

The FT3 Pilot Program

2023 Report

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1. Introduction

Precision medicine (PM) has become a reality, but its implementation remains inconsistent and it is often subject to myriad barriers.

Operating within this fragmented landscape, FT3 identified the need for a targeted approach to address inequities in access and implementation of PM. Challenges pervade the international, national, regional, and hyperlocal levels, with each requiring comprehensive understanding of their ecosystem to solve inequity and access challenges. It was clear that the targeted approach would include partnering with experts well situated in their particular contexts.

Building on existing research and the wealth of knowledge within FT3's global network, key implementation barriers surrounding biomarker testing, targeted therapy, and patient-provider communications were identified as natural starting points to build alliances of the willing, including patients, healthcare providers, industry, as well as payers and policy makers.

1.1. What is the Country Pilots Program & why is it important

Precision medicine (PM) has the potential to transform lives, but it has not yet become a reality for many patients who could benefit from it. Scaling access to precision medicine is highly fragmented across countries and conditions. Patients' ability to access precision medicine differs from one region or country to another. Even in countries where precision medicine is reimbursed, some patients who could benefit from personalized treatment do not receive access or may have a suboptimal care experience. This is due to many factors, including education and awareness, health system barriers, lack of trust in data sharing and fragmented data flow¹.

Multiple stakeholders, including local patients, patient organizations, healthcare professionals, hospitals and companies have an important and valuable role to play for greater unity in advancing access. However, they often need the right information and support for advocating for change. The [From Testing to Targeted Treatments \(FT3\) program community](#) allows a collaborative approach to this pressing problem, with multi stakeholder input and co-creation of solutions.

FT3 has, to date, a co-created toolkit for “champions” of precision medicine (e.g. patient advocates, ambassadors from the healthcare community, etc.) to help drive change at different levels, including at the individual, collective, and system level. It was proposed that applying these tools in the local context within the structure of a larger project would help to improve awareness of and access to PM in regions and areas where patients are not benefiting fully.

¹ Many factors are required to make PM a reality for all who can benefit from it. In 2023 the Country Pilots program mostly focused on addressing education and awareness, as well as health system barriers. More issues will be addressed in future pilots.

The goals of the Country Pilots Program were:

- Share global learnings from the FT3 community, including through a Community of Practice to share experiences and support local champions/advocates in improving access to PM
- Learn about (local) barriers and solutions to make PM more accessible to patients, learn about how to apply & improve FT3 tools locally to accelerate access
- Develop case studies to share learnings & good practices with the wider PM community

1.2. Overall methodology

We adopted a methodical approach to our initiative, commencing with the selection of a patient organization to spearhead the pilot and the formation of a dynamic local team comprising multiple stakeholders.

Central to our strategy was the seamless integration of a global-to-local methodology, fostering collaboration among local stakeholders to enhance precision medicine accessibility. Emulating FT3's successful patient-led model on a local scale was our guiding principle.

Our strategy involved convening key individuals and establishing a platform to:

- Chart existing activities, pinpoint common barriers and opportunities within the healthcare system and care delivery
- Identify and leverage best practices, ensuring their adaptability at the local level
- In cases where best practices were absent, engage in collaborative brainstorming to forge innovative solutions, drawing from existing knowledge
- Generate positive momentum and cultivate an active community of ambassadors for information sharing, collaboration, and dissemination of insights

These progressive steps collectively contribute to the development of practical tools for precision medicine champions and the generation of momentum for collective action.

Furthermore, we orchestrated the creation of a robust Community of Practice—a vibrant assembly of global and regional precision medicine advocates. This community actively convened to exchange insights, discuss challenges, and explore potential solutions. Throughout these gatherings, exemplary practices were shared, providing invaluable lessons for the pilot teams who, in turn, built upon prior work.

2. Country pilot in Spain: Situación de Acceso a BIOMARcadores en España (SABIOMARES)²

The Spanish Country pilot endeavored to clarify, highlight and help address access disparities and barriers across Spain's decentralized healthcare system by identifying access challenges to biomarker testing and patient needs and experiences.

2.1 Introduction to Spain's healthcare system

The decentralized Spanish healthcare system is financed through national taxation and consequent budget allocation divides funds between the 17 autonomous communities. Health technologies approved at the Spanish national level are eligible for reimbursement, the manner in which regional authorities integrate them into their reimbursement plans exhibits a degree of flexibility. This introduces a nuanced dynamic, where the diverse socio-economic landscapes of the 17 autonomous communities play a pivotal role in shaping the accessibility of innovative technologies and medicines.

The disparity in access stems from the unique economic, political and social realities of each autonomous community, creating a scenario where the availability of these cutting-edge technologies differs significantly across regions. This intricate interplay between national approval and regional implementation underscores the need for a nuanced and region-specific approach to ensure equitable access to advancements in healthcare across the country. Regional decision-makers can be mandated to reimburse new health technologies once the interterritorial Board of the national health system ("Consejo Interterritorial del Sistema Nacional de Salud") and the national government include them in the national health services catalog ("Cartera de Servicios del Sistema Nacional de Salud").

The Spanish country pilot sought to address regional disparities by raising awareness about the disparities, access challenges and patient needs. The pilot partners - Asociación Española de Afectados de Cáncer de Pulmón (AEACaP) and Fundación MÁS QUE IDEAS (FMQI) - and the From Testing to Targeted Treatments (FT3) program have the shared vision that all lung cancer patients who could benefit should have equitable access to precision medicine, including biomarker testing, within the Spanish National Health System (SNS).

2.2 Approach and methodology

Taking a first step towards addressing this complicated reality of the Spanish healthcare system, FT3 convened a local multi-stakeholder group. Co-led by the largest lung cancer organization in Spain - AEACaP -, and the seasoned health advocacy foundation FMQI, the steering committee was complemented with support from industry expertise.

² Disclaimer: the national situation is in continuous change. The context below addresses the reality during August 2022 and July 2023, which encompasses the timeline of the described activities.

With the aim to support advancements in equitable access to PM in Spain's healthcare system towards the shared vision that all lung cancer patients who could benefit should have the equal opportunity to access new technologies and treatments, the group defined three objectives:

- Highlighting disparities and delays in access to biomarker tests (types of biomarkers and how/when they are determined) among the Autonomous Communities.
- Providing information and knowledge to lung cancer patients about precision medicine, and about the centers where biomarker tests are conducted, based on patient information needs.
- Increasing awareness among different stakeholders about the situation faced by lung cancer patients (disparities and delays in biomarker access) and its consequences, to reduce these inequities at a national level.

Having decided to target deficits in access to biomarker testing and empowering patients with information and knowledge as the basis to increase awareness levels among a wider range of stakeholders of the challenges in a lung cancer patient's care pathway, the group co-created two qualitative research approaches in order to provide as rounded a picture as possible. On the one hand, a survey targeting pathologists and oncologists was designed to elicit on-the-ground information on the access situation, and, on the other hand, a survey aimed at lung cancer patients was thought to uncover their information needs and experience with biomarker testing. Additionally, patient testimonials were to complement the two surveys.

Access mapping survey

To determine where improvements in access to biomarker testing could be made across the 17 Autonomous Communities, the local steering committee decided to select four regions to start with. Andalusia, Cantabria, Catalonia and Extremadura served as diverse examples in terms of socio-economic reality and access to PM solutions. To map the real-world access situations around biomarker testing in each region, the access mapping methodology went through a stepwise design, developed with the locally recruited research partner (Nephila). This included:

1. A literature review with the objective of detecting similar initiatives and analysis variables for the design of the interview scripts and the questionnaire given to medical professionals. The team used PubMed research, using keywords such as non-small cell lung cancer, molecular diagnosis, biomarker testing, cancer diagnosis and Spain.
2. Three in-depth interviews to help outline and validate the survey dimensions and content. The team interviewed a medical oncologist, a molecular biologist and a pathologist.
3. Launching a survey of oncologists and pathologists to understand the current situation with regards to biomarker testing in Andalusia, Cantabria, Catalonia and Extremadura. This was a self-administered online survey, applied for one month. In total, 85 professionals across 82 hospitals were invited via email to participate in the survey.

Patient survey

The goal of the patient survey was to explore the level of knowledge of people with lung cancer about biomarkers, identifying difficulties in the information process and interest in learning more about this issue, as well as exploring the experiences of people with lung cancer during the diagnostic process and, more specifically, in relation to biomarker testing.

The survey was co-created by the steering committee, guided by the expertise of the group's co-lead FMQI. Following consultation of literature with the primary aim of analyzing similar national and international initiatives, as well as ascertaining the current evidence on biomarkers in lung cancer and their availability and accessibility in Spain. The questionnaire was tested by a group of ten people with lung cancer, who made suggestions on how to make the survey more understandable and coherent and on how to improve its content.

The online survey was self-completed anonymously by people with lung cancer. The survey consisted of 35 questions (33 closed and 2 open-ended) and the time period for completing the survey was from April 10 to May 15, 2023. The survey was distributed via social media channels and newsletter by AEACaP and FMQI.

Patient testimonials

To complement these activities and build on FT3's interview questionnaire to collect patient experiences, together with AEACaP, a Spanish version was adapted to the concrete needs of this project. The questionnaire was then sent to lung cancer patients from AEACaP's network in three autonomous communities selected for the access mapping. Underlining the impact biomarker testing may have on a patient; the testimonials were designed to enhance insights from the access mapping and patient survey with real-world patient experiences.

2.3 Results

2.3.1 Main Findings of Access Mapping Survey in Spain

A total of 33 professionals (18 pathologists and 15 oncologists) from 28 hospitals participated in the survey (response rate 38%). Of these, there are 15 professionals from 13 hospitals located in Andalusia, 13 professionals from 10 hospitals located in Catalonia, 4 professionals from 3 hospitals in Cantabria, and 1 professional in Extremadura. All carry out their care work in medium or large hospitals, with the most frequent being medium-sized hospitals (with more than 100 beds).

Planning and access to biomarker testing

When it comes to planning and facilitating access to biomarker testing, the landscape in Spain reflects a mixed scenario. Two out of four analyzed Autonomous Communities have concrete strategies or plans for precision medicine, including biomarker testing implementation.

In Catalonia and Cantabria, the majority of the surveyed oncologists and pathologists stated that they have a plan or protocol at the regional level. In Andalusia, 5 out of 15 surveyed oncologists and pathologists reported that hospital plans/protocols exist, and regional plans/protocols were reported as unavailable. In Extremadura, no plans were found or reported.

According to the majority of professionals surveyed in each autonomous community, the main form of financing for molecular diagnosis is the hospital's overall budget. An exploration into hospitals offering biomarker testing reveals a prevailing trend of in-house testing conducted within their own laboratories. Most hospitals (25) feature decision-making committees overseeing patient access to these tests. Tumor committees, primarily comprising pathologists and oncologists, dominate these decision-making bodies. Nearly half of those surveyed have molecular committees in their centers (13). A minority of professionals (from 4 centers) have reported the existence of specific molecular committees for lung cancer.

Despite the national clinical practice guidelines indicating biomarker testing should be conducted upon diagnosis irrespective of the disease stage, survey results indicate that the accessibility is more commonplace in the advanced stages of cancer across most regions, with Catalonia presenting an exception.

The survey results indicate that access to biomarker testing is viable across various cancer types (excluding small-cell cancer), ensuring accessibility for an impressive 86% of patients meeting the criteria for such testing.

Care network

Navigating the intricacies of the care network reveals a specific set of roles and responsibilities in the realm of biomarker testing.

According to those surveyed, the initiation of biomarker testing requests typically falls under the purview of medical oncologists and pathologists, with the latter often assuming the primary responsibility for selecting the testing technique. The execution of these tests is a collaborative effort involving both pathologists and molecular biologists, who carry out the tests using samples collected within the hospital laboratory.

While the American College of Pathologists advocates for a swift turnaround time of less than 14 days from sample availability to the reporting of final results, the average found in Spain based on the responses of the surveyed HCPs across the four selected regions was 19 days with variations reported across regions (between 13 and 31 days). Cantabria and Catalonia to stay close to the recommended time frame of 14 days, with patients in Extremadura and Andalusia who may have to wait one month to obtain the test results.

Biomarkers, techniques and barriers

In the intricate landscape of biomarkers, techniques, and the barriers that shape their utilization in Spain, a nuanced picture emerges.

The main reported barrier to access to molecular diagnostics in all the Autonomous Communities is the public financing deficit (13/33 HCPs from 13/27 hospitals), followed by inequity territorial in access

(11/33 HCPs of 10/27 hospitals); the complexity of some techniques to obtain results, the lack of recognition of the molecular biologist and the high cost of molecular diagnostic techniques (10/19 HCPs from 10/27 hospitals).

The most frequently reported barriers per Autonomous Community are:

- Andalusia: Difficulty of access to the infrastructure of the referring hospitals (8/15 HCPs) and inequality territorial access (8/15 HCPs)
- Cantabria: Lack of recognition of the biologist molecular (2/4 HCPs) and high cost of the techniques (2/4 HCPs)
- Catalonia: Complexity of some techniques (6/13 HCPs)

On the front of biomarkers, hospitals included in the study generally align with the recommendations set forth by the Spanish Society of Medical Oncology (SEOM) and the Spanish Society of Pathology (SEAP). Most of these essential biomarkers, supported by evidence, are accessible in most surveyed hospitals. Next-generation sequencing (NGS) is the most widely applied technology across all investigated regions. On the other hand, liquid biopsy is seldom used and access to it shows a low degree overall.

On average, the HCPs reported to be quite satisfied with the process of access of lung cancer patients to molecular diagnosis in their hospital. The degree of satisfaction is slightly higher than the average in Cantabria and Catalonia.

2.3.2 Main Findings of the Patient survey

148 patients participated in the survey, of which more than 80 had biomarker testing, 25.3% didn't know if or did not have biomarker testing, and all 17 autonomous communities were represented. Four patient testimonials were collected, one from each of the four autonomous communities included in the pilot.

The survey was mostly completed by women (63.5%). In the sample as a whole, the 45 to 64 age group (65.5%) and individuals with university studies (57.1%) stand out.

60.9% of participants resided in Madrid, Catalonia and Andalusia. Three out of four people were diagnosed with non-small cell adenocarcinoma-type lung cancer (76.7%). 55.8% of participants were diagnosed within the last three years. The majority of the sample had stage IV cancer (62.3%).

Patient satisfaction

The majority of the patients who responded to the survey are not satisfied with the information received on diagnosis and have difficulties understanding it. The information received during diagnosis can be improved for one in three people (30.3%). In addition, more than half of the people surveyed (58.2%) recognize difficulties in understanding their diagnosis. The main barrier reported was having little time to process the news and understand the information (31.5%), followed by not receiving clear enough information about the diagnostic process (21.9%).

Patient information needs

Patients reported a lack of information provided by medical teams about biomarkers and a low level of knowledge about them. Only half of the respondents (52.7%) claim to have been informed about biomarkers and biomarker testing by their medical teams. As a result, 41.7% of respondents stated that their level of awareness of biomarkers was inadequate (none/very low/low).

Timely access

Survey respondents reported delays at each of the different stages of biomarker testing. The process that involves the longest waiting time is from sample collection to receiving the results. 57.4% of the respondents had to wait more than two weeks. In addition, there are delays of more than two weeks in the period between the news of the diagnosis and the request for the test (30.7%), as well as from the request to the collection of the sample (15.9%).

Many biomarker tests are outsourced to other hospitals, but this does not necessarily mean a longer delay. 22.8% had to go to another medical center for the biopsy and 43.6% stated that their sample was analyzed at another hospital. Despite this, the data extracted from this survey shows no major delays in those cases that were outsourced to other medical centers.

Techniques used

Most of the biopsies are of tumor tissue and a request from the medical team was sufficient. 94.1% stated that the sample collection was done via tumor tissue biopsy and only 21.8% was done through a liquid biopsy. On the other hand, 10.9% of respondents indicated that additional procedures were required in addition to the request for medical equipment.

Usability and understanding of results

Biomarker tests are considered very important for the diagnostic and therapeutic process. A majority - 87.1% - of respondents considered it important to know the results of the biomarker tests and almost half of the respondents (47%) said that their therapeutic approach changed after learning the results of the biomarker test.

Patients reported that they are not provided with adequate information and understanding about the objectives and results of biomarker testing. 19% of the respondents say they have not received information from their medical team about the purpose of biomarker testing, and 9% say they are not sure if they have received it. There are some objectives that are only known to a small minority of patients, such as its value in predicting the toxicity of treatments (7%) or in detecting resistance (18%). As for the results of these tests, more than one out of every three respondents (37%) have not been able to understand them or do not even have access to them.

Despite this there is a high level of interest in learning more about biomarkers and precision medicine. Almost seven out of 10 patients surveyed said they have sought information on biomarkers at their own initiative and nine out of 10 would like to know more about biomarkers and precision medicine.

Main reported challenges

Hospital infrastructure, technology and public funding are the main challenges for biomarker testing in lung cancer. The people with lung cancer who were surveyed consider the main challenge to be the lack of infrastructure and technology in Spanish hospitals (67.2%), followed by a lack of public funding (60.5%).

2.4 Conclusions

This nuanced exploration sheds light on the multifaceted landscape of biomarker testing in Spain, showcasing both commendable strides and areas warranting further attention and strategic development. Although biomarker testing is more or less guaranteed, ease of access and timelines differ considerably between regions. The variation between regions was shown to be due to a variety of causes. Through these multi-pronged research efforts, five discrete information gaps and access barriers were identified. These are:

- **Access to patient-friendly information and education on biomarker testing.** Despite the eagerness of patients to learn more about biomarker testing, the results of the patient survey suggested they are under-informed and undereducated when it comes to biomarker testing, its value, its implications and their results, which they may not even be told. The latter is particularly concerning, given that the majority of patients expressed their desire to know the results of their molecular testing. Patients find the process complicated and difficult to understand but report not enough time being spent helping them to do so.
- **Regional (in)equity in biomarker testing within and across autonomous communities.** The four selected autonomous communities represent a snapshot of the varying socioeconomic realities of the 17 Spanish regions. Satisfaction rating by the surveyed HCPs, biomarker testing implementation plans, and preeminent access barriers highlighted by HCPs all indicate the need to streamline access to biomarker testing across and within the decentralized Spanish healthcare system to ensure all patients who could benefit have an equitable possibility of accessing these new technologies.
- **Insufficient public funding.** Barriers to biomarker testing access, notably the absence of public funding, cast a shadow across all assessed Autonomous Communities. Geographical disparities compound these challenges, with Andalusia particularly affected by this inequality. Addressing these barriers is crucial for fostering a more equitable and comprehensive utilization of biomarkers, ensuring that advancements in medical science are accessible to all, regardless of geographic location or financial constraints.
- **Delays in diagnosis and turnaround times.** Patients reported delays at all stages of biomarker testing. There were extended periods between sample collection and results, and also delays between diagnosis and biopsy. While the waiting period between sample collection and result is recommended to be no more than 14 days, in some instances, it was as protracted as 31 days, although the average across the four selected regions was 19 days. Cantabria and Catalonia were closer to the recommended timeframe than the other two selected regions. This temporal gap in reporting results holds critical implications, particularly in the context of patients with

advanced-stage and metastatic lung cancer. The prolonged duration can potentially lead to delayed treatment decision-making, exerting a negative impact on clinical outcomes.

- **Limited availability and access to liquid biopsy.** While the potential of liquid biopsy in both localized and metastatic lung cancer is well-established, its utilization remains modest to moderate across the four Autonomous Communities under scrutiny. The data from the patient survey suggests that the use of liquid biopsy is still only in a minority of cases in Spain, with just one in five of the patients surveyed providing their sample in this way.

Limitations of the research should be noted, as it involved only 4 out of 17 regions, with one region (i.e. Extremadura) contributing just a single response, affecting the comprehensiveness and generalizability of the findings.

These research results are used as a foundation for the next steps to improve the understanding of PM among lung cancer patients and empower them in care choices, and accelerate the establishment of structural foundations for broader and more timely access to biomarker testing across Spain.

2.7 Appendix

- Survey results (HCP access [mapping](#) survey results; [patient survey results](#))
- Outputs ([Andalucia country card](#) , Spain [country card](#))

3. Country pilot in Hungary

3.1 Introduction to Hungary's country pilot

The Hungary pilot is a multi-stakeholder initiative in Hungary led by Lélek-Zet with the mission to improve patient awareness of biomarker testing among patients with adapted materials. The objectives of this specific country pilot were to provide targeted and adapted educational support to newly diagnosed patients to improve awareness of biomarker testing & targeted therapies, and also clearly demonstrate that access to biomarker testing can be improved by driving awareness among patients who could benefit in an environment where testing is already available/reimbursed. The goal was to achieve this by adapting and testing fit-for-purpose educational materials for patients that can be handed out or referred to by HCPs or patient advocates in partnership with local HCPs.

3.2. Approach and methodology

A multi stakeholder group of local partners was convened, including Lelek Zet, University of Debrecen and the National Koranyi Institute of Pulmonology.

The co-creation approach was rooted in regular communication and meetings. Monthly calls helped to co-define the existing gaps and barriers and define a shared vision and solutions;

An [access-barrier cause effect canvas](#) was produced to help highlight the barriers and gaps along the patient journey. The group identified the barriers and the solutions on how to address them, and also

looked at the existing potential good practices resources that could be adapted to lung cancer and to the Hungarian context.

Among the resources leveraged for adaptation included:

- FT3 suite of adaptable resources, Q&A adaptable resource, biomarker testing adaptable resource and the targeted therapies one
- Materials from No One Missed Campaign from Lungevity
- Materials from “Get Checked Campaign” from LuCE

All these materials were reviewed, adapted to the local context and translated into local language. In total there were six lay language resources developed, including Q&As for different care moments and resources on biomarker testing and targeted therapies. The Hungary Country Card was developed and the LuCE "Get Checked!" campaign was adapted for the Hungarian context. Importantly, all resources were made accessible in lay-language Hungarian to patients on Lelek-Zet's website and Synapse platform.

In terms of wider dissemination, the adapted materials were presented at the Forum of Young Pulmonologists 2023 in Hungary and a conference at the University Hospital in Debrecen. More workshops were planned in the fall of 2023 to present the materials and gather additional feedback from patients and HCPs.

3.3 Results

The pilot had an immediate and concrete impact. The two multi stakeholder workshops led to the group co-identifying local needs and collaboratively creating multiple resources relevant to the Hungarian context. The completion of the Hungary Country Card for Lung Cancer has now provided a comprehensive framework for addressing the specific challenges and requirements of the region. The adaptation of six resources to cater to local patient needs has made a tangible difference in the lives of individuals battling lung cancer. Meanwhile, the outreach efforts coordinated by the local patient organization Lelek-Zet, in conjunction with the engagement of three medical centers/hospitals, have collectively reached more than 100 patients, underscoring the meaningful reach and impact of these initiatives.

In terms of wider systemic benefits, workshops and discussions in the summer of 2023 revealed uplifting case studies and quotes that reflect a notable increase in patient confidence when communicating with healthcare professionals about precision medicine. The feedback received after two workshops with healthcare providers, hospitals and centers, shows the usefulness of the new resources to support HCPs in explaining patients their treatment and in providing the right information at the right time.

Overall, significant progress has been made in fostering collaboration and progress in lung cancer care in Hungary. The engagement of diverse stakeholder groups, including patients, industry representatives, and onco-pulmonologists, has resulted in a robust network of partners dedicated to the cause. The overall satisfaction and valuable insights shared by these partners, as indicated in surveys,

signify the effectiveness and success of the collaborative efforts. Moreover, the FT3 community's support has led to an increased ability and eagerness among local stakeholders to work together. Through surveys, it has been demonstrated that this collaboration has generated a deeper understanding of patients' experiences and needs, consequently paving the way for tailored solutions and improved care. Finally, the lessons learned and exemplary models developed throughout this process have potential applicability in other countries, laying the foundation for scalability and further advancement in lung cancer care on a global scale.

Overall, the impact of the Hungary pilot's efforts is evident in the improved collaboration, patient-centric care, and valuable resources that have been established, leaving a lasting legacy for lung cancer patients and healthcare professionals alike.

3.4 Conclusions

The multi-stakeholder setting and collaborative spirit of the group proved successful in driving the impact of the pilot project. The approach was also proven to be effective, as co-defining the existing gaps by leveraging access barriers cause effect canvas was shown to be a very efficient way to unveil gaps and define solutions. Building on existing best practices and on the available adaptable resources enabled the group to reach these results in a more efficient and effective way, saving both time and resources. In terms of limitations, it is clear that the impact of the pilot is still dependent on the network available to the patient organization and HCPs involved.

Limitations: the impact of the pilot is still dependent on the network available to the patient organization and HCPs involved.

3.5 Appendix

All outputs available on PM Synapse Hungary pilot page, under the resources section [here](#)