

IMPAQTT Foundation

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Business Plan 2022-2025

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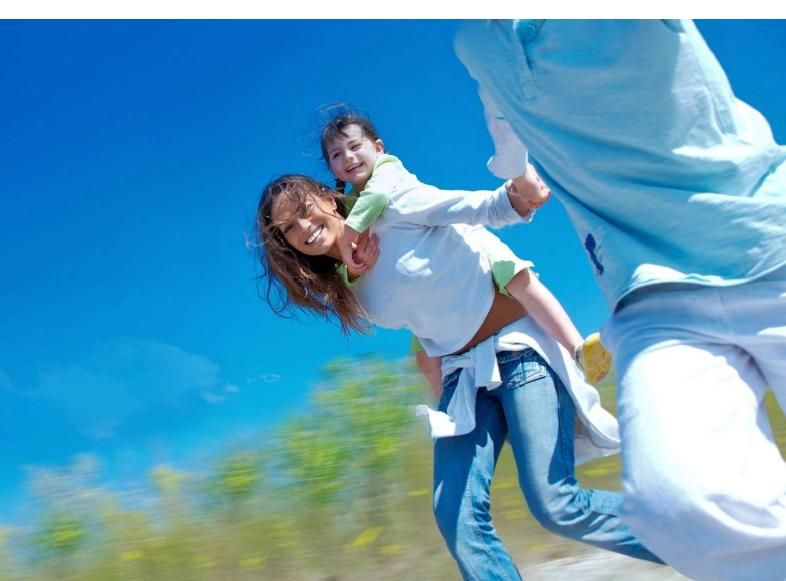


Table of Contents

Letter from the CEO	3
Executive Summary Impaqtt Foundation 2022-2025	4
1. Who We Are	5
2. Mission Statement	6
3. Problem We Are Solving	6
4. Strategy	7
5. Research Line	7
6. Dissemination	9
7. Leadership & Team	10
8. Competitors & Collaborators	10
9. Capital Requirements	11
10. Expenses	11
11. Marketing Plan	11
12. Call to Action	12

Letter from the CEO

We are in the middle of a transformation. Till September 2019 I focused mainly on my PhD program including the two clinical trials BeCet and COMTT. Therefore, I was not able to strengthen our Foundation with more volunteers. With my PhD program coming to an end, new opportunities arose to expand our reach. But the COVID-19 pandemic ensured, we had to put most of our activities on hold.

In this business plan I share with you the projects we are currently working on and new initiatives that we plan in order to help patients improve quality of life and prolong survival by managing side effects from their treatments.

To those of you who are not involved, I ask that you consider volunteering, and/or financially contributing to our foundation.

Patients with cancer experiencing severe and sustaining side effects from cancer treatment count on us, so on you too.

BOARD MEMBERS

Dr. Joel Epstein, President **Natasha Schrama,** Secretary **Vacant,** Treasurer

EXECUTIVE STAFF

Dr. Christine Boers-Doets, Founder & CEO

Christine Boers-Doets, Founder & CEO



Executive Summary Impaqtt Foundation 2022-2025

1. WHO WE ARE	2. MISSION
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The Impaqtt Foundation is an independent charitable nonprofit organization with goals to contribute substantially to lifesaving new cancer therapies. The focus is on the side effect management of the new treatment options including new targeted anticancer therapies.	The mission of the foundation is to enlighten the treatment of patients with cancer and advance the lives of millions of people living with cancer worldwide by facilitating breakthrough research and sharing cutting-edge knowledge about side effects resulting from cancer medication.
3. PROBLEM WE ARE SOLVING	4. STRATEGY
Many side effects are associated with targeted anticancer therapies. Patients may stop the therapy, delay treatment, or receive a dose adjustment due to the impact of the side effects upon their quality of life. Effective treatment options of the side effects will improve adherence of the lifesaving therapy and the quality of life will be less impacted resulting in improved patient outcome.	We initiate and write side effect management study outlines for our clients, perform our own research, and ensure that gained knowledge will be made available for patients and their support system.
5. RESEARCH LINE	6. DISSEMINATION PROJECTS
 BeCet trial (NCT01136005) COMTT trial (NCT01265810) Review 20 supportive care manuscripts annually Set-up new research studies Acquisition for Dissemination of gained knowledge 	We focus on analyzing the provided data and to get the results published into peer reviewed journals and getting translated into documentation for patients and healthcare professionals. Funding will make theses Dissemination projects happen.
7. LEADERSHIP & TEAM	8. COMPETITORS & COLLABORATORS
 Dr. Joel Epstein, President Natasha Schrama, Secretary Vacant, Treasurer Dr. Christine Boers-Doets, Founder & CEO 	Our cancer medication approaches are developed in close collaboration with members of MASCC, the Multinational Association of Supportive Care in Cancer.
9. CAPITAL REQUIREMENTS	10. EXPENSES
In order to realize our objective, we seek €250,000 in grant funding to be used the upcoming 4 years to cover the fixed annual expenses, onboarding more volunteers, and dissemination of the gained knowledge of our founders PhD project and the BeCet and COMTT trial.	We have a few fixed expenses: bank account, accountant, email provider and website costs, approximately €2000 annually. Additional expenses depend on the capital gained through sponsorship and donations as outlined in the Capital Requirements section.
11. MARKETING	12. CALL TO ACTION
We continue to market the Impaqtt Foundation on social media with special attention to LinkedIn and Twitter and to highlight it during CancerMed activities.	Consider giving a gift to our foundation. We operate solely to generate side effects knowledge and spread the word. Financial contributions are needed for operations, and as a match for our research line. Go to www.impaqtt.com/give to explore the options.

Business Plan Impaqtt Foundation 2022-2025

A growing number of patients with cancer will be treated with targeted anticancer agents, most frequently as outpatients and over a long-time span. Targeted anticancer agents may be used in combination with cytotoxic chemotherapy and radiation therapy. Cancer treatments including the more recently introduced targeted therapies, are associated with side effects.

Side effects knowledge of mechanisms of action, frequency, prevention, and treatment strategies are badly needed in order that people can comply with the needed therapy. This indicates a need for a patient-driven approach to side effects.

1. Who We Are

Science-based cancer medication knowledge made available for day-to-day care.

The Impaqtt Foundation operates as partner in the management of cancer treatment-associated side effects involving the skin and mucosal surfaces. Therefore, the foundation develops a scientifical program and a dissemination program to be able to provide patients and their support system with practical education and information.

Legal Form

The Impaqtt Foundation is an independent charitable nonprofit organization with goals to contribute substantially to lifesaving new cancer therapies. The need for study and development of side effects prevention and treatment strategies has led to the founding of the Impaqtt Foundation. The foundation was created by Christine B. Boers-Doets in 2012. This way we were able to continue ongoing clinical trials (the BeCet and the COMTT trial) in The Netherlands.

Organizational structure

Impaqtt is *Cancer*Med's independent **Side Effect Research & Development Foundation.** *Cancer*Med Side Effects Institute is our founder's company. *Cancer*Med focusses on training patient advocates, nurses, physicians, and pharmaceutical representative in becoming Side Effects Experts. While educating them, side effects knowledge gaps became identified. Consequently, our founder started to research them to give answer to the questions arisen. To keep research separated and clean, an independent foundation was set up.

Goals

The Impaqtt Foundations goal is to create an independent research and development platform. The Impaqtt Foundation overall objective is to:

- 1. Conduct leading research on targeted therapy-associated side effects, assessing frequency and severity, and their prevention and management.
- 2. Develop and disseminate widely best evidence for prevention and management of side effects of targeted therapy. Assessable and at no charge.

In short, our goal is to develop the evidence base, the tools, and to make the gained knowledge available to a broader audience. This way we can improve patient's adherence to the cancer therapy protocol in order to achieve the greatest impact with the best possible quality of life.

Nonprofit Strengths

Our strength is that we work with renown side effects experts from around the globe. Many of the current study collaborators are members of the Multinational Association of Supportive Care in Cancer (MASCC) based in the USA and Europe. Through MASCC, we have extensive contacts with a large group of world-class leaders in relevant fields, which gives us direct access to high-level partners. All programs are developed in close collaboration with these leaders, who have broad expertise and experience in the relevant therapeutic areas.

2. Mission Statement

Below we state our mission, vision & values.

Our Mission

The **mission** of the foundation is to enlighten the treatment of patients with cancer and advance the lives of millions of people living with cancer worldwide by facilitating **breakthrough research** and sharing **cutting-edge knowledge** about side effects resulting from cancer medication.

Our Vision

All stakeholders across the globe who deal daily with cancer medication know how to handle these drugs in all its facets, for the best outcome possible.

Our Values

All patients with cancer have the right to be managed by a health professional team with collective expertise in treatment of the cancer as well as in management of side effects of their cancer and cancer treatment.

The power and focus of this model are to optimize completion of each patient's lifesaving or lifesustaining treatment as planned.

3. Problem We Are Solving

Many side effects are associated with targeted anticancer therapies. Patients may stop the therapy, delay treatment, or receive a dose adjustment due to the impact of the side effects upon their quality of life. Effective treatment options of the side effects will improve adherence of the lifesaving therapy and the quality of life will be less impacted resulting in improved patient outcome.

Many proposals for patient information, skin care and oral care protocols are developed by different disciplines, institutions, departments, and countries and mainly assessable to a small

audience. This is a shame since ALL patients deserve access to information available in order to help them complete their lifesaving or life sustaining treatment as planned.

In conclusion, interdisciplinary approaches for developing effective side effects prevention and management strategies, and translation of science into clinical practice are our core goals.

4. Strategy

We initiate and write side effect management study outlines for our clients, perform our own research, and ensure that gained knowledge will be made available for patients and their support system.

We plan to strengthen our foundation by:

- Update our website to launch downloadable products & fact sheets
- Update our Privacy Policy as required
- Actively search for 20 volunteers
- Institute Global Advisory Board
- Raise funds to finance and support research into cancer treatment and measure the impact of our work, e.g., Oranje Fonds Collecte (In the Netherlands)

Research Goals

- Disseminate the findings of our founders research line. Since our fonder achieved the PhD title in 2019, the Impaqtt Foundation can now become principal investigator of future side effects studies.
- Generate 12 manuscripts with available research data from the COMTT & BeCet study into high impact peer reviewed journals and translate the outcomes of the trials into instant access for patients and healthcare providers.
- Reviewing 20 side effects manuscripts for scientific journals each year.
- Set up next level side effect trials that will help patients to maintain on therapy.

Dissemination Goals

• Institute annual Side Effects Symposium to spread available knowledge, gained through our research line and amplified with research performed by third parties.

This way we ensure people with cancer are informed about their treatment and know how to handle their cancer medication and the accompanying side effects.

5. Research Line

There is limited research on the mechanisms and upon managing the side effects of targeted therapy, and therefore no evidence-based guidance available. In order to generate evidence-based

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#ConquerSideEffects

#ContributeNow!

treatment options, randomized controlled trials are urgently needed. Our TARGET-method is evidence based and amplified with practice-based measures. In addition, we are analyzing the data of a trial to decrease the severity and duration of papulopustular rash (the BeCet trial) and off another trial on the exploration or oral complaints (the COMTT trial). That is just a start. These are the 5 research projects we are currently working on in our research line:

- 1. Elaborate the patient-driven co-care model
- 2. BeCet trial (NCT01136005)
- 3. COMTT trial (NCT01265810)
- 4. Review of 20 supportive care manuscripts annually
- 5. Find funding for new research projects

1. Patient-driven co-care model (PhD thesis)

Our Founders' PhD thesis was intended to provide an early view into a patient-driven approach to cancer medication-associated side effects conceptual co-care model which can have future impact. Targeted therapies inclusive immuno-oncology & endocrine therapy have her upmost attention. A growing number of patients with cancer will be treated with targeted anticancer agents, most frequently as outpatients and over a long-time span. In addition, targeted anticancer agents may be used in combination with cytotoxic chemotherapy and radiation therapy. This indicates a need for a patient-driven approach to side effects. The data in her research line identified three notable findings:

- 1. Current side effect measurement instruments may be of limited value for the assessment, reporting, grading, and evaluation of cancer medication-associated side effects. Overall, the incorporation of the voice of the patient is limited.
- 2. There is currently limited side effect evidence available to build evidence-based side effect treatment guidelines.
- 3. Available knowledge is not imbedded broadly in clinical practice.

Assessment of the side effects by patient reported outcomes (PRO) and treatment of side effects are important in cancer care. Targeted therapy-associated side effects should be approached in an integrated, interdisciplinary team model of care and in a systematic fashion. In order to obtain meaningful outcomes, the use of well-defined side effect terminology together with the development of appropriate side effect education, assessment, reporting, grading, and evaluation scales are needed to obtain an in-depth picture of the patient status and may conserve resources when intensive, time-consuming, and continuing side effect treatment can be avoided. All stakeholders should be involved in these efforts since a systematic patient-driven side effect approach may support the continuation of targeted treatment as planned. The findings in Boers-Doets' thesis may lead to:

- 1. The development of combined 3-part assessment and grading questionnaire that addresses the symptoms and signs of a side effect and their impact on health-related quality of life.
- 2. The generation of evidence-based side effect treatment guidelines.

3. The establishment of obligated training programs for healthcare providers especially for those involved in clinical trials and those who work on a daily basis with patients on targeted therapies.

With future research projects we intent to focus on these beforementioned findings.

2. The BeCet trial (<u>NCT01136005</u>)

The objective is to assess the preemptive effect of Bepanthen® on decreasing the incidence of specific ≥ grade 2 dermatological side effects of interest in respect of compliance to EGFRI agents, health-related quality of life and the adherence during the 6-week skin treatment period. The adherence to the study creams will also be studied. You can read detailed information about the BeCet trial here.

3. The COMTT Trial (NCT01265810)

The objective is to assess the relieving effect of Caphosol® oral rinse on clinical outcomes which include oral intake, swallowing function and pain associated with incidence of grade ≥ 1 oral side effects and the anticancer therapy cessation in patients treated with selected targeted anticancer therapy. You can read detailed information about the COMTT trial here.

4. Review 20 supportive care manuscripts annually

Before a manuscript of scientific work can be published into a peer reviewed journal, it needs to be reviewed by at least one independent anonymous peer reviewer. This procedure ensures that the work performed is of a scientifically high standard and also improves the readability of the provided work. This way it becomes easier for the Impaqtt Foundation to spread the gained knowledge, provided by other researchers. Therefore, our founders' goal is to review at least 20 manuscripts each year.

5. Find funding for new research projects

We will actively perform acquisition for new research projects and strengthen our collaboration with core stakeholders.

6. Dissemination

We have generated preliminary data within our research line (paragraph 5). We currently focus on analyzing the two clinical trials. With the current occupation, we do not have enough hands to start new projects in 2022. We focus on analyzing the collected data and to get the results published into peer reviewed journals and getting translated into documentation for patients and healthcare professionals. Funding will make these dissemination projects happen.

7. Leadership & Team

The Impaqtt Foundation has currently 2 board members and a CEO. We are seeking for more board members, with at least 1 patient/patient advocate as treasurer so Dr. Christine Boers-Doets can step down as CEO, which is currently her position. Once the board is complete, Dr. Christine Boers-Doets will hold the position as Chief Scientific Officer (CSO) so she can focus mainly on the core objectives of the foundation: perform cutting edge research and disseminate available knowledge about side effects through healthcare providers to patients. We want to establish a Global Advisory Board due to the need to support research and to translate the available and newly developed patient documentation into multiple languages and countries.

Our board members are unpaid volunteers. Our board members, like any other volunteers, may deduct expenses they incur in connection with their volunteer service, including mileage to travel to meetings using their own car.

Current Board

- 1. *President.* **Joel B. Epstein,** DMD, MSD, FRCD© FDS RCS(Edin); Director, Oral Medicine, Adjunct Professor; Division of Otolaryngology and Head and Neck Surgery
- 2. Secretary. Natascha A.W.P. Schrama, RN, MANP, OCNS:
- 3. Treasurer (Patient/Patient Advocate). Vacant

Executive Staff

Founder/CEO & Senior researcher. Christine B. Boers-Doets, MSc, OCNS

Volunteers

- Fundraisers. Vacant (2 positions)
- Junior Researchers. Vacant (3 positions)
- Medical Writer. Vacant
- English Native Copywriter: Mary Stefels
- Dutch Native Copywriter: Gera Krijt

8. Competitors & Collaborators

Competitors

Research programs of other organizations are focused on the effectivity of targeted therapies in cancer management, or in supportive care in cancer in general, while our program focuses on the side effects of such treatments with special attention to targeted therapies.

Collaborators

Our cancer medication approaches are developed in close collaboration with members of <u>MASCC</u>, <u>the Multinational Association of Supportive Care in Cancer</u>. MASCC is an international multidisciplinary organization dedicated to research and education in all aspects of supportive care

for people with cancer regardless of the stage of their disease. Their motto: Supportive Care Makes Excellent Cancer Care Possible. While MASCC focuses on supportive care, based on all kinds of strategies, the Impaqtt Foundation focusses on side effects research and development, based on the TARGET strategy developed by our founder.

9. Capital Requirements

In order to realize our objective, we seek €250,000 in grant funding to be used the upcoming four years to cover the fixed annual expenses, onboarding more volunteers, and dissemination of the gained knowledge of the PhD project and the BeCet and COMTT trial as follows:

Need for Finance	Amount
Fixed annual expenses. E.g., bank account, accountant, email provider & website costs; €2,000 each year	€8,000
Publication fees. For publishing the articles generated from the COMTT & BeCet trials into high rated peer-reviewed papers.	€17,000
Research Funding. For new projects	€140,000
Organize Impaqtt Symposium. €20,000 annually.	€80,000
Actively search for volunteers. Social Media Posts (Ad costs)	€2,000
Update our responsive website. To be able to launch downloadable products & fact sheets	€3,000
TOTAL BUDGET NEEDED:	€250,000

10. Expenses

We have a few fixed expenses: bank account, accountant, email provider and website costs, approximately €2000 annually. Additional expenses depend on the capital gained through sponsorship and donations as outlined in the Capital Requirements section.

11. Marketing Plan

We continue to market the Impaqtt Foundation on social media with special attention to LinkedIn and Twitter and to highlight the Impaqtt Foundation during *Cancer*Med activities.

12. Call to Action

Consider giving a gift to our foundation. We operate solely to generate side effects knowledge and spread the word. Financial contributions are needed for operations, and as a match for our research line. Consider a contribution to help the Impaqtt Foundation to achieve its goals. Go to www.impaqtt.com/give to explore the options.

