed an Invention Disclosure Form (IDF), which was reviewed in collaboration with Sebastiaan and Nataša. Together, they assessed the novelty of the invention, discussed potential filing strategies, and evaluated the right timing for protection. Based on this review, the team decided that early patent filing would be premature at this stage, but that thorough documentation and strategic planning now would safeguard future opportunities.

This approach allows BRIGHT to continue optimizing the bioluminescent protein sensor and generating supporting data, while ensuring the invention is carefully recorded and ready for future IP protection when the technology reaches a more mature stage.

[1] The complete one-year plan is available on the iGEM Eindhoven 2025 wiki (Entrepreneurship page)

10 | Risk Analysis

Despite extensive preparation for market entry, BRIGHT faces several potential barriers that must be addressed. A comprehensive risk analysis was conducted to identify potential barriers BRIGHT may encounter and to outline strategies for overcoming them. Table 10.1 summarizes the most relevant risks, ranked by probability and impact, along with mitigation strategies. A more detailed explanation of each risk is provided below.

Table 10.1: Risk analysis for BRIGHT

Risk	Probability	Impact	Risk rating	Mitigation
Technical Risks	Medium	High	High	Early feasibility testing on clinical samples
Unreceptive market	Medium	High	High	Targeted awareness campaign; partnerships with Crohn&Colitis NL; medical association outreach
Regulatory hurdles	Low	High	Medium	Engage regulatory experts in an early stage
Funding gap	Medium	Medium	Medium	Diversify funding sources; secure grants; leverage TU/e infrastructure
Supply chain disruption	Low	Medium	Low	Multiple suppliers; evaluation of synthetic alternatives
Competitors	Low	Medium	Low	Marketing and unique selling points

Technical Risks One of the primary challenges BRIGHT faces is demonstrating technical feasibility under real-world conditions. Both clinicians and patients emphasized the importance of a reliable and trustworthy diagnostic test. While the proof of concept has shown promise with synthetic bile acids, clinical validation remains essential to confirm performance in actual patient samples. To be effective, the sensor must be stable before use, sensitive enough to distinguish between individuals with BAM and healthy controls, and capable of delivering clear, interpretable results. Early clinical testing is therefore planned in collaboration with Dr. Daniël Keszthelyi at the MUMC.

A key technical risk is the potential difference in stool composition between synthetic and real-world samples, which could impact sensor performance. To address this, preliminary tests have been conducted using stool samples spiked with synthetic bile acids. These initial results indicate that the sensor remains functional under more complex conditions, supporting its continued development.

For a market-ready self-test, long-term stability under normal storage conditions is crucial. While this is less critical during the lab phase, the final product must remain effective during distribution, retail storage, and home use. Accelerated stress testing and long-term stability studies will be conducted to assess shelf-life and determine expiration dates before market release.

Market Acceptance Although BRIGHT has performed extensive market research, an unreceptive market remains a key risk. Across multiple market segments, the urgency of need and willingness to adopt new diagnostics appear relatively low. To address this, BRIGHT is developing an awareness campaign in partnership with Crohn&Colitis NL, strengthening connections with the NVMDL, and building early clinical collaborations in Maastricht..

Regulatory Hurdles Regulatory approval represents a significant barrier to market entry. Diagnostic devices must comply with increasingly strict EU requirements. For initial use, BRIGHT will require CE marking as a Class B diagnostic device, while the home-based test will fall under the more stringent Class C requirements. Achieving certification will take several years and require extensive documentation.

With support from regulatory experts at The Gate and an independent regulatory expert specialized in healthcare innovation, BRIGHT anticipates meeting all certification requirements without delay.

Funding Gap A common risk for early-stage startups is the interruption of funding. Over the past nine months, BRIGHT has secured over €40,000 in funding, as well as sponsored materials. To ensure financial continuity, we will collaborate with the TU/e, leveraging laboratory facilities and equipment to reduce costs. Additionally, BRIGHT is mapping out potential grants from both the EU and the Dutch government.

Supply Chain Disruption Another possible barrier is a disruption of the supply chain. The probability of this risk is considered low, as the BRIGHT sensor is produced using *E. coli*, which minimizes dependence on scarce raw materials or complex supply networks. In addition, the black boxes required for light concentration can be manufactured in-house through 3D printing, further reducing reliance on external suppliers. As a precaution, BRIGHT will maintain relationships with multiple suppliers for critical laboratory consumables and 3D printing materials to ensure continuity of production in case of unexpected shortages.

Competitors Alternative detection methods could hinder BRIGHT's market entry. To prevent this, marketing, especially in the beginning, will be very important for market adoption. Our unique selling points are strong and in demand by both patients and clinicians.

To conclude, while BRIGHT faces notable risks related to technical feasibility, regulatory approval, financing, and market acceptance, each of these challenges is paired with a clear mitigation strategy. Early clinical validation, strong academic and clinical partnerships, proactive regulatory engagement, and diversified funding sources form the backbone of BRIGHT's risk management approach. By addressing these risks in a structured and transparent manner, BRIGHT is confident in its ability to navigate barriers and advance towards the successful commercialization of its diagnostic sensor.

11 | Financial plan

As outlined in Sections 8 and 9, the initial development of the BRIGHT test for BAM will take place in collaboration with TU/e. During this phase, we will optimize and validate the test through Janneke's Master's graduation project and a subsequent PhD trajectory. TU/e will cover key expenses such as lab space, materials, office space, and software. Additionally, TU/e offers the possibility to file intellectual property. Since BRIGHT is still in the optimization and validation phase, salary, marketing, and legal costs are not yet applicable. To ensure long-term sustainability, BRIGHT will pursue funding rounds during this phase, aimed at forming strategic partnerships and building a solid financial foundation in preparation for its transition into a startup.

To provide a clear overview of BRIGHT's projected cash flow as a startup, the optimization and validation phases have been excluded from Table 11.1. Instead, the table presents projected expenses and income for the years 2031 through 2035, which correspond to the anticipated startup phase. These projections are based on comprehensive market research combining direct supplier quotes from major laboratory suppliers (Sigma-Aldrich, VWR International, Fisher Scientific), government statistic databases (CBS), university partnership agreements with TU/e and Twice Eindhoven, and validated industry benchmarks. All cost estimates represent middle-to-upper range pricing to ensure conservative financial planning. Expenses are categorized into Production, Marketing, Office, and General Costs, and are based on a team of four employees until 2033, expanding to eight by 2035. We are currently a team of three, as mentioned earlier, but we aim to expand to four members in the near future, particularly by adding someone with expertise in entrepreneurship. A brief overview of costs is provided below, with further details available on the iGEM Eindhoven 2025 wiki.

Production Costs decrease from €244,300 in 2031 to €84,000 in 2035, with the initial spike driven by essential laboratory equipment purchases for the first year, totaling approximately €207,500. Major equipment includes an Imager (€40,000, based on Bio-Rad ChemiDoc pricing), ÄKTA Protein Purification System (€80,000, Cytiva/GE Healthcare), Plate Reader (€15,000, BioTek/Agilent), NanoDrop Spectrophotometer (€15,000, Thermo Scientific), and additional infrastructure (€69,700) including incubators, thermocyclers, and safety equipment validated through the Charter Capital laboratory equipment database. After 2031, annual consumables will lower to €7,200 before growing synchronously with market demand to €40,200, covering chemical supplies and laboratory consumables from major suppliers. Lab space costs progress from €15,000 to €25,000 (Quote from Twice Eindhoven) by 2033 to enable production growth. Software expenses remain stable at €9,100 annually through 2033, covering MATLAB (€6,320 for four users, MathWorks startup licensing), Microsoft 365 with Copilot (€1,613), and AI tools (€1,200), scaling to €18,300 in 2035 for eight users. Hardware costs of €500 annually support prototype development for the smartphone-compatible light-controlled measurement box required for the home-based POCT.

Marketing Costs focus on congress participation and gastroenterologist outreach, based on analysis of major European conferences, including United European Gastroenterology (UEG, €830 registration) and comparable healthcare conferences (€500–€1,000). Congress budgets of €6,500–€7,500 annually through 2033 cover multiple conference registrations and promotional materials, declining to €2,900 in 2034–2035 as brand awareness grows. Travel costs of €10,000 annually to support visits to Dutch clinicians, stakeholders, congresses, and international markets, validated through European business travel benchmarks and discussions with industrial partners. Additional advertising budgets support digital marketing and trade publication campaigns aligned with medical device startup benchmarks.

Office Costs are based on direct quotes from Eindhoven startup incubators. Twice Eindhoven offers university-affiliated rates of €245–€345 per month, including 24/7 access and meeting facilities, with costs increasing from €2,900 (2031) to €4,100 (2033) as rates are dependent on the development phase. Microlab Eindhoven alternatives (€210–€450 per month, depending on space type) validate pricing competitiveness. Office materials include substantial initial setup costs of €109,400 in 2031 (computers at €2,000 per employee, business internet at €1,400 annually, and €10,000 foundational infrastructure), declining to €4,400 annually for maintenance, then increasing to €9,100 in 2034–2035 with team expansion.

General Costs comprise the largest expense category. Salaries of €45,000 per employee align with Dutch government data (CBS) showing laboratory workers with university degrees earn €41,640 annually, with BRIGHT's figure including employer benefits and recruitment costs. Team scaling drives salary

Table 11.1: BRIGHT's Projected Expenses and Income (2031–2035)

Category	2031	2032	2033	2034	2035
Total Expenses	**€477,100**	**€250,200**	**€261,300**	**€366,500**	**€478,100**
Production Costs					
Lab Space	€15,000	€20,000	€25,000	€25,000	€25,000
Lab Materials	€219,700	€7,200	€15,200	€25,200	€40,200
Software	€9,100	€9,100	€9,100	€13,700	€18,300
Hardware	€500	€500	€500	€500	€500
Subtotal (Production)	**€244,300**	**€36,800**	**€49,800**	**€64,400**	**€84,000**
Marketing					
Congresses	€7,500	€6,500	€6,500	€2,900	€2,900
Travel Costs	€10,000	€10,000	€10,000	€10,000	€10,000
Additional Advertising	€5,000	€5,000	€2,500	€1,500	€1,000
Subtotal (Marketing)	**€22,500**	**€21,500**	**€19,000**	**€14,400**	**€13,900**
Office Costs					
Office Space	€2,900	€3,500	€4,100	€4,100	€4,100
Office Materials	€19,400	€4,400	€4,400	€9,100	€9,100
Subtotal (Office Costs)	**€22,300**	**€7,900**	**€8,500**	**€13,200**	**€13,200**
General Costs					
Salary	€180,000	€180,000	€180,000	€270,000	€360,000
Legal Advisor	€4,000	€0	€0	€0	€2,000
Patenting	€2,000	€2,000	€2,000	€2,000	€2,000
Insurances	€2,000	€2,000	€2,000	€2,500	€3,000
Subtotal (General)	**€188,000**	**€184,000**	**€184,000**	**€274,500**	**€367,000**
Income					
Funding Round	€200,000	€250,000	€300,000	€300,000	€300,000
Revenue	€0	€100,000	€650,000	€1,500,000	€3,100,000
Total Income	**€200,000**	**€350,000**	**€950,000**	**€1,800,000**	**€3,400,000**

growth from €180,000 (four employees, 2031–2033) to €360,000 (eight employees, 2035). Legal expenses include €4,000 for entity formation and contract drafting in 2031 (validated through startup legal service consultations), with €2,000 reserved for initial POCT legal documentation in 2035. Patenting costs of €2,000 annually cover maintenance fees and future filings, based on TU/e IP guidelines for student startups. Insurance costs (€2,000–€3,000 annually) exceed typical small business coverage (€600–€1,200) to ensure comprehensive protection, including business liability, professional indemnity, and disability coverage as recommended by the Dutch Chamber of Commerce (KVK).

Income projections reflect staged funding rounds totaling €200,000–€300,000 annually to support operational scaling, supplemented by grant opportunities including Biotech Booster, NWO, and EIT Health. Revenue begins in 2032 following market entry, with pricing set at €100 per test aligned with healthcare reimbursement rates. Market penetration progresses from 1,000 tests (2032 pilot customers) to 31,000 tests (2035), representing 30% Dutch market share and €3,100,000 revenue. This growth trajectory is validated through healthcare technology adoption curves and comparable medical diagnostic product launches.

12 | Future Impact and Responsibility

As healthcare continues to move toward personalization and decentralization, BRIGHT stands at the forefront of a transformative shift in diagnostic care. Yet, as with any technological advancement, it also brings challenges that must be acknowledged and addressed. Recognizing both sides of this evolution allows us to proactively evaluate and mitigate long-term risks while maximizing the benefits of our innovation for patients, clinicians, and society as a whole.
By lowering diagnostic barriers through our innovative test, BRIGHT empowers both patients and healthcare professionals to identify BAM earlier and more efficiently. Early detection can significantly improve patients' quality of life by reducing years of uncertainty, misdiagnosis, and ineffective treatments. For many individuals struggling with chronic, unexplained gastrointestinal symptoms, access to a simple, accurate, and accessible test represents not just a medical innovation but a renewed sense of control and understanding over their own health.

Our technology is designed with the patient's experience at its core. By enabling home-based diagnostics, BRIGHT supports the growing movement toward decentralized and patient-centered care, allowing individuals to take a more active role in managing their health while maintaining close collaboration with their healthcare providers. This approach not only enhances convenience but also reduces the burden on clinical facilities and lowers overall costs for healthcare systems, insurers, and society at large.

We are, however, deeply aware that innovation in diagnostics comes with responsibility. From conversations with healthcare providers, we have identified real challenges that we aim to address proactively, including the risk of misinterpretation without professional guidance and the danger of overlooking other conditions if our test were to be used in isolation. To mitigate these risks, BRIGHT is committed to developing comprehensive educational materials, clinical guidelines, and digital support tools for both patients and healthcare providers.

Rather than replacing existing diagnostic pathways, our test is meant to complement and strengthen them. By integrating seamlessly into established care protocols, we ensure that BAM testing is considered within a broader, holistic view of the patient's condition. Through close collaboration with clinicians, researchers, and patient organizations, BRIGHT aims to build trust and foster the responsible use of our technology in daily practice.

Ultimately, our mission is not only to improve diagnostic accuracy but also to empower patients and clinicians alike, bridging the gap between innovation and compassionate, evidence-based care. With BRIGHT, we are shaping a future where diagnostic precision and patient well-being go hand in hand.

13 | Strategic outlook and Final Remarks

At BRIGHT, our long-term vision is to transform the diagnosis and management of bile acid malabsorption through accessible, affordable, and scalable technology. By streamlining BAM diagnostics, BRIGHT has the potential to significantly shorten patient suffering and reduce healthcare costs.

We aim to make BAM easily diagnosable, not only within OECD countries, but across the whole world. By increasing awareness among clinicians and integrating BAM into standard treatment guidelines, BRIGHT envisions a future where chronic diarrhea patients are no longer left in the dark. Early intervention will prevent unnecessary patient suffering, lead to better patient outcomes, and reduce diagnostic delays.

Our goal is to develop a home-based POCT that is widely available in general drugstores and pharmacies. It will be designed for ease of use, ensuring that patients feel comfortable and confident using it. By enabling home-based testing, we aim to reduce the workload of gastroenterologists and general practitioners, allowing healthcare professionals to focus on treatment rather than lengthy diagnostic processes.

Looking ahead, the BRIGHT bile acid sensor is currently being optimized for the detection of bile acids in vitro. However, its modular design offers promising potential for adaptation to other molecular targets. As long as the receptor subpart undergoes a conformational change upon binding, thereby exposing a secondary binding site, the sensor can be adapted to multiple targets. This could enable a broader range of home-based tests, bringing healthcare to the patient. While BRIGHT does not currently pursue active development in this direction, we recognize the growing potential of de novo protein design and AI-driven binder discovery. These advancements may, in time, enable the creation of new sensors tailored to other diagnostic needs. For now, however, the expansion of our binding library will remain a future prospect.

We further envision integrating BRIGHT with digital health systems. By connecting our sensor outputs to mobile applications that interface directly with general practitioners, patients could share diagnostic data ahead of appointments, facilitating more informed and efficient consultations. Beyond clinical use, our technology holds promise for research applications, supporting innovation in biomedical science through high-resolution, real-time molecular sensing.

To conclude, BRIGHT is more than a diagnostic tool; it's a step toward transforming how bile acid malabsorption is understood and managed globally. By combining innovation, accessibility, and patient empowerment, BRIGHT aims to reshape diagnostics and bring clarity and light to a condition that has too often remained in the shadows. With the right support, we are ready to turn this vision into reality and redefine the future of digestive health.

If you are interested in learning more about BRIGHT, exploring collaboration opportunities, or discussing the continuation of this project, you can get in touch with:

Janneke van de Ven – Master's Thesis Researcher (BRIGHT)

- **E-mail:** j.e.a.v.d.ven@student.tue.nl

As a team member who continues to work on BRIGHT as part of her Master's graduation project, she is the right person to answer your questions.

14 | References

[1] O. Gómez-Escudero, "Approach to the adult patient with chronic diarrhea: A literature review," *Revista de Gastroenterología de México*, vol. 86, no. 4, pp. 387–402, 2021.

[2] K. D. Fine and L. R. Schiller, "Aga technical review on the evaluation and management of chronic diarrhea," *Gastroenterology*, vol. 116, pp. 1464–1486, June 1999.

[3] K. Han, X. Wang, X. Niu, T. Li, and E. Linghu, "Prevalence and associated factors of chronic diarrhea among adults with obesity in the united states: Evidence from the national health and nutrition examination survey 2005 to 2010," *Obesity Research Clinical Practice*, vol. 18, pp. 328–335, Sept. 2024.

[4] World Health Organization, "Obesity and overweight," May 2025. Fact sheet.

[5] J. R. F. Walters and R. Sikafi, "Managing bile acid diarrhea: aspects of contention," *Expert Review of Gastroenterology & Hepatology*, pp. 521–528, Sept. 2024.

[6] D. C. R. Fernandes, D. Poon, L. L. White, and H. J. N. Andreyev, "What is the cost of delayed diagnosis of bile acid malabsorption and bile acid diarrhoea?," *Frontline Gastroenterology*, vol. 10, pp. 72–76, January 2019.

[7] P. Vijayvargiya, M. Camilleri, A. Shin, and A. Saenger, "Methods for diagnosing bile acid malabsorption: a systematic review," *BMC Gastroenterology*, vol. 19, no. 1, p. 71, 2019.

[8] cleveland clinic, "Bile acid malabsorption: Symptoms, causes & treatment." Medically reviewed.

[9] A. S. Bannaga and C. P. Selinger, "Bile acid malabsorption: mechanisms, diagnosis and therapy," *Clinical Medicine (London)*, vol. 15, no. 3, p. 279–285, 2015.

[10] L. E. Hughes, C. Ford, M. J. Brookes, and R. Gama, "Bile acid diarrhoea: Current and potential methods of diagnosis," *Annals of Clinical Biochemistry: International Journal of Laboratory Medicine*, vol. 58, pp. 22–28, Jan. 2021.

[11] P. Vijayvargiya, M. Camilleri, A. Shin, and A. Saenger, "Comparison of fecal bile acid vs sehcat in chronic diarrhea," *Clinical Gastroenterology and Hepatology*, vol. 18, no. 3, p. 582–588.e2, 2020.

[12] B. M. Association, "Nhs backlog data analysis," April 2025.

[13] OECD, "Health at a glance 2023: Waiting times for elective surgery." OECD Report, November 2023.

[14] N. Z. (NZa), "Rapport wachttijden medisch-specialistische zorg: Verdiepend onderzoek." Government report, July 2017.

[15] N. Z. (NZa), "Stand van de zorg 2024." Government report, October 2024.

[16] Independer, "Enorme wachtlijsten: helft poliklinieken haalt afgesproken norm wachttijden niet," December 2024.

[17] J. Buono, R. Carson, N. Flores, E. Raughley, and N. Talley, "Health-related quality of life, work productivity, and indirect costs among patients with irritable bowel syndrome with diarrhea," *Health and Quality of Life Outcomes*, vol. 15, no. 1, pp. 1–10, 2017.

[18] J. Tack, M. Camilleri, and L. Chang, "Economic burden of irritable bowel syndrome with diarrhea in europe: indirect costs and lost productivity," *PMC Journal of Gastroenterology*, vol. 18, no. 2, pp. 87–96, 2023.

[19] C. B. voor de Statistiek, "Werkenden — dashboard arbeidsmarkt," August 2025. Statistical data: percentage and number of employed persons aged 15-75; Netherlands.

[20] C. Ma *et al.*, "Epidemiologic burden and treatment of chronic functional bowel disorders in the united states," *The American Journal of Gastroenterology*, vol. 115, pp. 1596–1603, Oct. 2020.

[21] M. Camilleri and P. Vijayvargiya, "The role of bile acids in chronic diarrhea," *The American Journal of Gastroenterology*, vol. 115, pp. 1596–1603, Oct. 2020.

[22] NVMDL, "Magma," 2025.

[23] M. Kårhus, A.-M. Ellegaard, M. Winther-Jensen, S. Hansen, F. Knop, and L. Kårhus, "The Epidemiology of Bile Acid Diarrhea in Denmark," *Clinical Epidemiology*, vol. Volume 15, pp. 1173–1181, Dec. 2023.

[24] NVMDL, "Lijst van mdl-artsen in nederland," August 2024.

[25] D. Daoud, M. Bouin, L. Bellemare, and M. Nemer, "A179 PREVALENCE OF CHRONIC DIARRHEA AMONGST PATIENTS FOLLOWED IN GASTROENTEROLOGY," *Journal of the Canadian Association of Gastroenterology*, vol. 1, pp. 264–264, Mar. 2018.

[26] U. Utrecht, "Maag-, darm- en leverziekten specialisme," August 2024.

[27] Capaciteitsorgaan, "Infographics medisch specialisten," 2022.

[28] Statistics Netherlands (CBS), "Population counter," September 2025. Accessed: 2025-09-16.

[29] G. Johnson, "Assessing the clinical utility of a new assay for bile acid diarrhoea." https://biohithealthcare.co.uk/assessing-the-clinical-utility-of-a-new-assay-for-bile-acid-diarrhoea/, November 2022.

[30] A. S. Bannaga, L. Kelman, M. O'Connor, C. Pitchford, J. R. F. Walters, and R. P. Arasaradnam, "A single faecal bile acid stool test demonstrates potential efficacy in replacing SeHCAT testing for bile acid diarrhoea in selected patients," *Frontline Gastroenterology*, vol. 11, pp. 280–286, July 2020.

[31] N. foundation, "Addressing health care workforce shortages." https://nihcm.org/publications/addressing-health-care-workforce-shortages, July 2025.

[32] M. Phillion, "Flattening the curve of care with at-home diagnostics." https://www.psqh.com/analysis/flattening-the-curve-of-care-with-at-home-diagnostics/, February 2024.

[33] F. M. Insights, "At-home testing market trends & growth 2025–2035," 2025. Accessed September 2025.

[34] P. Research, "Self-testing market set to grow with rising demand for at-home health solutions," 2025. Accessed September 2025.

[35] L. M. van der Velden, M. V. Golynskiy, I. T. G. W. Bijsmans, S. W. C. van Mil, L. W. J. Klomp, M. Merkx, and S. F. J. van de Graaf, "Monitoring bile acid transport in single living cells using a genetically encoded föster resonance energy transfer sensor," *Hepatology*, vol. 57, p. 740–752, Feb. 2013.

[36] Y. Ni, R. Arts, and M. Merkx, "Ratiometric bioluminescent sensor proteins based on intramolecular split luciferase complementation," *ACS Sensors*, vol. 4, Dec. 2018.

[37] M. R. Gemmell, T. Jayawardana, S. Koentgen, E. Brooks, N. Kennedy, S. Berry, C. Lees, G. L. Hold, *et al.*, "Optimised human stool sample collection for multi-omic microbiota analysis," *Scientific Reports*, vol. 14, July 2024.

[38] L. Neuberger-Castillo, W. Ammerlaan, and F. Betsou, "Fitness for purpose of stabilized stool samples for bile acid metabolite analyses," *Scientific Reports*, vol. 11, Apr. 2021.

[39] Rijksoverheid, "Medische hulpmiddelen en technologie." https://www.rijksoverheid.nl/onderwerpen/medische-hulpmiddelen/veiligheid-en-toezicht-medische-hulpmiddelen. Accessed: 2025.08.05.

[40] Rijksoverheid, "Welke producten moeten een ce-markering dragen?." https://www.rijksoverheid.nl/onderwerpen/bouwproducten/vraag-en-antwoord/wat-is-een-ce-markering-en-wanneer-moet-ik-deze-op-mijn-product-aanbrengen. Accessed: 2025.08.05.

[41] E. Union, "Regulation (eu) 2017/746 of the european parliament and of the council on in vitro diagnostic medical devices." Official Journal of the European Union, L 117/176, 5 May 2017, 2017. Accessed: 2025.08.11.

[42] E. Union, "Regulation (eu) 2017/746 – in vitro diagnostic medical devices (ivdr)." https://eur-lex.europa.eu/eli/reg/2017/746/oj/eng. Accessed: 2025.08.11.

[43] International Organization for Standardization (ISO), "Iso 13485:2016 – medical devices — quality management systems — requirements for regulatory purposes." ISO standard 13485:2016, 2016. Accessed: 2025.08.11.

[44] R. Ferreira, A. Azzoni, and S. Freitas, "Techno-economic analysis of the industrial production of a low-cost enzyme using e. coli: the case of recombinant -glucosidase," *Biotechnology for Biofuels*, vol. 11, p. 81, 2018.

A | Appendix

A.1 | Letter of support from NVMDL

Note: This is a translation of the original Dutch document.

TU Eindhoven K.M. Hoogenboom Human Practices Captain, iGEM 2025 [redacted]

Haarlem, 2 June 2025 RS/IL/78.26

[redacted]

Subject: Statement of Support iGEM TU/e – Diagnostics of Bile Acid Malabsorption

Dear Sir or Madam,

On behalf of the Dutch Society of Gastroenterologists (NVMDL), we hereby express our support for the iGEM project of the student team from Eindhoven University of Technology (TU/e), which focuses on the development of an innovative sensor for the diagnosis of bile acid malabsorption (BAM).

Bile acid malabsorption is an underrecognized cause of chronic diarrhea, a condition that can significantly impact patients' quality of life. Although effective treatment options exist, establishing the correct diagnosis remains a challenge. Current diagnostic methods – such as the SeHCAT test, serum tests (C4, FGF19), and fecal examinations – face limitations in terms of availability, accuracy, and patient-friendliness. This often results in underdiagnosis and delays in initiating appropriate treatment.

The iGEM team's proposal to develop an accessible, rapid, and patient-friendly sensor for the detection of bile acids represents a valuable addition to the existing diagnostic toolkit. The NVMDL welcomes the commitment of young researchers to medical innovation in an area where considerable progress can still be made.

We therefore underline the importance of this project and wholeheartedly support the team in their participation in the international iGEM competition, where innovation and multidisciplinary collaboration take center stage. We hope that this development will eventually contribute to improved diagnosis and care for patients with chronic diarrhea as a result of bile acid malabsorption.

Sincerely,

drs R.W.M. (Ruud) Schrauwen, Secretary NVMDL