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D2.5_Global Specifications Report

E-QuoL Consortium

e·QuoL
Equality · Quality of Life · Survivorship

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AUTHORS

Charlotte Demoor-Goldschmidt
1_HUGO
e-QuoL Scientific Coordinator
Charlotte.DemoorGoldschmidt@chu-angers.fr

Marion Beauchesne
1_HUGO
e-QuoL Coordinator
Marion.Beauchesne@chu-angers.fr

Benoit Gerfault
1.1_CHUA
Project Manager
Benoit.Gerfault@chu.angers.fr

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1 Introduction

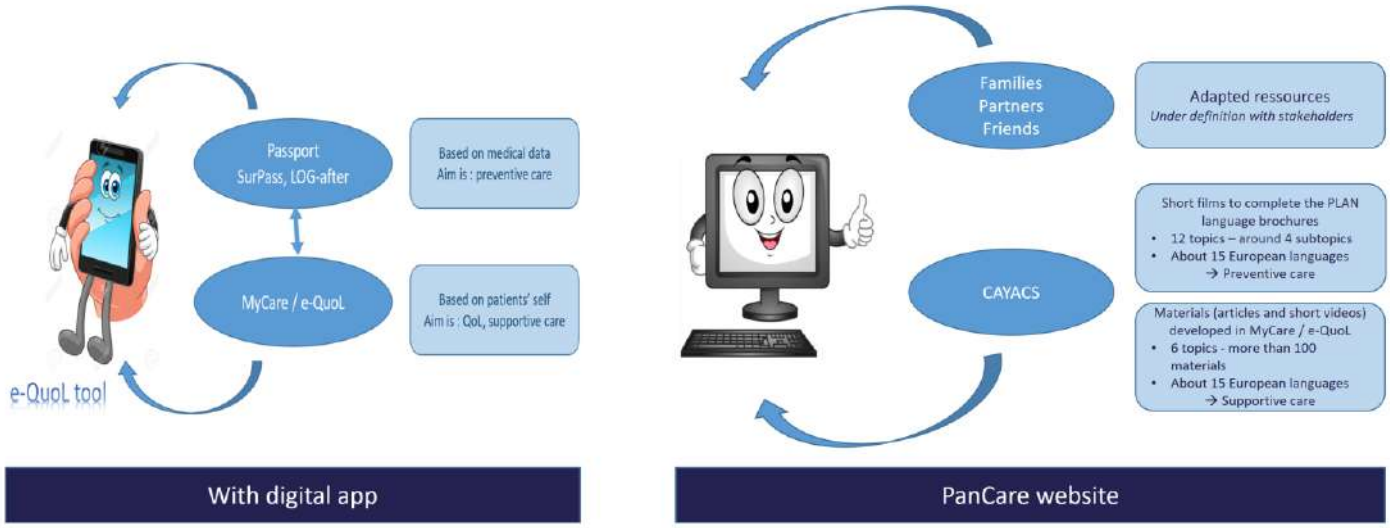
This Global Specification Report (GSR) is providing the current state of specifications pertaining to the digital solutions and educational materials provided and developed by the e-QuoL Consortium, this after 1 year of project implementation. This document provides an overview of the achievements of tools and approaches for survivorship in the e-QuoL project, talking into considering project objectives and end goals.

Implementation of tools does not go at the same speed regarding the country as the CAYACS survivorship is not developed at the same level. Nevertheless, our aim is to increase equity in Europe by sharing all the materials and translate them.

This report will firstly provide the results of the digital survey to encompass the digital tools specifications in countries, and then introduce the e-PSCT solutions (entitled MyCare$_{e\text{-}QuoL}$) developed by Resilience, and finally present the current level of development and considered development of the two digital passports (Log-After and Surpass) to be used in the countries during the clinical study.

This deliverable is the result of a joint collaboration engaging all the industrials partners from the passports and the MyCare$_{e\text{-}QuoL}$ solutions, as well as clinical research healthcare professionals engaged in the development of educative videos specifications, aiming to be disseminated during the project.

Equity & comprehensive survivorship in e-QuoL project



Leveraging past efforts to drive progress and maximize impact

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2 e-QuoL digital survey to define the users preferences and initial specifications

2.1 Methodology

The survey was an online survey conducted via the Sphinx platform between February 28, 2024, and April 30, 2024. Participants were recruited through e-QuoL partners, PanCare members, and supporting organizations, with an invitation to disseminate the survey within their networks. Inclusion criteria required participants to complete at least 75% of the 424 questions. The survey was divided into five sections:

- Profile of responders including detailed insights on LTFU care pathways in their centre/country.
- Specification of Needs: Identifying critical features and content for digital tools
- Descriptive and Technical Information: evaluating importance and feasibility of the different items
- Enabling Digital Tools: Exploring usability and potential barriers to tool adoption.
- Current Engagement with Digital Tools: Assessing past experiences and satisfaction with existing solutions – and for non-current-users perceived benefits and fears

Participants included patients, parents, healthcare professionals (HCPs, such as oncologists and nurses), and others (e.g., researchers or association representatives). Some individuals identified with multiple profiles (e.g., patient and HCP, or HCP and epidemiologist) and were categorized as HCPs for analysis. Participants were also grouped geographically into three regions: North (Finland, Sweden, UK, Ireland), West (France, Belgium, Spain, Italy, Netherlands, Germany), and East (Romania, Bosnia and Herzegovina, Hungary, Croatia, Slovenia).

Descriptive analyses were performed for all variables, including standard deviation to evaluate the agreement between responders. Verbatim were summarised by topics.

2.2RESULTS

2.2.1 PARTICIPANT

The survey involved 53 participants, of whom 46 completed more than 75% of the questions, corresponding to Part A of the survey. Among these, 45.7% of participants were actively involved in the e-QuoL project. Additionally, 39 participants completed 100% of the survey (Part A and Part B), while 7 participants responded only to Part B, which did not include their demographic profile. The mean age of respondents was 45 years, with female participants constituting the majority (n=35, mean age 44). Male participants (n=9, mean age 49.9) represented 20% of the cohort, and two participants chose not to disclose their gender.

Participants represented diverse professional and personal backgrounds. Healthcare professionals (HCPs) formed the largest group (n=25), including pediatric oncologists (n=13), nurses (n=3), radiotherapy oncologists (n=6), one general practitioner, one pediatrician, and one gynecologist. Patient and patient advocacy representatives comprised 15 participants, while parents were represented by 3 individuals. Additional roles included epidemiologist, data manager, and patient experience program manager (n=3). Among male respondents, there were four pediatric oncologists, three patients, one parent, and one radiotherapy oncologist. HCPs reported an average of 18.8 years of experience working with adolescent and young adult (AYA) cancer survivors, with 12 HCPs having more than 20 years of experience, while 8 had less than 10 years. Expertise in long-term follow-up care was self-rated on a scale of 2 to 10. Most participants rated their expertise as high, 7 or above for 82%. Those less expert were from Germany, Finland and Bosnia, including 2 HCP, and 2 other professionals. Among patients and parents, nine participants were board members of patient advocacy associations, including eight patients and two parents.

Geographically, the survey included participants from 15 European countries, with France (24%), Germany (20%), Romania (11%), and Finland (9%) being the most represented. The distribution ensured a comprehensive understanding of perspectives from various regions, including both Western and Eastern Europe.

Table 1. Characteristics of the responders

Characteristics	%	n
Sex		
Male	20%	9

Female	76%	35
Do not wish to specify	4%	2
Age		
≤25 ans	9%	4
26-35	22%	10
36-45	28%	13
46-55	11%	5
56-65	28%	13
> 65 ans	2%	1
Countries		
France	24%	11
Germany	20%	9
Romania	11%	5
Finland	9%	4
Belgium	4%	2
Bosnia and Herzegovina	4%	2
Hungary	4%	2
Ireland	4%	2
Italy	4%	2
Sweden	4%	2
Croatia	2%	1
Netherlands	2%	1
Slovenia	2%	1
Spain	2%	1
United Kingdom	2%	1
Personal/ Professional background		
Patient or Patient association representative	31%	15
Parent representative	6%	3
Pediatric oncologist	27%	13
Radiotherapy oncologist	13%	6
Paediatrician	2%	1
Gynecologist	2%	1
General practicioner	2%	1
Nurse	6%	3
Other (epidemiologist, data manager)	10%	5
Self estime concerning survivorship expertise (on a scale up to 10)		
10	20%	10

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8-9	37%	18
6-7	35%	17
5	4%	2
2	4%	2

2.2.2 CURRENT LTFU PRACTICES AND DIGITAL TOOL USE IN EUROPE

The questionnaire included different open questions regarding long-term follow-up care and digital solutions already in place in their country. It revealed significant variability in LTFU practices across Europe. In the North (Finland, Sweden, United Kingdom, Ireland), practices are more structured, with Finland standing out for its standardized passport system used in all five centers, although only one employs a digital tool for follow-up, which also uses a digital system based on auto-questionnaires and supportive care. Finnish centers also have dedicated teams for managing late effects. In the United Kingdom, the IAM portal is widely used, designed specifically for young survivors to monitor their health, emotional well-being, and social life. In the West and South (France, Belgium, Spain, Italy, Netherlands, Germany), LTFU practices vary between countries and even regions with coordination often led by pediatric hematologists/oncologists. These countries have implemented digital tools—LOG-after in France and SurPass in Germany, non-Francophone regions of Belgium and Italy—though neither is universally applied across all hospitals. LOG-after is linked with videos and three are designed for supportive care. In Germany, there is only one transition clinic, with LTFU either provided by the childhood cancer hospital or managed by general practitioners, depending on the case. In Belgium, they also used a tool collecting –PROs to support patients. In the Netherlands, LTFU is highly organized, with survivors—regardless of the time since treatment—having access to comprehensive care that aligns with international guidelines. In the East (Romania, Bosnia and Herzegovina, Hungary, Croatia, Slovenia), disparities in LTFU practices are evident. In Romania, the absence of a standardized LTFU plan and limited government support are significant barriers, with patient organizations stepping in to provide resources. Additionally, online tools are fragmented and often unavailable in Romanian. In Bosnia and Herzegovina, follow-up traditionally ends when patients turn 19 or five years post-treatment, with parents' associations playing a vital role in psychosocial rehabilitation and reintegration into daily life.

Only 11 participants (5 HCPs, 5 patients or parents, and 1 epidemiologist), 8 of whom are partners of e-QuoL reported using after-cancer digital tools or apps

tailored for post-cancer care plans, and 4 had access to a tool that included tailored supportive care. Among these users, 77.7% rated their satisfaction with these tools above 7/10. For 5 out of 7 participants, the tools improved their confidence in managing long-term follow-up care (on a scale from 0 to 10, where 0 indicated a decrease and 10 indicated improvement). Specifically, 1 patient scored a 7, 1 nurse, 1 pediatric oncologist, and 1 radiotherapy oncologist each scored a 9, and 1 pediatric oncologist scored a 10. The remaining 2 participants (an epidemiologist and a nurse) indicated that the tools had no impact on their confidence. None of the respondents felt that the tools decreased their confidence in managing survivorship. In comparison, among the non-user group, 2 out of 29 participants stated that using a digital tool would decrease their confidence. One patient expressed that they are already confident in how their long-term follow-up is managed by doctors without a digital tool, and 1 radiotherapy oncologist shared similar sentiments. The remaining respondents in this group included 15 HCPs and 11 patients or parents. Among them, non-cancer specialists were convinced it could help: a general practitioner rated the tool's potential impact on their confidence at 10, while a pediatrician rated it at 9 [figure 1]. Of the non-users, 76.7% (23/30) are willing to have a digital survivorship tool, while 6.7% (2/30) are not interested and 5 don't know.

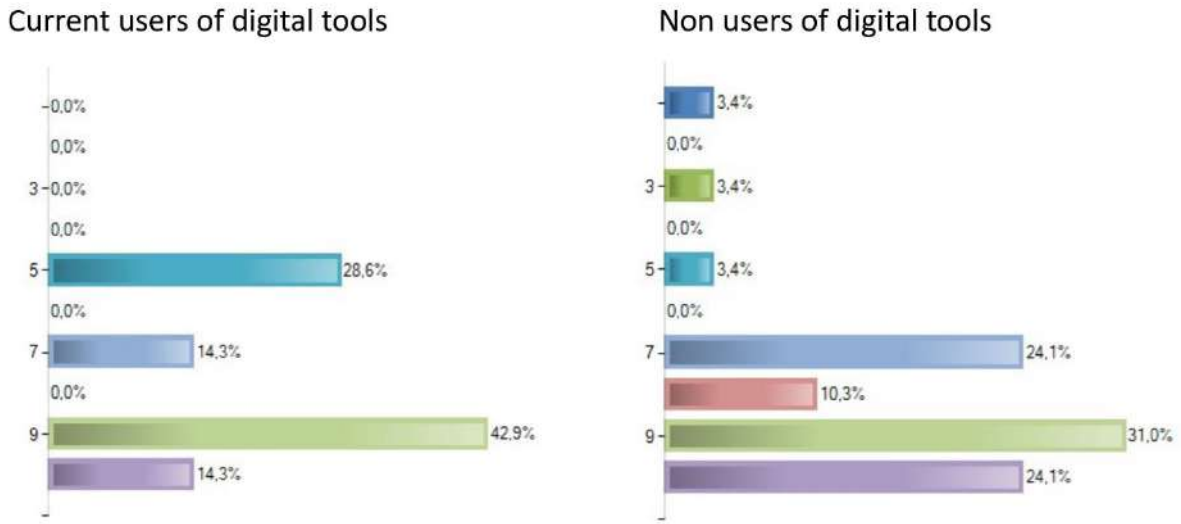

Figure 1. Confidence in managing long-term follow-up with a digital survivorship tool depending on the current use of such tools on a scale from 1 (less confident) to 10 (more confident)

Current users shared positive and negative feedback. One user appreciated the tool's usefulness in facilitating communication, allowing them to "message [their] health team and ask when [they're] unsure" (a patient from Finland). Another underscored its efficiency in a healthcare setting as it "reduces staff workload," (a

patient), it can “increase equality” (pediatric oncologist) by the use of the “algorithm” (other LTFU HCP), and increase communication with the other HCP “my GP is better informed” (a patient from Germany). Some users highlighted the convenience and accessibility of the tool, mentioning that it "helps keep all medical records in one place," and it "provides reminders for follow-up appointments," which they found particularly helpful for managing their care. The ease of use was also noted, with one participant stating that the tool is "intuitive and user-friendly," making it easier to navigate through their care plan. Regarding PROs, the just balance is not easy with some thinking that the “questionnaires [are] too long” (pediatric oncologist) while some patients were disappointed because they could just answer questionnaires “once a month”. Others mentioned accessibility issues, with one stating, "Not accessible for all survivors in my country". Another pointing out the tool's limitations in addressing mental health (a nurse and a patient), or fertility (a patient): "It doesn't observe enough the quality of life, e.g., mentally".

2.3 Specification Regarding An After-Cancer Digital Tool

Expectations and priorities from Open-Ended Questions

The thematic analysis of responses highlighted five core domains: content and features, tool design and functionality, data privacy and ethics, target audience and timing, and challenges and opportunities.

2.3.1 CONTENT AND FEATURES

In response to an open-ended question at the very beginning of the questionnaire, which captured participants' initial and spontaneous thoughts, the most frequently cited needs included access to information on late effects of treatments received, guidelines for managing these effects, and a summarized history of their disease and treatments [figure 2].

Figure 2. Word cloud illustrating the primary objectives of a digital survivorship tool (word size is proportional to frequency, indicating users' priorities and needs in managing their post-treatment journey)

Several respondents identified the need for comprehensive and personalized medical information. Key suggestions included the inclusion of treatment summaries, follow-up plans, potential late effects of treatment, and links to trusted resources, national databases, and healthcare specialists. The ability to track medical appointments and receive reminders for follow-ups was also frequently mentioned.

Psychosocial support emerged as a crucial feature. Participants proposed incorporating mental health assessments, connections to psychological specialists, and forums for survivors to share experiences and build support networks. Tools designed to assist survivors in managing anxiety, depression, or other psychological challenges were highly valued. Additionally, features to foster community building—such as discussion forums and peer connections—were considered essential.

Beyond cancer-specific care, respondents emphasized the value of broader health management resources. These included lifestyle advice, such as maintaining a healthy diet and managing fatigue, fertility information, and support

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for transitioning from pediatric to adult care. Collectively, these features were seen as essential for empowering patients and their families to manage survivorship effectively.

2.3.2 TOOL DESIGN AND FUNCTIONALITY

Participants emphasized the importance of inclusivity in the design of digital tools. Respondents highlighted the need for tools that are accessible to individuals with varying disabilities, including hearing impairments, visual impairments, and motor disabilities. Multilingual support was identified as critical, especially in international or multicultural contexts, with suggestions to tailor interfaces to local languages and cultures.

Ease of use was a recurring theme, with respondents advocating for intuitive interfaces that avoid excessive medical jargon. Tools that integrate seamlessly into patients' existing devices (e.g., smartphones, tablets, computers) and hospital systems were preferred. Additionally, respondents stressed the importance of tools offering meaningful feedback, such as personalized insights or progress updates, to encourage sustained engagement.

2.3.3 DATA PRIVACY AND ETHICS

Data protection and privacy concerns were cited by 52.4% of participants, with a greater emphasis on this issue among HCPs (58.2%) compared to parents and patients (47.3%). Ensuring data security and confidentiality was considered paramount. Participants stressed that access to personal information should be limited to authorized healthcare professionals and explicitly consented to by the patient.

Control over data sharing was another critical issue. Respondents strongly supported the idea that patients should retain ownership of their data and have the ability to decide with whom it is shared. Some participants expressed concerns about potential misuse of data by external parties, such as insurers or commercial entities, and recommended clear communication about how data would be handled.

2.3.4 TARGET AUDIENCE AND TIMING

Respondents recognized the diverse needs of the target audience, which includes children, adolescents, young adults, and parents. For 68.3% of respondents, it was

deemed important that parents' access to the e-health tool differs from the patient's access, reflecting distinct roles and information needs. Many emphasized that the tool should account for different developmental stages and provide tailored support accordingly. For younger users, parental involvement was considered essential, particularly for children under 10 years old.

The timing of tool introduction was an area of divergence. While some participants advocated for introducing the tools at the time of diagnosis to ensure early access to support, others preferred their introduction during follow-up care to avoid overwhelming patients and families during the acute treatment phase. Although there was no significant difference in preference between the "passport" tool and the one dedicated to supportive care, a slight trend was noted for introducing the supportive care tool earlier. Furthermore, there was strong agreement among respondents on the need for a personalized follow-up plan addressing the risk of complications or sequelae from the medium term—starting immediately after treatment ends—rather than waiting to enter the "long-term" survivorship phase.

2.3.5 CHALLENGES AND OPPORTUNITIES

Several challenges were identified in developing a comprehensive digital tool. Respondents highlighted the complexity of addressing the diverse needs of patients, families, and healthcare providers in a single platform. Additionally, ethical and logistical barriers in collecting long-term patient data were noted as significant obstacles.

Despite these challenges, respondents saw immense opportunities in leveraging technology to facilitate personalized healthcare. Suggestions included the use of artificial intelligence to create tailored follow-up plans, provide real-time feedback, and prioritize patient-reported concerns. The potential for such tools to enhance patient autonomy, improve care coordination, and foster meaningful connections between survivors and their communities was widely acknowledged.

2.3.5.1 CHARACTERISATION OF THE AIM OF THE DIGITAL TOOL

When prioritizing features for a digital LTFU tool (see Figure 3), participants rated "increasing general well-being" as the most critical, followed closely by "improving physical health status" and "providing information and education for patients."

These features were consistently rated highly, with most participants scoring them between 8 and 10 on a 10-point scale.

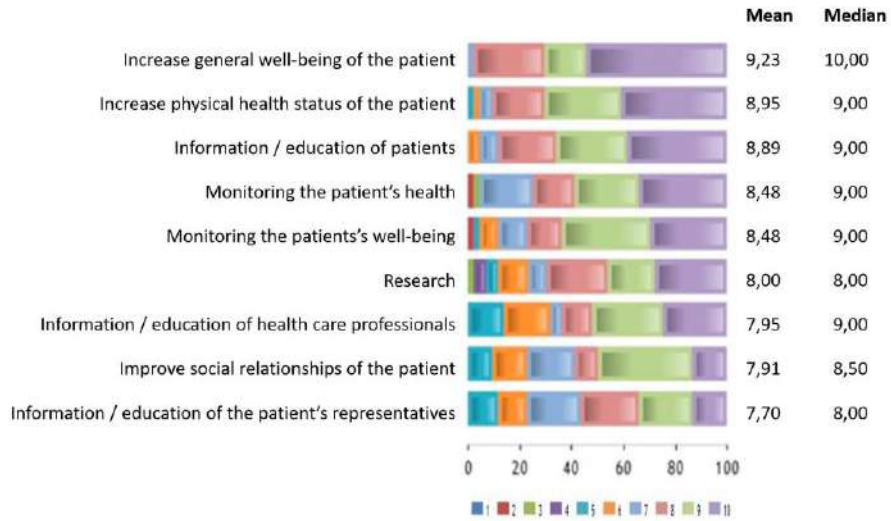

Figure 3. Prioritized Features for Digital Tools in Long-Term Follow-Up Care as Rated by Participants

Additionally, when asked to rank educational resources, respondents consistently prioritized access to detailed guidelines for managing late effects, with 81.3% of participants underscoring its importance (HCPs: 89.2%; parents and patients: 73.5%, p=0.22). The second highest priority was providing a summarized history of disease and treatments, noted by 76.1% of respondents (HCPs: 84.6%; parents and patients: 67.2%, p=0.26). Moreover, parents and patients placed a high value on clear and accessible educational materials tailored for both survivors and caregivers; 62.9% of participants expressed a need for health promotion programs focused on physical activity, mental health, and cognitive rehabilitation. On a scale from 1 (useless) to 10 (absolutely necessary), across all profiles, "Risks of late effects" received the highest average score of 9.41, followed by "Fertility" (9.02) and "Sexuality" (8.91). While these topics were consistently rated as top priorities by both healthcare professionals and parents/patients, patients and parents specifically placed "Sexuality" (8.94) ahead of "Fertility" (8.82) [figure 4].

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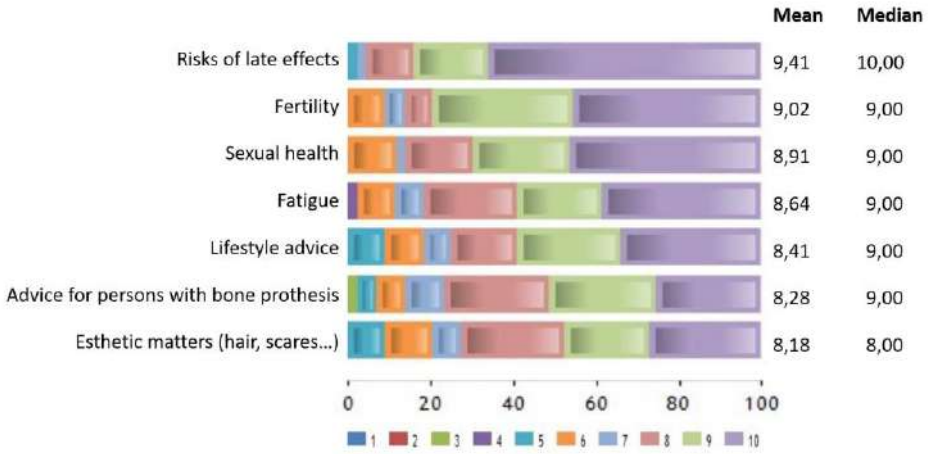

Figure 4. Prioritized suggested clinical topics as scored by participants

The survey highlighted that the digital tool is primarily considered essential for direct care providers and patients. No significant differences were observed in the perceived need for profile access based on the respondent's background as a patient, parent, or healthcare professional.Oncologists were rated the highest, with an average score of 9.71 out of 10, with only one respondent—a survivor from an Eastern country where survivorship care does not exist—scoring below 8 (at 6). Patients or their representatives were also highly prioritized, with an average score of 9.63; however, two respondents (a patient from a Western country and a pediatric oncologist from Eastern Europe) scored it at 5. Radiotherapy oncologists followed with an average score of 9.29, and hospital healthcare professionals such as nurses and medical doctors involved in follow-up care were rated 9.24. General practitioners were also considered important, with an average score of 9.02, though one survivor from a Western country scored access at 5. In comparison, access for surgeons (8.22), other medical doctors (5.93), registries (7.54), and researchers (7.51) was considered less critical. Notably, one epidemiologist scored access to radiotherapy oncologists and surgeons as 3, deeming it unnecessary.
The open-ended responses further elaborated on the specific needs for general practitioners (GPs). Respondents emphasized the necessity of a comprehensive medical record system that includes treatment histories, risks of late effects, and complications to support evidence-based care. A follow-up coordination feature, such as a digital calendar with reminders for check-ups and screenings, was also considered essential to streamline LTFU care. Some explained that GPs expressed a need for secure and efficient communication channels with specialized healthcare providers, such as oncologists, radiotherapists, and LTFU teams. Additionally, the integration of decision support systems—providing access to

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clinical guidelines and diagnostic aids—was seen as highly beneficial, particularly for addressing late effects. Ethical considerations were also paramount, with many highlighting that GPs should access only patient-approved information to ensure confidentiality and compliance with data protection regulations.

2.3.5.2 CONTENT

The questions focused not only on the level of importance but also on the feasibility of implementation. The analysis of responses revealed a significant degree of consensus among participants, as reflected by an overall mean standard deviation of 2.29, indicating general agreement on most items. Notably, 15 items had a standard deviation of less than 1.5, reflecting strong consensus. Agreement was higher for questions on importance (mean standard deviation: 1.93) compared to those on feasibility, where the standard deviation was 2.66 for already treated patients and 2.41 for newly diagnosed patients.

The survey results underscore the critical need for comprehensive summaries of disease and treatments within digital tools for LTFU care, while also highlighting differences in priorities across respondent profiles. Key elements, such as treatment history and follow-up plans, were consistently identified as essential. Among all respondents, the inclusion of a follow-up plan for the risk of sequelae in the first five years of follow-up was the highest priority, receiving an average score of 9.62 among patients, parents, and associations. Similarly, a long-term follow-up plan was rated highly across all groups, with healthcare professionals (HCPs) slightly favoring this component as their top priority (9.32). The specification of the type of follow-up required (e.g., cardiac or pulmonary monitoring) was also highly valued (8.95). Regarding which complications should be registered, balancing the level of importance and the level of feasibility for former patients and new diagnosed ones, the results show that those that have not resolved should be taken into account (mean score 8.27 versus all mean score 6.93, grade III or more mean score 7.67 or selected ones mean score 8.14)

Supportive care items, such as fertility preservation, were widely deemed important, with patients and parents assigning higher scores (9.14) compared to HCPs (8.00).

The items with the highest level of agreement (standard deviation < 1.5) and a high importance score (≥ 9) included: allogeneic stem cell transplantation, fertility preservation, unresolved complications (permanent complications), selected complications (e.g., cardiac, pulmonary), follow-up plans for the risk of sequelae in the first five years of follow-up, long-term follow-up plans, date of birth, an

algorithm to propose follow-up plans based on the other selected sections, and the ability to send reminders to patients or their representatives. Conversely, 11 items had a standard deviation > 3. Of these, 9 pertained to the feasibility of implementation for patients already treated, 1 related to newly diagnosed patients (cumulative corticosteroid dose), and 1 to the importance of items (name and surname).

Geographical and professional variations further influenced the perceived importance of certain items. Differences between healthcare professionals (HCPs) and patients were particularly pronounced for items related to the feasibility of documenting data for older patients and the importance assigned to specific items. Patients and parents consistently expressed a need for much more detailed information than healthcare professionals, assigning higher scores across 46 items compared to HCPs., particularly in areas such as radiotherapy, chemotherapy, and surgical treatments. For example, patients and parents prioritized detailed tracking of cumulative chemotherapy doses (9.07), precise information on irradiated organs (9.31), and specifics on surgical interventions (9.64), whereas HCPs generally preferred broader or partially summarized information for these categories. Interestingly, some radiotherapy oncologists who rated their survivorship expertise as ≥9 scored items with precise radiotherapy data—such as field, prescribed dose, specific data on organs at risk, and type of radiotherapy (e.g., proton, brachytherapy, photon)—above 9. When taking into account level of importance and feasibility, for new diagnosed patients, detailed information seem feasible (min, mean and max dose for organ at risk, mean score 8.80 – precise dose/volume data, 8.33 – field and prescribed dose and type of radiotherapy, 8.99). For 11 items, the difference in scores between patients and HCPs exceeded one point, notably for items such as autologous stem cell transplantation, allogeneic stem cell transplantation, and the center where radiotherapy was delivered. The largest discrepancies (greater than 1.9 points) were observed for items deemed more important by patients and parents: cumulative doses of corticosteroids, biopsies, surgical treatment due to previous complications, number of episodes of febrile neutropenia (e.g., requiring IV antibiotics), number of red cell transfusions, number of platelet transfusions, all complications (including those resolved), and place of residence at the time of diagnosis or during follow-up. For items where the discrepancy exceeded three points (e.g., biopsies, number of platelet transfusions, and all resolved complications), this gap tended to narrow among patients who self-identified as experts (score ≥ 8) in long-term follow-up, with the most noticeable reduction seen for platelet transfusions. The location of care, such as radiotherapy centers, exhibited wide score ranges (2–10) across all

groups, with no clear patterns based on country size or respondent profiles. Similarly, rare treatments like hyperthermic chemotherapy showed significant professional differences, with notably lower ratings from epidemiologists (scores of 1 and 2, respectively). Administrative data, such as the inclusion of the patient's place of residence at diagnosis, showed substantial variability, with patients and parents assigning an average score of 8, while HCPs rated it lower at 5.35. These discrepancies reflect differing perspectives on the level of detail necessary for effective follow-up care.

Table 2. Specification of the contents of a survivoship digital tool

Content items	All	Patients Parents Associa-tions	Health Care Profes-sionals	Other	
	Mean score	Mean Score	Mean Score	Mean score	Range
Information about past oncologic treatments					
Stem cell transplantation					
Including allogeneic stem cell transplantation	9,15	9,08	9,55	7,25	5-10
Including autologous stem cell transplantation	9,05	9,23	9,36	6,75	5-10
Including type of allogeneic stem cell transplantation	8,65	9,17	8,71	6,75	2-10
Radiotherapy					
Including field of radiotherapy and dose prescribed	9,03	9,64	8,82	8,50	2-10
Including some approximate information about irradiated organs (min, max, mean)	8,92	9,31	8,82	8,25	5-10
Including type of radiotherapy (proton, photon, electron, brachytherapy…)	8,89	9,67	8,68	7,75	2-10
Including precise dose/volume of irradiated organs	8,73	9,00	8,68	8,25	2-10
Including center where the radiotherapy was delivered	7,27	7,45	7,27	6,75	2-10
Chemotherapy					
Including cumulative dose of main substances (alkylating agents as CED1, anthracyclines as DIE2…) based on which screening or surveillance is usually recommended	8,98	9,07	9,18	7,50	5-10
Including cumulative dose of each chemotherapy substance (IV, per os, new drugs/targeted therapies, immunotherapies, intrathecal)	8,63	9,07	8,55	7,50	2-10
Including cumulative doses of corticosteroids	7,51	8,85	6,91	6,50	4-10
Surgery					
Including type of surgery	8,95	9,64	8,59	8,50	5-10
Including existence of prosthesis	8,87	9,33	9,05	6,50	4-10
Including surgical treatment because of previous complications	8,00	9,69	7,45	5,50	2-10
Including surgery for reconstruction	7,73	8,91	7,64	5,00	2-10
Including center where the surgery was done	6,80	7,86	6,41	5,25	2-10
Including biopsies	6,67	8,92	9,55	4,75	1-10
Other information					
Dates of each treatment	8,38	9,43	7,68	8,50	2-10
Rare treatments as radiofrequency, hyperthermic chemotherapy	7,82	9,33	7,45	5,25	1-10
Supportive Care					
Fertility					
Including fertility preservation	9,05	9,14	9,18	8,00	5-10
Including type of fertility preservation	8,38	9,08	8,32	6,50	2-10
Including place where the fertility preservation is conserved	7,65	8,93	7,23	5,50	1-10

Including date of fertility preservation	7,55	8,92	7,09	6,00	1-10
Transfusion and febrile neutropenia					
Including number of red cells transfusion	6,29	7,83	5,55	5,75	1-10
Including number of episodes of febrile neutropenia (ie lot of IV antibiotics)	6,00	7,25	5,27	6,25	1-10
Including number of platelets transfusion	5,58	7,75	4,36	5,75	1-10
Information about complications during treatment					
Including all complications (including those resolved)	7,37	9,42	6,14	8,00	1-10
Including all complications grade III or more (including those resolved)	8,45	9,17	7,91	9,25	1-10
Including all complications that have not resolved (permanent complications)	9,29	9,67	9,18	8,75	6-10
Including some selected complications (as cardiac, pulmonary…)	9,18	9,50	9,09	8,75	7-10
Information about other health history					
Including some specific items about personal health history	8,11	8,83	7,77	7,75	5-10
Including all items of personal health history (with ICD10 classification for example)	7,53	8,00	7,14	8,25	3-10
Including personal congenital anomalies/syndromes	8,55	8,42	8,77	7,75	4-10
Including personal genetic predisposition to cancer	8,82	8,25	9,23	8,25	5-10
Including familial cancer history	8,50	8,25	8,77	7,75	5-10
Including some specific item about familial health history	7,33	7,09	7,62	6,50	4-10
Including other Permanent/ chronic illnesses at the time of cancer diagnosis (= static section)	8,57	8,50	8,81	7,50	6-10
Including other New chronic illnesses diagnosed after the cancer diagnosis (=evolutive section)	8,75	9,18	8,71	7,75	6-10
Personalised follow-up plan					
Including follow-up plan for risk of sequelae in the first 5 years of follow-up	9,33	9,62	9,23	9,00	6-10
Should include follow-up plan for risk of relapse	8,31	9,31	8,09	6,25	2-10
Including long-term follow-up plan	9,23	9,46	9,32	8,00	6-10
Specifying the type of follow-up (cardiac, pulmonary…)	9,03	9,23	8,95	8,75	1-10
Specifying the type of screening (ultrasound, blood test, …)	8,87	9,23	8,73	8,50	1-10
Indicating a schedule (at which frequency each screening should be done)	8,90	9,31	8,82	8,00	4-10
Including synchronization to a calendar	8,21	9,31	7,82	6,75	2-10
Follow-up section					
Registering the results of the screenings (question per exam)	8,11	9,33	7,50	7,67	1-10
Registering the results of the subnormal or anormal screening only (question per exam)	8,06	8,00	8,23	7,00	1-10
Registering the health status at each follow-up	8,03	8,69	7,55	8,50	1-10
Registering the health status at regular intervals (for example each 4 or 5 years)	8,28	9,10	8,00	7,75	3-10
Allowing only the declaration of a significant health event with the date according to A predefined listing of events	6,86	6,90	6,86	6,75	1-10
Allowing only the declaration of a significant health event with the date according to ICD 10 classification	7,00	6,78	7,14	6,67	2-10
Allowing only the declaration of a significant health event with the date according to CTCAE classification	7,09	6,88	7,23	6,75	2-10
Administrative section					
Including names of doctors who treated the patient (oncology, surgery, radiotherapy)	6,65	7,64	6,05	6,50	1-10
Including name and surname of the patient	7,85	8,86	7,23	7,75	1-10
Including place of residence at time of diagnosis	6,35	8,00	5,36	6,00	1-10
Including place of residence during the follow-up	6,98	8,14	6,09	7,75	1-10
Including date of birth	9,23	9,31	9,55	7,25	3-10

2.3.5.3 KEY FUNCTIONALITIES FOR DIGITAL TOOLS

The survey results highlight critical functionalities for a digital tool in long-term follow-up (LTFU) care, reflecting diverse needs and preferences across different user groups. The most highly rated feature was the inclusion of an algorithm to propose follow-up plans based on selected sections, with an overall score of 9.25. This functionality was rated

slightly higher by healthcare professionals (HCPs: 9.07) than by patients and parents (8.93). The ability to send reminders was particularly valued for patients or their representatives, general practitioners (GPs), and hospital physicians, with respective mean scores of 9.25, 8.03, and 7.65. Agreement was highest for patient-directed reminders (SD = 1.22), while variability was greater for GPs and hospital physicians (SD = 2.15 and 2.35, respectively), with HCPs rating them particularly low (6.67 and 6.25).

Patients also rated a calendar feature designed to integrate follow-up schedules highly. This feature received lower scores among non-specialists such as GPs and nurses (scores below 5) compared to oncology specialists, who rated it significantly higher (scores of 8–10). Other functionalities, such as the ability to download personalized follow-up plans and documents, were also highly valued, especially by patients (9.33). The inclusion of auto-questionnaires for follow-up care (8.92) and research (9.00 for patients) received strong support (SD = 1.23 and 1.77, respectively).

Table 3. Prioritized Functionalities for Digital Tools in LTFU Care

Functionalities	All	Patients Parents Associa-tions	Health Care Profe-ssionals	Other	
	Mean score	Mean score	Mean score	Mean score	Range
Include the possibility to send reminders to the patients or their representatives	9,25	9,14	9,23	9,75	5-10
Include an algorithm to propose a follow-up plan based on the other selected sections	9,10	9,14	9,14	8,75	6-10
Possibility to download some documents (summary, personalised follow-up care plan,...)	8,66	9,33	8,27	8,75	1-10
Possibility to add auto-questionnaires used for follow-up care	8,21	8,92	8,41	8,75	5-10
Include the possibility to do exports of your own data (from your hospital)	8,68	8,83	8,64	8,50	4-10
Possibility to add auto-questionnaires used for research	8,45	9,00	8,09	8,75	1-10
Possibility to add professional questionnaires used for research (e-CRF hosting)	8,47	8,67	8,36	8,50	1-10
Capacity to discuss with health care professionals	8,43	9,50	7,77	8,25	2-10
Include the possibility to screen/search for specific patients from your own hospital regarding some characteristics (ie possibility of filters)	8,26	8,23	8,18	8,75	1-10
Possibility to upload/store additional files/documents	8,53	9,00	8,41	7,75	4-10
Possibility to generate letter / report on a pdf sheet including some points recorded in the software	8,18	8,15	8,09	8,75	3-10
Include the possibility to do regular imports of data from a registry or a local database or to be linked with them	8,26	8,62	8,18	7,50	1-10
Possibility to change the language of the user interface	8,14	9,27	7,71	7,25	2-10
Internet access without the necessity to download a software	8,15	8,54	8,05	7,50	3- 10
Include the possibility to do one import of data from a registry or a local database	8,21	8,31	8,27	7,33	1-10
Include the possibility to send reminders to the general practitioners	7,68	9,14	7,64	6,25	1-10
Software or application to download	7,60	8,29	7,50	7,00	2-10
Change in appearance (on the patient list) of deceased patients	7,38	7,50	8,14	6,50	1-10
Multilanguage support to generate letter / report	7,36	7,62	7,95	6,50	2-10
Include the possibility to send reminders to the hospital health care professionals	7,35	8,36	7,45	6,25	1-10
Capacity to discuss between patients (app community)	7,26	8,43	7,09	6,25	2-10
Email/SMS reminders when something is due (for professionals)	7,30	7,94	7,00	6,25	1-10
Email/SMS reminders when something is due (for patients)	8,51	8,71	8,27	9	4-10

Email or alarm when something is wrong/needs attention (questionnaire / result of exam…) (for professionals)	8,52	8,75	8,27	9	1-10
Indicating a schedule (at which frequency each screening should be done)	8,90	9,31	8,82	8,00	4-10

The user experience of digital tools, including the need for these tools to be engaging, easy to use, and customizable, was highlighted by 66.7% of respondents (parents and patients:72.4%, HCP:60.1%, p=0.59). Entertainment was not an important feature. Regarding the MARS questionnaire, engagement (fun, interesting, customisable, interactive (e.g. sends alerts, messages, reminders, feedback, enables sharing), well-targeted to audience), the score was 7.80 (with entertainment 6.03, interest 7.93, customisation 7.97, interactivity 8.09, target group 8.96). Functionality was scored as 8.95 (performance 8.66, ease of use 9.09, navigation 9.06, gestural design 8.97) and esthetics 8.48. Information was scored at 8.26 with quality as the most important point (9.31).

Table 4. Prioritized Features regarding the MARS questionnaire by subset of interface (passeports, e-PSCT for patients or ePSCT for health care providers)

	Type of tool Profil of user	Mean	Median	Range
Engagement fun, interesting, customisable, interactive (e.g. sends alerts, messages, reminders, feedback, enables sharing), well-targeted to audience				
Entertainment *(should it be fun/entertaining to use? Should it use any strategies to increase engagement through entertainment (e.g. through gamification)*	Passports	5,53	5	1-10
	e-PSCT	6,53	8	1-10
Interest *(should it be interesting to use? Should it use any strategies to increase engagement by presenting its content in an interesting way?)*	Passports	7,62	8	1-10
	e-PSCT	8,24	9	1-10
Customisation (*should it provide/retain some settings/preferences for apps features, e.g. sound, content, notifications, etc.)*	Passports	7,84	8	1-10
	e-PSCT	8,09	8	1-10
Interactivity *(should it allow user input, provide feedback, contain prompts as reminders, sharing options, notifications, etc.)*	Passports	7,82	8	1-10
	e-PSCT	8,36	9	1-10
Target group *(should the content (visual information, language, design) be appropriate for the target audience, ie, designed specifically for the target population)*	Passports	8,91	9	5-10
	e-PSCT	9	9	5-10
Functionality app functioning, easy to learn, navigation, flow logic, and gestural design of app				
Performance (*how accurately/fast should the features (functions) and components (buttons/menus) work?)*	Passports	8,57	9,00	5-10
	e-PSCT (patients)	8,70	9,00	5-10
	e-PSCT (HCP)	8,70	9,00	5-10
Ease of use (*should be pay attention how easy it is to learn how to use the app; how clear should the menu labels/icons and instructions be?)*	Passports	9,16	10,00	4-10
	e-PSCT (patients)	9,16	10,00	4-10
	e-PSCT (HCP)	8,95	10,00	6-10
Navigation *(should navigating between screens be logical/accurate/appropriate/ uninterrupted; should be paid attention that all necessary screen links are present)*	Passports	9,07	10,00	6-10
	e-PSCT (patients)	9,02	10,00	6-10
	e-PSCT (HCP)	9,10	10,00	6-10
Gestural design *(should we pay attention that interactions (taps/swipes/pinches/scrolls) are consistent and intuitive across all*	Passports	9,05	10,00	4-10
	e-PSCT (patients)	8,96	10,00	4-10

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components/screens?)	e-PSCT (HCP)	8,90	10,00	4-10
Aesthetics graphic design, overall visual appeal, colour scheme, and stylistic consistency				
Layout *(should we pay attention that arrangement and size of buttons / icons / menus / content on thescreen are appropriate or zoomable if needed?)*	Passports	8,78	9,00	6-10
	e-PSCT (patients)	8,76	9,00	6-10
	e-PSCT (HCP)	8,22	8,00	4-10
Graphics *(should we pay attention how high is the quality/ resolution of graphics used for buttons/icons/menus/ content?)*	Passports	8,40	8,00	4-10
	e-PSCT (patients)	8,47	8,00	4-10
	e-PSCT (HCP)	7,98	8,00	4-10
Visual appeal *(how good does the software/app look?)*	Passports	8,68	9,00	5-10
	e-PSCT (patients)	8,95	10,00	5-10
	e-PSCT (HCP)	7,95	8,00	3-10
Information contains high quality information from a credible source				
App / software description *(should it have a page of description)*	Passports	8,23	8,00	1-10
	e-PSCT (patients)	7,98	8,00	1-10
	e-PSCT (HCP)	8,40	8,00	3-10
Goals *(should it contain a page with information about the goals ? Should it precise specific, measurable and achievable goals?)*	Passports	7,82	8,00	1-10
	e-PSCT (patients)	7,82	8,00	1-10
	e-PSCT (HCP)	8,05	8,00	5-10
Quality of information *(how important is wording, clarity of items)*	Passports	9,41	10,00	7-10
	e-PSCT (patients)	9,36	10,00	7-10
	e-PSCT (HCP)	9,15	10,00	6-10
Quantity of information (1) *(should we pay attention that information is comprehensive but concise?)*	Passports	9,02	9,50	1-10
	e-PSCT (patients)	8,91	9,00	1-10
	e-PSCT (HCP)	8,85	9,00	5-10
Quantity of information 2 *(should links to more information and resources be present?)*	Passports	8,41	9,00	5-10
	e-PSCT (patients)	8,66	9,00	5-10
	e-PSCT (HCP)	8,15	9,00	1-10
Visual information *(should we pay attention that visual explanation of concepts – through charts/graphs/images/videos, etc. – are clear, logical, correct?)*	Passports	8,93	10,00	5-10
	e-PSCT (patients)	9,00	10,00	5-10
	e-PSCT (HCP)	8,64	9,00	2-10
Credibility 1 *(should information on how it has been built, the references be described ?)*	Passports	7,09	7,00	2-10
	e-PSCT (patients)	7,02	7,00	2-10
	e-PSCT (HCP)	7,48	8,00	2-10
Credibility 2 *(should the strategy of maintaining up to datedness be described ?)*	Passports	7,60	8,00	3-10
	e-PSCT (patients)	7,35	7,00	3-10
	e-PSCT (HCP)	7,98	8,00	4-10
Evidence base *(should information about eventual trial going on or published results be mentioned somewhere ?)*	Passports	7,63	8,00	2-10
	e-PSCT (patients)	7,67	8,00	2-10
	e-PSCT (HCP)	8,40	9,00	2-10

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2.3.6 BARRIERS AND STRENGHTS TO THE ADOPTION OF DIGITAL TOOLS

2.3.6.1 STRESS AND ANXIETY

Responses regarding "Stress and anxiety of survivors" and "Stress and anxiety of parents of survivors" showed variability across demographic, professional, expertise, and geographical profiles. For "Stress and anxiety of survivors," the mean score was 7.32 (SD = 2.22), with a range of 1–10 [table 4]. HCPs, such as pediatric oncologists and gynecologists, provided consistent scores (mean = 7.75, SD = 1.65), while participants from patient/parent associations exhibited higher variability (mean = 7.50, SD = 2.50).
Participants with moderate expertise gave the highest mean scores for both "Stress and anxiety of survivors" (mean = 7.82, SD = 2.16) and "Stress and anxiety of parents of survivors" (mean = 7.71, SD = 2.05), while those with high expertise assigned lower scores for survivors (mean = 6.87, SD = 2.32) and parents (mean = 6.52, SD = 2.31). Geographically, Northern Europe exhibited the highest variability (SD > 3.00), Western Europe showed more consistent scores (SD < 2.00), and Eastern Europe had moderate variability (SD ≈ 2.20).

2.3.6.2 BARRIERS TO DIGITAL TOOL IMPLEMENTATION

Several barriers to adopting digital tools for LTFU care emerged across respondents among open-questions, categorized as follows:
Interoperability Issues: A lack of compatibility between digital tools and existing healthcare systems, such as hospital information systems (HIS) and electronic medical records (EMR), was frequently noted.
Digital Literacy and Accessibility: Limited access to devices, poor internet connectivity, and varying levels of digital literacy among survivors and HCPs posed challenges.
Complexity of Tools: Concerns were raised about overly complex tools, lengthy questionnaires, and their potential to overwhelm users.
Data protection and security concerns, privacy laws.

Resource and Financial Constraints: Challenges included insufficient funding, lack of dedicated personnel, and time constraints for HCPs to manage tools or respond to alerts.
User-Centered Issues: Some tools were perceived as impersonal or failing to address patient needs adequately, with limited engagement from users.
Cultural and Socioeconomic Barriers: Issues like cultural attitudes towards technology and socioeconomic barriers, such as lack of internet or devices, were highlighted by respondents from three different countries, emphasizing broader concerns about accessibility.
Specific items related to retrospective data collection for already treated patients received feasibility scores ≤ 5. For instance, fertility scored 9.05 in importance but 6.7 in feasibility for previously treated patients, reflecting practical challenges.

Among respondents, three—two HCPs and one patient representative—stood out as more sceptical. They came from regions without routine survivorship care, did not consider themselves experts in survivorship, and highlighted concerns over integrating digital tools into existing practices. Their responses highlight uncertainties linked to the lack of established survivorship programs in their regions, limited exposure to digital tools in clinical workflows, and concerns over how such tools could be effectively integrated into their current healthcare practices.

2.3.6.3 STRENGTHS OF DIGITAL TOOLS

Despite these barriers, respondents widely recognized the strengths of digital tools. Mean scores for their perceived benefits ranged from 8 to 10, with high ratings for improving adherence to follow-up care (8.9) and supporting motivation (8.8) than for increasing anxiety and stress. E-tools were also rated highly for improving the quality of life of survivors (8.5) and their parents (8.3), as well as health outcomes (8.6). Healthcare professionals gave consistently high scores (mean = 9.0) for e-tools' ability to enhance care, while patients and association representatives showed slightly more variability (mean = 8.7). Geographical differences were evident: participants from Western and Northern Europe provided the highest scores, while respondents from Eastern Europe rated e-tools positively but noted challenges related to infrastructure and resources.

Table 5. Potential barriers and strengths

Perceived barriers and strengths	Mean score
Adherence to follow-up care	8,55
Quality of life of survivors	8,39
Health status of survivors	8,25
Adherence to recommendations by supporting motivation and the ability to adhere	7,80
Quality of life of parents of survivors	7,75
Adherence to recommendations via change of behavior	7,57
Stress and anxiety of survivors	7,32
Stress and anxiety of parents of survivors	6,93

2.3.6.4 DISCUSSION

This first survey done during the e-QuoL project highlighted critical functionalities and barriers in the adoption of digital tools for after-cancer follow-up care, emphasizing their role in enhancing survivorship practices for CAYACS. Major findings of this study was the broad agreement on the aims and the essential features. The willing aims are firstly to increase general well-being and improve physical health status, then to provide information to empower CAYACS for managing their survivorship, and thirdly to monitor their well-being and health. This means that digital tools should include PROMS. Research was also well scored, before improving social relationships. Essential shared features such as follow-up algorithms, automated reminders, and personalized care plans were consistently rated as critical for improving adherence to follow-up protocols and alleviating the mental burden on survivors and their caregivers. This will guide the adaptation of our digital tools and the prioritization of necessary features.

In addition, the survey identified several barriers to their implementation, including technological challenges such as interoperability with existing healthcare systems, financial constraints and disparities in resource availability between countries further complicated the development and sustainability of these tools. Privacy and data security concerns were also highlighted, particularly in regions with stringent regulatory environments. Knowing these points, this will help to implement the tools in the different centres in the next years of the e-QuoL project.

The psychosocial impact of digital tools emerged as another critical consideration. While some respondents expressed concerns that e-tools could exacerbate stress and anxiety, others emphasized their potential to provide valuable psychosocial support. This dichotomy is supported by existing studies, such as Blaauwbroek et al. (2012). In this study from Netherlands, authors found that when follow-up care was conducted by general practitioners using a web-based survivor care plan, many survivors (77%) had experienced reawakened memories of their past illness, and 34% stated that all the supplied information had worried them (Blaauwbroek et al. 2012). Conversely, meta-analyses like Zhang et al. (2022), including randomized and non-randomized technology-assisted interventions, have shown that these interventions can yield positive psychosocial outcomes, particularly in improving mental health and reducing anxiety. Moreover, another study reported that online interventions provide benefits for the psychological well-being and improve mental health of survivors (Chandeying and Thongseiratch (2021). Thus, strategies to improve the communication of health risks and to provide robust psychological support are essential to mitigate these risks (Zebrack et al., 2012). Psychosocial health is one of the themes identified for the development of the e-PSC, which will be linked with the two 'passports.' In this way, it could ultimately provide a significant opportunity to reduce anxiety and improve mental health.

2.3.7 VALORISATION OF THE RESULTS

- Oral presentations: PanCare congress, Ljublajna, Slovenia 2024 – 6th AYA congress, Melbourne, Australia, 2024
- 2 articles (under submission process)

3 Survivorship passports in e-QuoL project

The e-QuoL project aim to support the deployment of 2 different survivorship passport during the e-QuoL project. One solution is the Surpass application, developed by Cineca

in Italy, and the second solution is the Log-After application, developed by EPICONCEPT in France.

Clinics participating in the eQuoL project can adopt the platforms by establishing internal workflows, such as managing survivor visits and issuing the Passport. The most effective approach is to learn from clinics that already have experience with the platform.
It's crucial to ensure compliance with legal and regulatory requirements, such as obtaining ethical committee approvals or adhering to data protection officer guidelines.

To support languages not yet available on the platform, clinics nned to translate content (e.g. form labels, platform interface) into the local language using an Excel template with variable lists.

3.1 SPECIFICATIONS OF the Surpass passport & WAY FORWARD

3.1.1 DESCRIPTION OF THE CONTENT AND FUNCTIONALITIES

3.1.1.1 OVERVIEW

SurPass, also known as the Survivorship Passport, is an advanced platform developed to support childhood cancer survivors (CCSs) by providing a systematic, personalized view of their cancer history and long-term care needs. It

offers a structured, automated approach to survivorship care planning based on internationally approved guidelines.
Because of the built-in algorithms that ease the preparation of the standard Survivorship Care Plan for HCPs, the SurPass tool (v2.0) has been certified as a Class I medical device (UDI-DI Code 8059793870019; Italian Ministry of health registration number 2328038) according to the EU Regulation 2017/745 (MDR). As reported in the declaration of conformity, the manufacturer (Cineca) has implemented the procedure for post-market surveillance as requested by MRD.
In addition to the Medical Device certification, SurPass v2.0 carries the interoperability feature, through the HL7 FHIR standard32, allowing bilateral data transfer from and to institutional or national Electronic Health Record (EHR) systems. This feature allows that the SCP as well as any new information obtained during follow-up can be easily transferred to hospital and/or national information systems.

Details regarding SurPass is presented in appendix 1.

3.1.1.2 CORE FEATURES

A- Treatment Summary (TS)

Collects over 240 standardized variables, including demographic, diagnostic, treatment, and clinical event data.
Uses international vocabularies and classifications such as ICD-O-3, ICCC-3, and ATC for consistency and global applicability.
Documents details of therapies, surgeries, and clinical milestones for survivors.

B- Personalized Care Plan (CP)

Automatically generates risk-based, evidence-driven care plans using algorithms linked to clinical guidelines.
Includes organ-specific follow-up recommendations, educational notes, and chronic condition management.
Physicians can review and adjust recommendations while maintaining traceability.

C- Passport Document

Outputs a comprehensive, multilingual PDF for survivors, including:

Personal data, treatment history, follow-up recommendations, and chronic conditions.
Final notes and patient-agreed future care plans.
QR codes link directly to the survivor's private digital area.

D- Survivor Private Area

Provides secure survivor access to download Passports, view care plans, and manage follow-ups.
Supports multilingual interfaces and document creation

E- Interoperability

Implements the HL7 FHIR standard for seamless integration with institutional and national Electronic Health Record (EHR) systems.
Supports Extract, Transform, Load (ETL) operations for data standardization, validation, and transformation.
Enables API integration for external applications to interact with the platform.
User Roles and Access Control

F- Designed with role-based privileges

Data Entry (for clinicians entering survivor data).
Data Manager (for data oversight and corrections).
Read-Only Access (for viewing without editing).
Survivor Profile (for survivor engagement).
Includes a robust audit trail system for tracking and verifying all data modifications.

G- Data Protection and Compliance:

Certified as a Class I Medical Device under EU Regulation 2017/745.
Adheres to GDPR and local regulations for data security and privacy.
Hosted on secure servers with daily backups and advanced encryption.
Documentation includes Data Protection Impact Assessments (DPIA) and Data Processing Agreements (DPA).

H- Platform Architecture

Modular architecture includes separate components for user management, survivorship data, and FHIR server integration.
Centralized data repositories ensure scalability and performance.

Secure URL routing and multi-factor authentication enhance system security.

I- Training and Support

Comprehensive user manuals and HL7 FHIR interoperability guides are available. Online support includes real-time ticketing and live chat for technical and clinical queries.

3.1.2 COUNTRIES WHERE IT WILL BE IMPLEMENTED

Germany, Croatia
Still under reflexion: Hungary, Denmark
This includes the need of translation in these different languages.

3.1.3 NECESSARY ADAPTATIONS FOR IMPLEMENTATION

Clinics participating in the eQuoL project can adopt the SurPass platform by establishing internal workflows, such as managing survivor visits and issuing the Passport. The most effective approach is to learn from clinics that already have experience with the platform.
It's crucial to ensure compliance with legal and regulatory requirements, such as obtaining ethical committee approvals or adhering to data protection officer guidelines.
Clinics should also formalize a data processing agreement (DPA) with Cineca to clarify the specific purposes of data management. A Data Protection Impact Assessment (DPIA) is also mandatory to conduct a risk analysis and to describe the implemented security measures.
To support languages not yet available on the platform, clinics can translate content (e.g. form labels, platform interface) into the local language using an Excel template with variable lists.

3.2 LOG-after Specification

3.2.1 DESCRIPTION OF THE CONTENT AND FUNCTIONALITIES OF THE CURRENT TOOL

3.2.1.1 OVERVIEW

LOG-after is an advanced medical software tool designed to enhance the follow-up care of childhood and adolescent cancer survivors. The software supports the implementation of personalized survivorship care plans (PSCP) and facilitates coordination among healthcare providers while empowering patients through accessible health management features.

Demoor-Goldschmidt et al. has presented an overview of the software in this article (Demoor-Goldschmidt C, Veillon P, Esvan M, Leonard M, Chauvet S, Bertrand A, Carausu L, Delehaye F, Lejeune J, Rouger J, Schneider P, Thomas C, Millot F, Claude L, Leseur J, Missohou F, Supiot S, Bihannic N, Debroise I, Jeanneaud C, Lebreton E, Roumy M, Aguerris L, Chrétien JM, Gandemer V, Pellier I. A software tool to support follow-up care in a French childhood cancer cohort: construction and feasibility. BMC Cancer. 2024 Jan 25;24(1):130. doi: 10.1186/s12885-024-11857-y. PMID: 38267891; PMCID: PMC10809785.)

3.2.1.2 CORE FEATURES

A- Data Management

Maintains a comprehensive electronic medical record (EMR) for each patient.
Collects and integrates detailed patient data (over 240 standardized variables, regarding demographic, diagnostic, treatment, and clinical event data), including:
Diagnosis and treatment history (e.g., surgery, chemotherapy, radiotherapy) – Other past medical events and eventual genetic predisposition.

Uses international vocabularies and classifications such as ICD-O-3, CIM10 for consistency and global applicability.
Socio-demographic and psychosocial information.
Health outcomes, lifestyle factors, and long-term follow-up (LTFU) details.
Data entry includes support for multiple user profiles (e.g., clinicians, data managers).

B- Personalized Follow-Up Care

Incorporates an algorithm-driven module to generate tailored PSCP based on:
Cancer type and treatment details.
Individual risk factors, such as genetic predispositions and comorbidities.
International and national clinical guidelines (e.g., IGHG, PENTEC, PanCare recommendations) (with bibliography, level of proof)
Provides automated and adaptable recommendations for monitoring, including examinations, frequency, and educational tools.
With this tool, physicians can review and adjust recommendations while maintaining traceability.

C- Patient Empowerment

Offers a patient interface to access key medical records, follow-up schedules, and notifications.
Enables patients to participate in self-reported questionnaires and educational activities (films and written information).
Supports transition from pediatric to adult care with tools for autonomy and health management.

D- Integrated Planning and Notifications

Includes a planning module to schedule and send reminders for follow-up visits.
Tracks adherence to follow-up plans and flags interruptions or adjustments.

E- Data Sharing and Collaboration

Allows secure sharing of patient records with general practitioners and other healthcare professionals.
Facilitates coordination between hospital-based clinicians and community care providers.
Enables export of anonymized data for clinical studies and analyses.

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F- Linkages with National and Regional Databases

Integrates with other registries, such as the National Pediatric Radiotherapy Database (PediaRT).
Supports automatic data imports to reduce manual entry effort.

G- Regulatory and Security Compliance

Complies with GDPR and French CNIL standards for health data protection.
Hosted on a certified health data server (HDS) ensuring robust data security and privacy.

H- Adaptability and Scalability

Modular design allows for customization and expansion based on local healthcare needs.
Potential for integration with new functionalities, such as quality-of-life modules or additional databases.

I- User-Centered Development

Co-designed with input from healthcare professionals, patients, and patient advocacy groups.
Continuous improvements based on user feedback and feasibility studies.

J- Additional available Resources

Provides access to pre-filled prescriptions, clinical study documents, and multimedia educational materials.

K- Training and Support

Comprehensive user manual and on-line tutorials are available.
Online support includes real-time ticketing and live chat for technical and clinical queries.

3.2.2 COUNTRIES WHERE IT WILL BE IMPLEMENTED

Belgium, Bosnia, Hungary
This includes the need of translation in these different languages.

3.2.3 NECESSARY ADAPTATIONS FOR IMPLEMENTATION

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Implementing the LOG-after tool in different settings needed to evaluate the impacts (notifications, printable documents, adaptations of French components (addresses, studies, etc.), etc.)
In addition, we will improve the ergonomics for healthcare professionals in the context of internationalization, in link with the survey done.
Below is a list of some examples that require adaptations.

3.2.3.1 FUNCTIONALITIES

-Sending SMS messages in other countries requires adaptations
-In France, the tool is linked to the radiotherapy database; however, this is not possible in other countries as they do not have a similar database....

3.2.3.2 CONTENT

-Additional chemotherapy protocols need to be included.
-Some advice in the follow-up care plan require adaptation. Some messages invite the survivors to visit French website, resources or links for further help or information.
Resilience integration and impact on patient access and patient inclusion workflow

3.2.4 CONSULTATIONS WITH COUNTRIES

In order to ensure a good understanding of the use of Log-After, a series of presentation with the interested countries has been organised starting during the summer of 2024, aiming at presenting the usage of the tool, as well as the existing features and the end product (eg the report). Participants were able to further discuss with the EPICONCEPT team about the different variables existing and the ones they might need.
Dr. Charlotte Demoor-Goldschmidt made a presentation on how to add a CAYAC in the sotfware, which allowed partners to understand in details how the solution could be adapted to their needs.

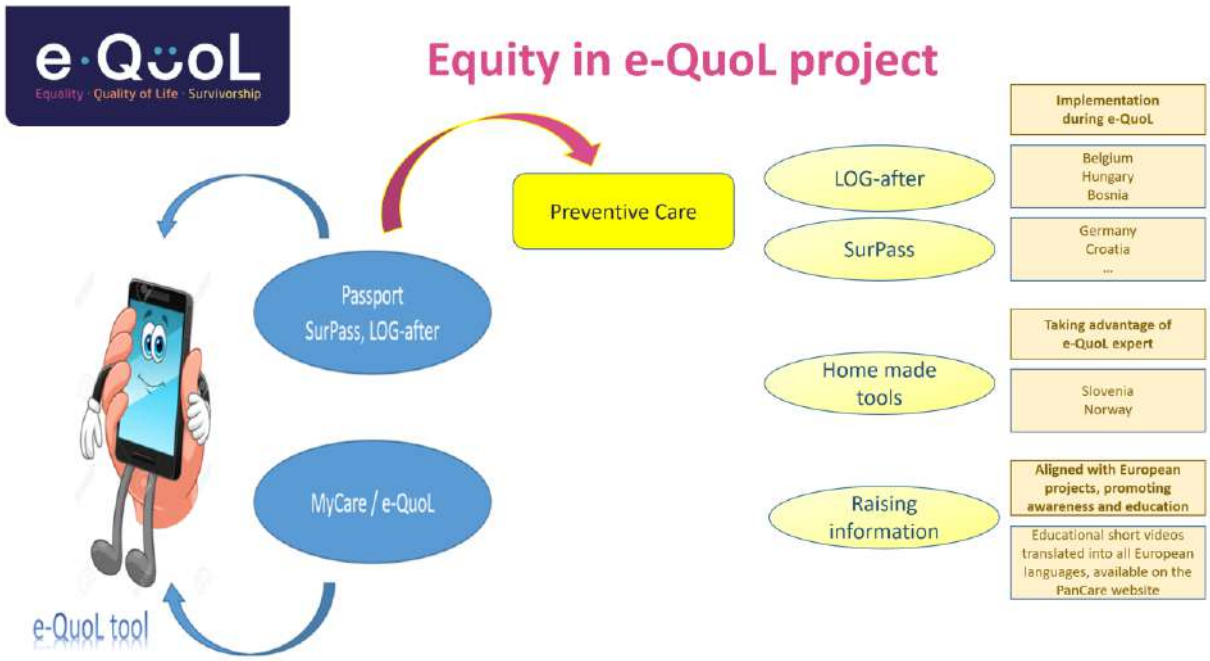
During the next months, the EPICONCEPT team will focus its work on developping the following aspects below, always with a strong concertations and consultations:

- Impacts of internationalization (notifications, printable documents, adaptations of French components (addresses, studies, etc.), etc.)

- Improved ergonomics for healthcare professionals in the context of internationalization

3.3 Other digital tools

Slovenia and Norway have decided to create their own tool, mainly because of legal barriers. They will benefit from the experience of SurPass, LOG-after and SALUB-type (Finland) experience and expertise.



4 e-PSCT tool (MyCare$_{e\text{-}QuoL}$)

Resilience solution enables the assessment of patients' needs, symptom monitoring, and referral to supportive care or specialized consultations when necessary. Through a dedicated mobile app to be used for patients and a dashboard for healthcare professionals, MyCare$_{e\text{-}QuoL}$ will facilitate the monitoring of ePRO data, improves treatment adherence, ensures better care coordination and increases the communication loop between patients and HCPs.

Resilience current tool

When personalized with specific patient date, the application also offers self-care programs and personalized educational resources aimed at improving patients' quality of life (QoL) and well-being. Medical experts & creative minds are collaborating hands to hands design best-in class immersive experiences tailored to patients' individual needs.

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Resilience current application

The current use is adult cancer patient, mainly during their on-going treatment. In the e-QuoL, the current tool will aim to be adapted

- to a different purpose: CAYAC survivorship, and,
- a different target of users : mainly adolescents and young adults.

The tool will, though, incorporate long term follow up topics and issues defined in concertation and collaboration, as the patients expected to use the tool are all in remission, sometimes since many years.

4.1 Compliance to standards

Resilience adheres to rigorously proven standards, regulations, and methodologies to ensure global availability and guarantee the quality, security, and compliance of the tools used.

Resilience standards, methods and compliance

4.1.1 VALIDATED TOOLS

Resilience's tools (MyCare/e-QuoL) rely on validated surveys, such as NCI PRO-CTCAE, EORTC QLQ-C30, and EQ-5D-5L, which are internationally recognized as reliable instruments for assessing patient-reported outcomes (ePRO). Additionally, Resilience uses certified sensors and wearable devices, including products with CE marking or FDA clearance, ensuring compliance with the strictest safety and quality standards worldwide.

In e-QuoL, we are working with EORTC adapted for CAYACS, as well as the STRONG-AYA partners, to include in the app the right questionnaires. CLB (France), HUPON (Hungary), UNILU (Swiss partner) in the WP2 and UNIOSL (Norvegian partner under WP3 – contents specifications) worked this first year to target the unmet needs of the CAYACS.

4.1.2 RELIABLE TECHNOLOGY

Resilience adopts standard data formats, such as HL7/FHIR, to ensure seamless interoperability and data exchange with major electronic health record (EHR) systems. The company also works with certified Health Data Hosting (HDS) providers, ensuring secure and compliant management of patient health data. This will be the same for e-QuoL.

4.1.3 QUALITY AND SECURITY METHODS

Resilience follows strict quality management methods, certified under ISO 13485 for Quality Management Systems (QMS), ensuring continuous optimization of processes for the development and management of medical devices. In terms of security, the company adheres to ISO 27001 for Information Security Management (ISM), and regularly conducts security audits and vulnerability assessments to protect data and ensure optimal risk management.

4.1.4 REGULATORY COMPLIANCE

Resilience's devices comply with Class 2a medical device status (under the European EuMDR regulation), ensuring they meet strict safety and performance requirements. Additionally, the company complies with the General Data Protection Regulation (GDPR), ensuring the protection and confidentiality of patients' personal data at all stages of the process.

These standards and methodologies ensure that Resilience provides an innovative, reliable, and compliant approach to care, offering maximum availability and security at a global scale.

4.2 Adaptations needed for the personalised supportive care digital tool

The main objective of e-QuoL is to improve the quality of life (QoL) and well-being of CAYACS and their families through comprehensive supportive care that addresses their physical, psychosocial, and informational needs, based on best practices and accessible, affordable digital tools. To achieve this, e-QuoL aims to assess and address the unique needs of CAYACS and their families while enhancing their quality of life by developing, for CAYACS, an electronic Personalised Supportive Care Tool (originally referred to as e-PSCT in the grant agreement). The tool has since been renamed *MyCare*$_{e\text{-}QuoL}$ to emphasize autonomy and active engagement. As a partner, Resilience, supported by the consortium,

will develop this digital companion to support CAYACS self-monitoring, improve knowledge and self-management, and integrate supportive care modules.

Resilience is involved in the creation and adaptation of the modules, leveraging its expertise in developing innovative content (articles, audio, video) and creating sustainable, certified products for both patients and healthcare professionals.

Resilience will also ensure the integration of this digital tool into clinical practices and adapt MyCare$_{e\text{-}QuoL}$ to different local contexts, healthcare systems, and languages. Additionally, Resilience and the consortium will make sure the tool is accessible to everyone by creating resources that are understandable, regardless of health literacy levels.

4.2.1 MYCAREE-QUOL DEPLOYMENT

e-PSCT will be deployed in all countries engaged in the e-QuoL clinical study. These countries are Italy, Germany, Norway, France, Belgium, Slovenia, Hungary, Switzerland and maybe Spain. *(see 3.6 below)*.

4.2.2 MYCAREE-QUOL EXPECTED FUNCTIONALITIES

Within the e-QuoL project, MyCare$_{e\text{-}QuoL}$ will be developed to provide the following functionalities to meet the study's objectives:

- Mobile application for patients, offering tailored content and self-assessment tools:
    - Needs and symptoms assessment questionnaires:
        - These questionnaires will enable the collection of key information about the patient's physical and psychosocial needs. Based on patient responses, the app will personalize the patient's experience, offering customized recommendations and resources.
        - The patient's answers will be securely transmitted in real-time to the caregiver interface (HCP), allowing healthcare professionals to monitor the patient's status.
    - Patient Activation Measure (PAM) questionnaire:
        - Integration of the PAM questionnaire will assess the patient's ability to manage their own care and the level of support they require.
    - Adapted Quality of life questionnaires for CAYACS are currently under definition, with the need to use validated and adapted questionnaires
    - Satisfaction questionnaire
- Healthcare Professional (HCP) interface:

- This interface will allow HCPs to include patients in the system and track the completion of questionnaires.
- It will provide HCPs with access to real-time data, including symptom and needs assessments.

These features will help MyCare$_{e\text{-}QuoL}$ tool support patients' self-monitoring, and enhance overall patient care by enabling a more personalized and responsive approach to their needs.

4.2.3 CAYACS NEEDS

e-QuoL is a participatory project. Several workshops are currently taking place to define and to test a prototype of MyCare$_{e\text{-}QuoL}$. The primary goal of these workshops is to assess whether the tool effectively addresses the specific needs and expectations of the CAYACs in terms of user experience. These sessions are designed to gather direct feedback from the users and ensure that the tool is intuitive, accessible, and truly meets their requirements, following the FormIt method

During the workshops, participants review various aspects of the app, including the clarity and appropriateness of the wording used, the structure and format of the responses, as well as the overall design and navigation of the tool. The feedback provided by the CAYACs are crucial in identifying any areas that need improvement or adjustment to better align with their preferences and needs.

Based on these insights, the MyCare$_{e\text{-}QuoL}$ will undergo necessary adaptations to enhance its usability and effectiveness. The adaptation process of the tool will be documented in the detailed specification report, which will outline all the changes and improvements made to ensure that the ePSCT delivers an optimal user experience for the CAYACs.

4.2.4 FUNCTIONAL AND TECHNICAL SPECIFICATIONS

The functional and technical specifications of Resilience adapted to e-QuoL needs will be defined in the following stages:

1. Needs analysis phase (under finalisation): Analysis of patient pathways and issues encountered, descriptions of stakeholder and patient expectations, with associated prioritization of each need according to level of importance and complexity. Several workshops are ongoing to defined the needs of CAYACs population and how MyCare$_{e\text{-}QuoL}$ will answer them.
2. Definition phase: Definition phase of the proposed pathways and experience with associated prioritization (MoSCOW method: Must Have / Should have /

Could have / Won't have) in order to define a gap analysis with the existing tool and identify the necessary developments.
3. Functional and technical specifications phase: Precise study of how to implement the proposed pathways and experiences based on the gap analysis performed (potentially, few gaps identified) and cost study based on priorities.
4. Validation phase: Validation of the final functional scope according to the costs, benefits and risks of each functional evolution.
5. Implementation phase: Development of functionalities by technical teams.

Adaptation process of the MyCare$_{e\text{-}QuoL}$ for CAYACS will be reported in the detailed specification report.

4.2.5 RESILIENCE WORKSTREAMS

In order to adapt the Resilience tool to the e-QuoL study, Resilience is working on 3 streams:

1. Stream 1: Patient Inclusion and Downloading the Resilience App

Specific steps at the time of inclusion: during a consultation in person or remortely, the HCP will inform the patient, collect the consent, create the patient on Resilience tool.

2. Stream 2: Questionnaires for Patients

Defining the questionnaires is a central element in understanding both the data required for inclusion and the data collected by Resilience throughout the study.

- The PAM questionnaire (PAM13 and PAMparent) defined in the study protocol will be implemented as is in ePSCT.
  Please refer to appendix 1 and 2 for PAM13 and PAMParent questionnaires
- For the "Needs & Symptoms Assessment" questionnaires, different details must be clarified and will be part of the detailed specification report:
  - How many questions will be asked to the patients, and what will the frequency be?
  - What will the content of these questions be, and what answer options will be provided?
  - What formats will be used for the questions and answer choices? (e.g., multiple choice, rating scales, free text, etc.)
  - What user experience will be provided for completing questionnaires? Specifically, how will the app handle starting, pausing/resuming, completing, and validating questionnaires?

These 2 last aspects are being explored through user testing and patient workshops (some already conducted, others planned).

3. Stream 3: Providing Relevant Information, Advice, and Support

To ensure a consistent experience and engage patients in using the app and completing the questionnaires, the information, advice, and support offered must be tailored to the phase the patient is going through and the specific needs identified through the questionnaires. Additionally, this content must evolve as the patient progresses through the study.

To build this framework, we need to address the following points, that will be part of the detailed specification report

- What are the patients' needs at each stage of their journey, and how can we provide relevant information and advice to meet those needs? (Workshops with patients panel are ongoing).
- What specific questions will be included in the questionnaires, and what follow-up actions will be taken?

Once these questions are answered, Resilience will finalize the personalized care pathway, identify any gaps compared to the current solution, and define the functional and technical specifications for the tool.

4.3 MyCare$_{e\text{-}QuoL}$ Contents

4.3.1 CONTENT CATEGORIES

The e-QuoL ePSCT will contain 6 main topics:

Contents categories

- Moving forward: an overview of the journey ahead for cancer survivors, emphasizing hope and practical steps for transitioning into life post-treatment.
- Coping with fatigue: provide practical tips and expert advice for managing cancer-related fatigue.
- Dealing with relationships and stigma: address the complexities of relationships post-cancer, includinf family, friends, and romantic partners.
- Fostering mental and psychosocial health: provide resources to support mental health and well being, emphasizing the importance of mental health care in recovery and towards the “new” life.
- Coping with cogitive difficulties: address cognitive challenges and provide strategies to manage and improve cognitive fiunction.
- Dealing with sexual health and fertility issues: support regarding sexual health preoccupations and fertility post cancer.

4.3.2 CONTENTS FORMAT

Each content category will display different contents’ format:

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- Introductory video: an overview of the theme, the associated challenges, and an outline of the answers that may be given within the category.
- Collections: to address a specific issue as a whole through didactic, concrete and helpful resources.
- Videos: for testimonials as well as for expert insights on the targeted themes.
- Articles: to go further and provide a more detailed understanding on a specific topic.
- Survivors' testimonies: with several survivors of different nationalities sharing their experiences, advices and reassuring words that come along.

4.3.3 CONTENTS PROPOSAL

The contents proposal is still being validated and will be detailed in the specification report. The current proposition outlines +100 contents in total: 73 videos and 30 articles all created specificlly for CAYACS.

Contents categories			
Category	*Nb of video contents*	*Nb of article contents*	*Nb of collections*
Moving forward	15	4	1
Fatigue	14	11	3

Social stigma & relationships	8	2	1
Psychosocial health	10	8	2
Cognitive challenges	8	3	1
Fertility and sexual health	18	2	2
TOTAL	73	30	10

Contents categories proposal

4.4 ePSCT translation process

2 levels of intervention:

1. Localization of the mobile application: translation of the app (interface, text & functionalities).
2. Translation of the content (video and articles): delivered first in English by Resilience.

4.4.1 LOCALIZATION OF THE MOBILE APPLICATION

Resilience will manage the localization of the mobile app: translation of the app interface, text and functionalities.

1. Create a new local in the app
2. Create and activate new local
3. Translate app labels (app interface, text and functionalities)
4. Check local regulation and registration
5. Adapt to local specificites: prepare legal requirements and integrations within the app
6. Adapt region related features and content (emergency numb, date format, phone number format)
7. Make it available in stores: integrate in stores (Apple and Android) and translate product page
8. Prepare support temas for new languages: customer support and stores reviews
9. Test the app locally

4.4.2 TRANSLATION OF THE CONTENT FOR MYCARE$_{E\text{-}QUOL}$

The translation process for contents is still under definition (particularly regarding the level of certification needed) and will be specified in the detailed specification report. Resilience will coordinate the translation of the contents (articles & videos) and then deliver the contents in all languages.

4.4.2.1TRANSLATION OF THE ARTICLES

1. Articles production: Resilience writes the articles in English (35% of total content) and delivers them by batch to the local experts for review, adaptation and validation
2. Articles translation: the translation process is still under definition and will be described in the detailed specification report.
3. Resilience ensures the implementation of the final articles in the app.

4.4.2.2 TRANSLATION OF THE VIDEOS

1. Videos production: Resilience produces videos in English (65% of total content) and delivers them by batch to the local expert (SRT format) for review.
2. Translation and post-production: the translation process is still under definition and will be described in the detailed specification report. A solution including AI is being considered.
3. Resilience ensures the implementation of the final videos in the app.

4.5 MyCare$_{e\text{-}QuoL}$ technical specifications

4.5.1 ARCHITECTURE

The Resilience architecture is mainly divided in two parts:

- In the HCP platform, the HCP will be able to include their patient and monitor the responses to the questionnaires.
- In the mobile app, patients will have access to questionnaires designed to identify their needs, symptoms, and quality of life. Based on their responses, specific content will be offered to them.

4.6 Patient inclusion process – e-QuoL study

The real number of countries that will participate is still under validation. Additional countries, beyond those initially outlined in the grant agreement, will participate : Belgium, Switzerland, Slovenia and 1 is under consideration, Spain. This will enable to follow the spirit of e-QuoL to promote and support the QoL of each survivor, regardless their country.

As part of the e-QuoL study, patients will be included by the healthcare professional (HCP) during an inclusion visit. The HCPs will generate an initial "passport", meaning a summary of the disease and a long-term follow-up care plan for each consented CAYACS. In some centers, this passport will be digitized using tools such as the LogAfter or SurPass solutions, and for other it can be a paper versión. During the visit, all consented CAYACS will be invited to log into the Resilience app, where $\text{MyCare}_{\text{e-QuoL}}$ will be available. A direct link from the passport interface is also under consideration. The inclusion of the patient into the Resilience environment will be carried out by the HCP on the HCP platform.

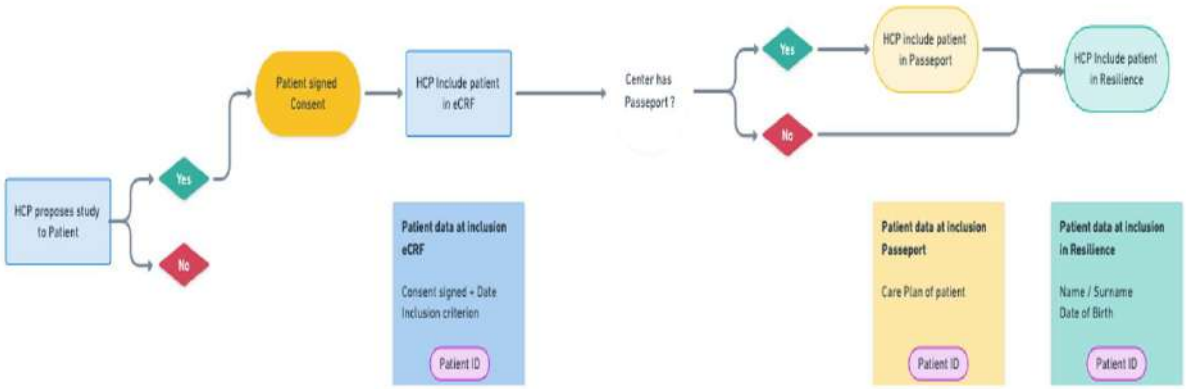
The use of multiple digital tools requires a unique patient identification across these tools. The process for creating a patient ID, which will be used in all tools, is currently being defined and will be outlinedin the detailed specification report. We are currently exploring the possibility of using an eCRF to generate this patient ID as mentionned below in the inclusion process proposal.

4.6.1 CASE OF A CLINICAL CENTER WITH A PASSPORT

1. Inclusion of the patient in the eCRF generating a patient ID.
2. Enter the patient ID In the passport
3. Inclusion of the patient in Resilience:
    - This will be done manually by the HCP in the Resilience HCP interface, by entering the patient ID and patient information (name, telephone number, e-mail address, pathology, etc.).

4.6.2 CASE OF A CLINICAL CENTER WITHOUT A DIGITAL PASSPORT:

1. Inclusion of the patient in the eCRF, generating a patient ID.
2. Inclusion of the patient directly in the Resilience caregiver interface (patient ID and patient information).



4.7 Overall data flow and link between tools

Once integrated into the Resilience platform, Resilience tool will provide the same experience to e-QuoL's patients as any other remotely monitored patient but providing tailored questionnaires and content (articles, videos, podcasts).

The interoperability between passports and MyCare$_{e\text{-}QuoL}$ via an API is not anymore considered.

The rationale for this decision includes the following points:

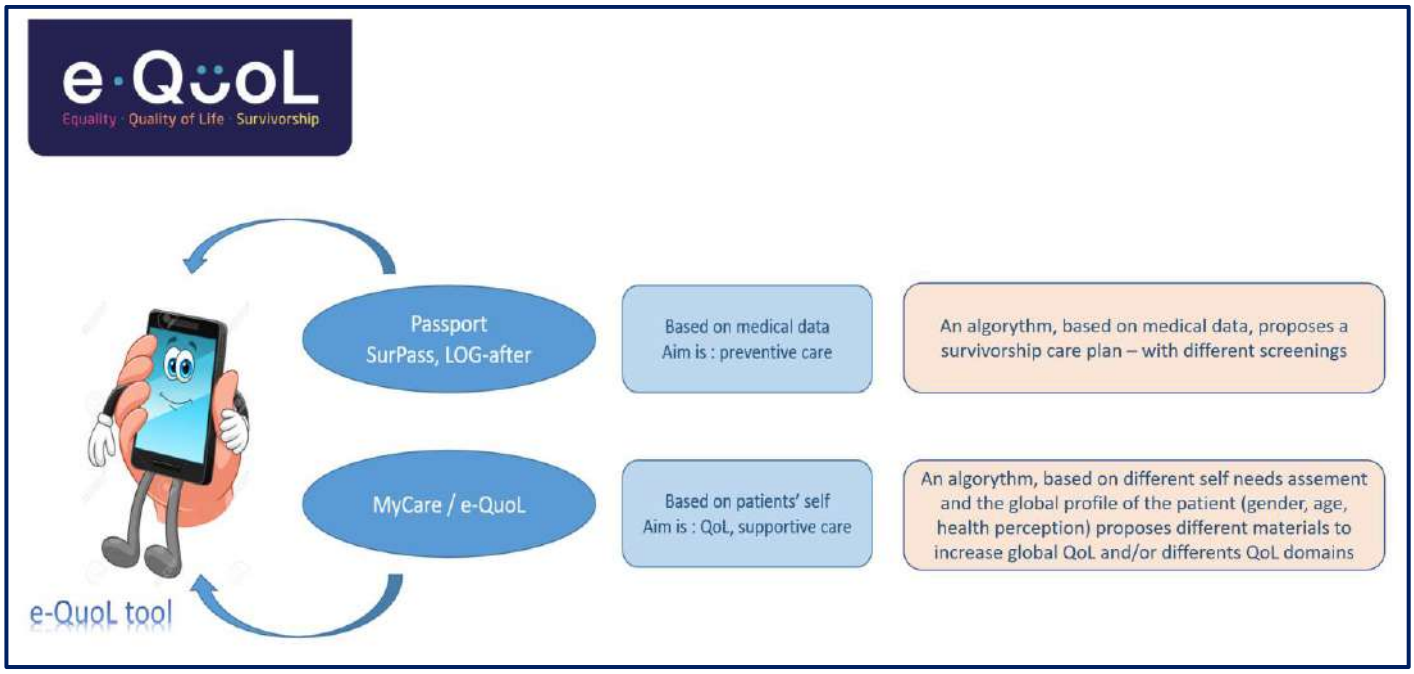
- The primary objective of MyCare$_{e\text{-}QuoL}$ is to deliver supportive care content tailored to enhance QoL. This personalization is only derived from patient-reported data (e.g., responses to questionnaires) rather than clinical or medical data.
- From an ethical perspective, delivering information related to medical data—such as fertility risks—should be approached thoughtfully to ensure patients fully understand their individual situation. Instead of directly pushing information via the app based on medical data, MyCaree-QuoL could first assess the patient's awareness of their own level of risk (e.g., "I am at high/medium/low risk" or "I don't know"). Based on their response:

    - If the patient knows their level of risk, the app can provide tailored content about available support and guidance.
    - If the patient is unaware of their level of risk, the app can encourage them to discuss this with their healthcare professional (HCP) before accessing further digital resources.

  This approach ensures that sensitive topics, such as fertility, are addressed appropriately and in consultation with HCPs, who are best equipped to explain complex risks and provide personalized advice. The app's role would then complement these discussions by offering tailored content aligned with the patient's level of understanding and specific needs.
- To ensure robust data protection, MyCare$_{e\text{-}QuoL}$ aims to minimize the sharing of sensitive medical data across devices unless strictly necessary. In this way, we do not want to collect data that won't be used to personnalise the patient's experience.
- The cancer- and treatment-related information is already shared by the "passport,"

Considering these factors, MyCare$_{e\text{-}QuoL}$ is being designed as an add-on module that complements passports without duplicating their functionalities. The following options are being explored:

- No medical data is shared with MyCare$_{e\text{-}QuoL}$. Personalization is based solely on patient self-assessment.
- A minimal set of data is shared (e.g., type of cancer, date of treatment completion), but for fewer than five data points, interoperability may not be efficient.



4.8 Data reporting specifications

Below is described the Resilience tool data model and related metadata specifications. The final format depends on the integration but the overall model would remain the same.

4.8.1 ENTITIES DATA MODEL

4.8.1.1 PATIENT

Field	Type	Nullable	Description	Values Examples (if relevant)
resilience_patient_id	string	no	Resilience's patient identifier	
inclusion_datetime	datetime	no	Datetime the practitioner has registered the patient	
first_monitoring_datetime	datetime	yes	Datetime the patient has started his monitoring for the first time (first questionnaire assigned)	
is_monitored	boolean	no	Flag to know if the patient is still monitored or not	
partner_patient_id	string	no	Partner's patient identifier, could be eCRF ID in case of clinical trial	

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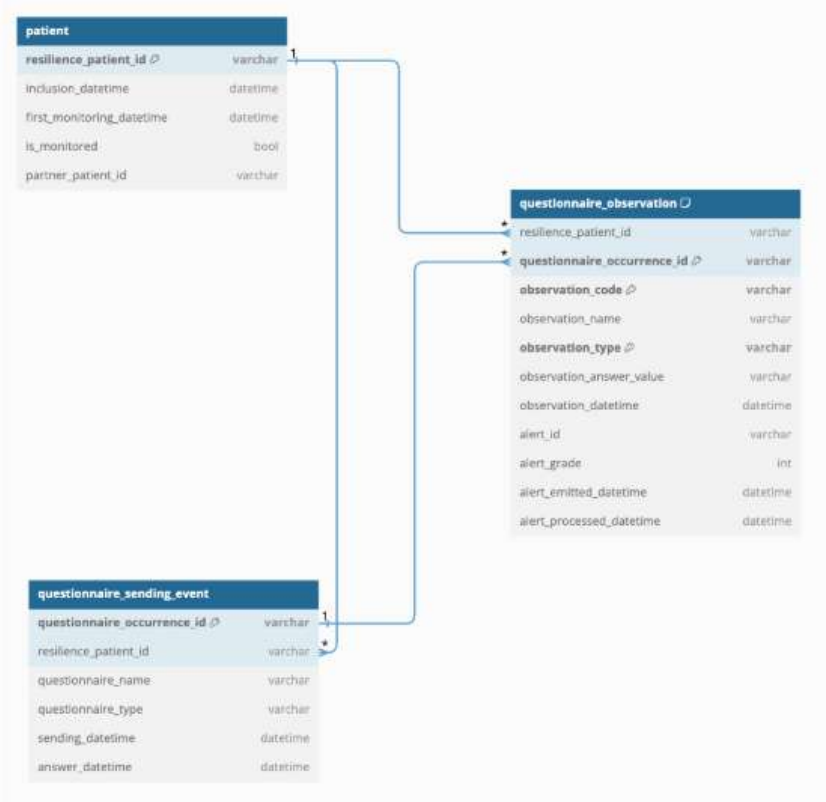
4.8.1.2 QUESTIONNAIRE SENDING EVENTS

Field	Type	Nullable	Description	Values Examples (if relevant)
questionnaire_occurrence_id	string	no	Resilience's identifier generated each time a questionnaire is sent	
resilience_patient_id	string	no	Resilience's patient identifier	
questionnaire_name	string	no	Resilience's internal questionnaire name	toutk00004, toutk00003, toutk00005, folfiribeva, paclitrastubreast, nivolumabipilimumab, toutk00001, folfirinox, anaemefulveletrotamo, toutk00002, capecitabinemonotherapy, folfox, epicyclobreast, cabopaclipembro, cfp, notr, pembro, trastumonotherapy, anticdkfoursixhormono, care1, doh
questionnaire_type	string	no	Resilience's internal questionnaire type (RPM for remote monitoring, DOH for determinants of health)	RPM, DOH
sending_datetime	datetime	no	Datetime the questionnaire has been sent to the patient	
answer_datetime	datetime	yes	Datetime the patient has answered the questionnaire, if he has answered	

4.8.1.3 QUESTIONNAIRE OBSERVATION

Field	Type	Nullable	Description	Values Examples (if relevant)
resilience_patient_id	string	no	Resilience's patient identifier	
questionnaire_occurrence_id	string	no	Resilience's identifier generated each time a questionnaire is sent	
observation_name	string	no	Symptom, adverse event or determinant of health asked to the patient	Access to care, Addiction frequency, Alcohol quantity, Anorexia, Anxiety, Arthralgia, Ataxia, Constipation, Cough,
observation_code	string	no	CTCAE code related to the observation_name	C143725, C146764, C58185, C146753, C57788, C57141, C80446, C57896, C57118, C143485, C9232, C20641, C146778, C143679, C143433, C143527, C55447, C58028, C143736, C143799, C58006, C55339, C143549, C143726, C143852, C64329, C143427, C146737, C37941, C146700, C143908, C3143, 10055798, C55060, C146747, C143688, C143298, C146771, C146763, C143424, C143649, C146687
observation_type	string	no	Observation type related to the question asked to the patient	presence, interference, frequency, thermometer, severity, kilogram, celcius, undefined
observation_answer_value	string	no	Patient's answer, mainly PRO-CTCAE scale for RPM questionnaires	
observation_datetime	datetime	no	Datetime the patient has reported this observation	

4.8.2 PSEUDO RELATIONAL MODEL



4.9 Technical support

Every Resilience user has access to technical support in case of a technical problem or need for assistance. In case of any issue, the user can send an e-mail to support@resilience.care. This email will be reviewed and managed by Resilience's Customer Support Manager. Alerts are managed via a ticketing system in the event of escalation, and are categorized according to their level of criticality:

- Blocker: the issue leads to inaccessibility or unusability of the main service. More specifically, bugs with an impact on device safety or primary clinical function.
- Critical: the issue leads to inaccessibility or unusability of the main service, with no major impact on patient care.
- Major: the issue prevents normal use of the service, but has no impact on patient safety.
- Minor: minor issue with no impact on device safety or primary clinical function

- Trivial: the issue has a very slight impact on the use of the service.

Resilience's support is available Monday to Friday, from 8:00 am to 6:00 pm (CET time zone).

4.10 Deviation from the initial proposal

4.10.1 MYCARE$_{E-QUOL}$ DEPLOYMENT

- MyCare$_{e-QuoL}$ will be deployed in all countries involved in the e-QuoL study, extending its reach to more countries than initially planned *(see 3.6 above)*. This broader deployment will enable the dissemination of critical information to a wider audience.
- A lite version of the app will not be deployed for countries not participating in the study. This decision was made after careful consideration of several factors:
    - Significant regulatory constraints for usage outside of a clinical trial context.
    - Challenges related to usage by minors outside the study, which could limit access to essential information for those who need it most.
    - The lite version was initially envisioned as beneficial for patients in non-participating countries (particularly those with fewer patients or without survivorship care programs) and for CAYACS lost to follow-up. However, the communication efforts required to promote awareness of the lite version would be substantial, with limited feasibility to effectively reach the target audience.

➔ After discussions with the PanCare (https://www.pancare.eu/) board, it was decided that it would be more effective and legitimate to centralize all patient-relevant information on a single platform. This consolidated approach will include:

- Preventive care resources, such as the PLAIN brochures currently being developed in other projects (PanCareFolluwUp) (https://www.pancare.eu/plain-language-summaries/)
- Educational materials, including French MOOC videos that will be translated into multiple languages (Berger C, Casagranda L, Sudour-Bonnange H, Massoubre C, Dalle JH, Teinturier C, Martin-Beuzart S, Guillot P, Lanlo V, Schneider M, Dal Molin B, Dal Molin M, Mounier O, Garcin A, Fresneau B, Clavel J, Demoor-Goldschmidt C. Personalized Massive Open Online Course for

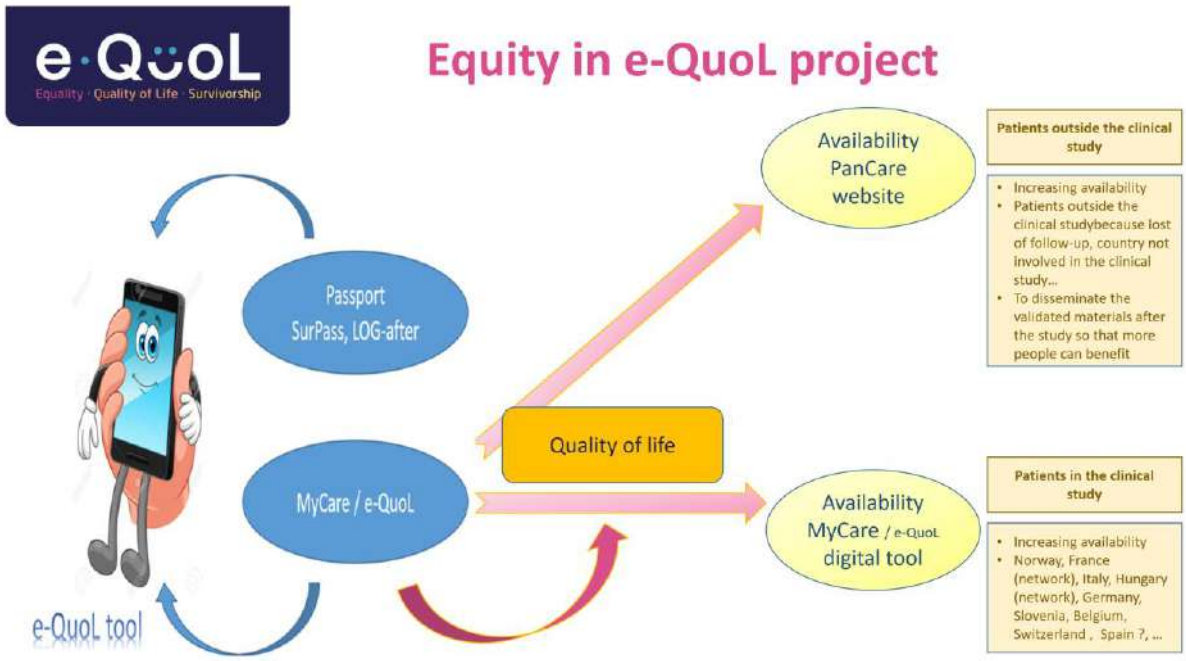
Childhood Cancer Survivors: Behind the Scenes. Appl Clin Inform. 2021 Mar;12(2):237-244. doi: 10.1055/s-0041-1725185. Epub 2021 Mar 24. PMID: 33763845; PMCID: PMC7990573.)

- Additional content developed through MyCare$_{e\text{-}QuoL}$.

By integrating these resources, this approach not only ensures a comprehensive offering for patients but also strengthens connections with other ongoing and past European projects.

This adjustment will require a reallocation of the budget between RESILIENCE and PanCare partners to support these modifications effectively.

In conclusion, the spirit of the project remains the same: maximizing the sharing of useful digital information to improve quality of life (QoL).



4.10.2 INTEROPERABILITY FROM "PASSPORT TO MYCARE$_{-E\text{-}QUOL}$

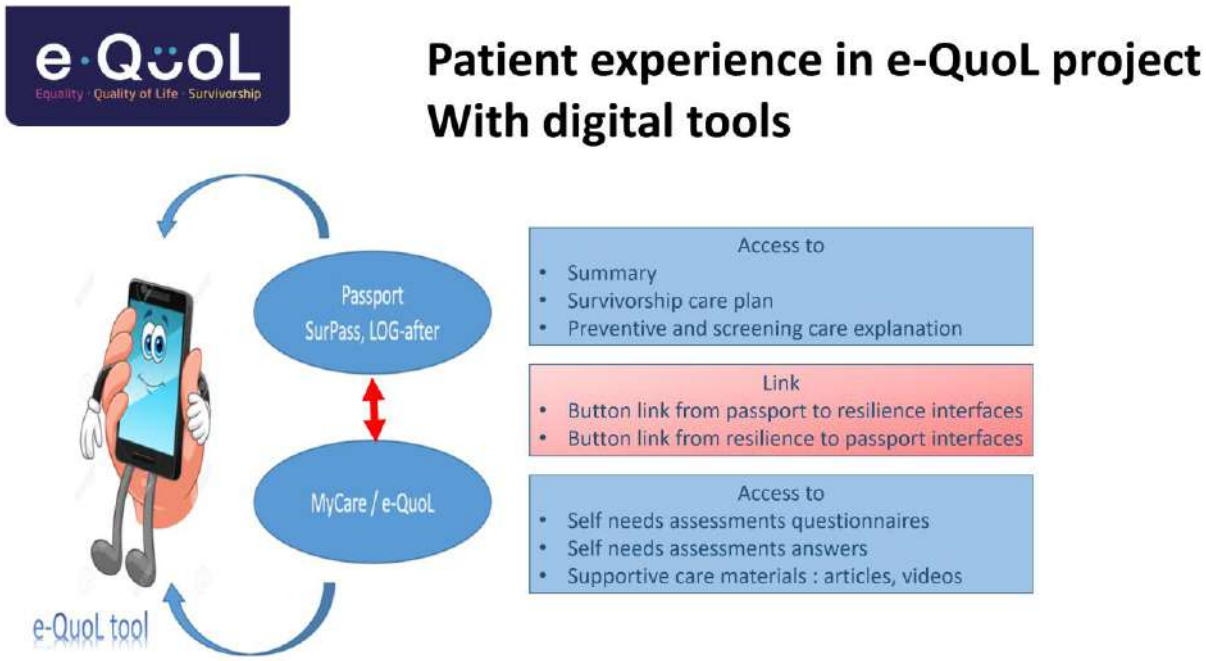
As explained above, this point is not anymore considered.

Some aspects could not be anticipated at the time of the proposal as we were not fully aware of the scope of needs we would address. It was necessary to determine whether medical data integration will be highly, moderately, or only slightly relevant. This

assessment was done in a participatory approach during the first year. As explained, our final decision was also guided by ethical considerations and efficiency.
This adjustment could require a reallocation of the budget between RESILIENCE and IGG partners to support these modifications effectively in link with the potential necessity of a bigger e-CRF.
However, the essence of the project remains unchanged, focusing on delivering a comprehensive tool for patients, combining:

- A passport dedicated to preventive care, based on the patient's medical history.
- An additional module for QoL and supportive care, tailored to the needs expressed by the patients.

Nevertheless, a link (as hypertext link) is under consideration to facilitate the CAYACS's navigation among these tolos



5 Specifications regarding the educational films

5.1 Content Design and Structure

5.1.1 MODULES

The MOOC "Childhood Cancer: Living well, after" comprises 11 modules: three addressing transversal topics (e.g., lifestyle, psychological support, fertility) and eight covering organ-specific sequelae.
Each module combines expert interviews and patient testimonies to provide both scientific and human perspectives.
Pedagogical scenarios were rigorously validated by multidisciplinary teams, ensuring medical accuracy and accessibility.
They are all currently in French and presented in this article Berger C, Casagranda L, Sudour-Bonnange H, Massoubre C, Dalle JH, Teinturier C, Martin-Beuzart S, Guillot P, Lanlo V, Schneider M, Dal Molin B, Dal Molin M, Mounier O, Garcin A, Fresneau B, Clavel J, Demoor-Goldschmidt C. Personalized Massive Open Online Course for Childhood Cancer Survivors: Behind the Scenes. Appl Clin Inform. 2021 Mar;12(2):237-244. doi: 10.1055/s-0041-1725185. Epub 2021 Mar 24. PMID: 33763845; PMCID: PMC7990573.

5.1.2 PRODUCTION FEATURES

Modules are presented as dynamic video segments, integrating animations, illustrations, and professional soundtracks to enhance engagement.
Testimonies and expert insights are carefully edited for brevity and clarity, maintaining an appropriate rhythm to cater to diverse attention spans.

5.1.3 NECESSARY ADAPTATIONS FOR IMPLEMENTATION IN THE E-QUOL PROJECT

Contextual Customization

5.1.3.1 TRANSLATION / ADAPTATION

The MOOC interface and modules require translation into local languages.
Specific cultural and linguistic nuances must be incorporated into both textual and spoken content.
Adaptation can be required to reflect local healthcare systems, guidelines, and legal frameworks for long-term cancer survivorship. In addition, testimonies with local survivors in the different countries to be shot again are under examination and will be detailed in the detailed specifications.

Text in the videos will be translated.
Subtitles will be added to allow survivors with hearing difficulties to have access to them.

5.1.3.2 COUNTRIES INTERESTED IN USING THE MODULES

The video will be translated in all the languages of the different partners.
Examination to do more languages is under consideration.

5.1.3.3 TECHNOLOGICAL ENHANCEMENTS

Development of AI tools and voice cloning technologies is underway to automate translation.
Translation will be then validated by native speakers, and corrected if necessary. (appendix 2).

6 Families and Friends needs : development of a web-based information tool for survivors'support network

Here are some global specifications:

- Target group: Survivors' support network: parents, siblings, partners, friends and other close connections
- Website characteristics :
    - Integrated within the PanCare website
    - Living website: periodically updated
    - Generic evidence-based information related to CAYA cancer
    - Relevant topics for participants from all countries: cancer information, late effects, coping, etc.
    - Refer to existing websites
    - Country-specific information and adjustments
        - Translate generic information to local languages
        - Check for cultural appropriateness
        - Include links to country-specific information

The develpment did not start and will be made by co-creation, in a participatory way. After having assessed the needs in reviews and in the Needs assessment study under the WP2, the priority topics will be shared during workshops with stakeholders (families, friends, social network). It will also be discussed how the information should be presented. Then the content will be developed taking the specifications proposed during the consultative workshops into account. Finally, in a Delphi type study, the contents will be finalized by receiving stakeholders input and contributions

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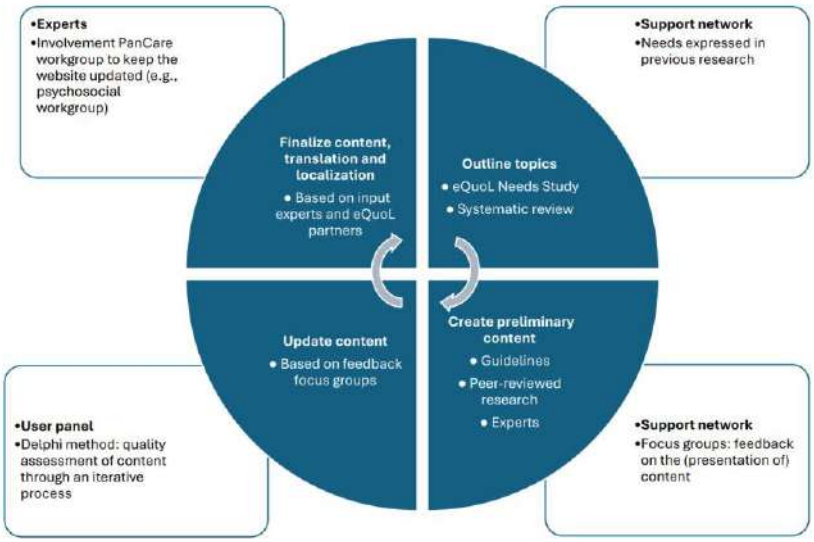
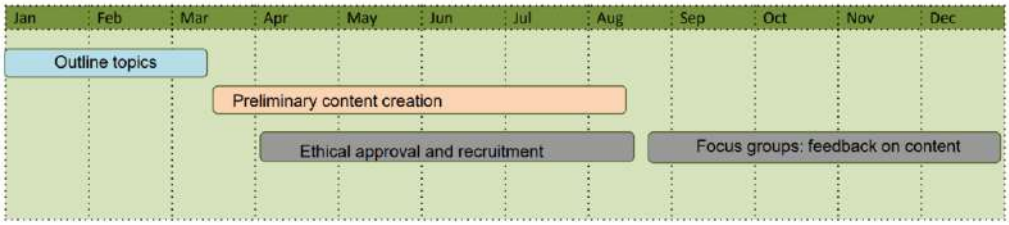


Key words

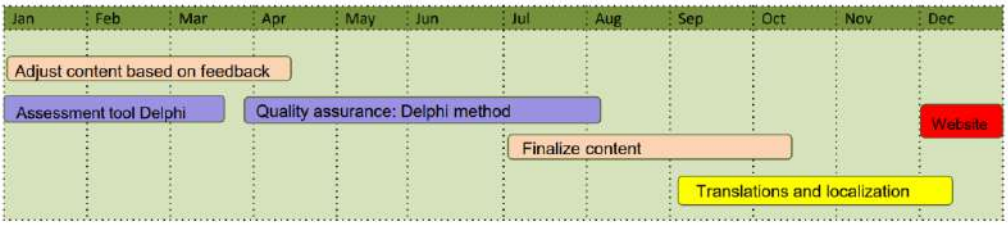
- Collaborative effort
- Co-creation
- Iterative process

TIMELINE

2025



2026



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7 Appendix

Appendix 1 – SurPass

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Overview

Survivorship Passport

The Survivorship Passport or SurPass provides childhood cancer survivors (CCSs) and their legal representatives with a comprehensive, systematic and personalized view of their cancer history and treatment (Treatment Summary - TS). Based on the TS, automated follow-up and screening plans (Care Plans - CP) are proposed using internationally approved guidelines.

The CP or long-term screening plan monitors and identifies potential medium or long-term risks of survivors at an early stage. It gives survivors and healthcare professionals access to medical history, making them aware of the potential risks or late effects of the previous disease and treatment they received. Together, the TS and CP form the Passport document (Passport).

A dedicated follow-up form is available to help monitor and document any complications in survivors. The platform supports the creation of new Passports when updated diagnostic, treatment or follow-up information becomes available, so all records are always up-to-date and comprehensive.

In the document, information is divided by sections: the TS that reports demographic, diagnosis, treatment data (chemotherapy, radiation therapy, surgery, transplantation) and relevant clinical events, the CP that provides personalized recommendations. The Passport contains also a follow-up that provides updated information on clinical conditions at each follow-up visit.

The platform was developed in collaboration with clinicians and has been refined through various European and national projects. It is currently implemented at the following institutions:

Istituto Giannina Gaslini (IGG), Italy
St. Anna Kinderkrebsforschung (CCRI), Austria through SUPA App (AIT)
Katholieke Universiteit Leuven (KU Leuven), Belgium
Universitaet Zu Luebeck (UZL), Germany
Viesoji Istaiga Vilniaus Universiteto Ligonine Santaros Klinikos (VULSK), Lithuania
Fundacion Para La Investigacion Del Hospital Universitario La Fe De La Comunidad Valenciana (HU La Fe), Spain

The platform is also currently utilized in clinics associated with the Associazione Italiana Ematologia e Oncologia Pediatrica (AIEOP) in Italy and with the German Childhood Cancer Registry (GCCR) in Germany.

The platform supports multiple languages, enabling the interface to be displayed in various languages (English, German, Spanish, Italian, Dutch, Lithuanian) and the creation of Passports in these languages as well.
Access to the system is limited to authorized clinicians. Survivors can access and download their Passports through a private area on the platform. Additionally, a printed version of the Passport is available for survivors during their clinic visits.
The platform features an interoperability function utilizing the HL7 FHIR standard for the data exchange between institutional or national electronic medical records. The Implementation Guide is published at the following link: https://hl7.eu/fhir/ig/pcsp/. A relevant example of the platform's interoperability capabilities is demonstrated by the Lithuanian clinic VULSK, which interfaces with the Passport system. This connection allows treatment data entered within SurPass to be transmitted to hospital systems, making the generated Care Plan accessible to survivors.
The SurPass can be integrated into other software applications using APIs, enabling the generation of personalized Care Plans. It also supports data integration from various sources, diverse data types within a single survivor profile.

Class I Medical Device

Because of the built-in algorithms that ease the preparation of the standard Survivorship Care Plan for HCPs, the SurPass tool (v2.0) has been certified as a Class I medical device (UDI-DI Code 8059793870019; Italian Ministry of health registration number 2328038) according to the EU Regulation 2017/745 (MDR). As reported in the declaration of conformity, the manufacturer (Cineca) has implemented the procedure for post-market surveillance as requested by MRD.
In addition to the Medical Device certification, SurPass v2.0 carries the interoperability

feature, through the HL7 FHIR standard32, allowing bilateral data transfer from and to institutional or national Electronic Health Record (EHR) systems. This feature allows that the SCP as well as any new information obtained during follow-up can be easily transferred to hospital and/or national information systems.

SurPass in eQuoL project

Clinics participating in the eQuoL project can adopt the SurPass platform by establishing internal workflows, such as managing survivor visits and issuing the Passport. The most effective approach is to learn from clinics that already have experience with the platform. It's crucial to ensure compliance with legal and regulatory requirements, such as obtaining ethical committee approvals or adhering to data protection officer guidelines.
Clinics should also formalize a data processing agreement (DPA) with Cineca to clarify the specific purposes of data management. A Data Protection Impact Assessment (DPIA) is also mandatory to conduct a risk analysis and to describe the implemented security measures.
To support languages not yet available on the platform, clinics can translate content (e.g. form labels, platform interface) into the local language using an Excel template with variable lists.

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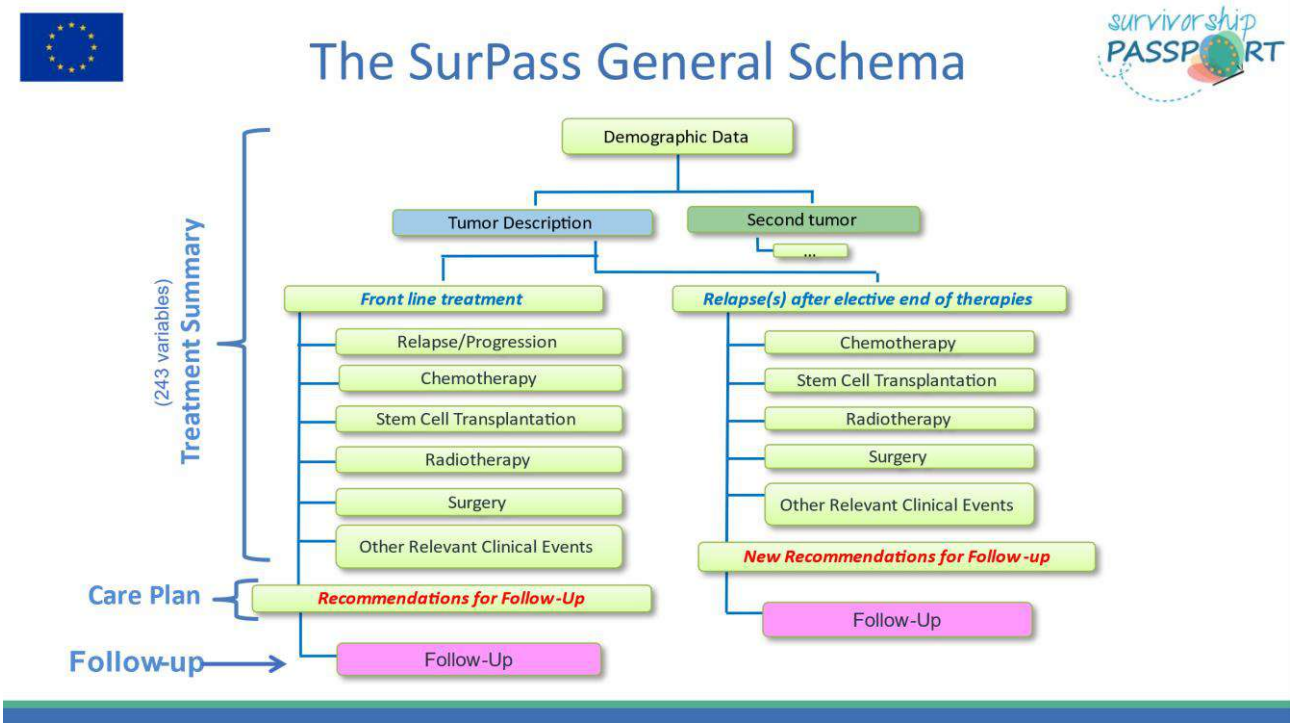
Specifications

Treatment Summary

The Treatment Summary collects 241 variables, standardized using vocabularies such as ICD-O-3 (Topography and Morphology), ICCC-3, Orphanet or ICD-9 (for cancer predisposing syndromes), ATCs (for antineoplastic drugs), and other relevant treatment-related variables.



All information collected in the Treatment Summary is relevant to allow the system to generate the Care Plan.

Algorithms in the SurPass platform link each survivor's treatments to risk factors identified by evidence-based clinical practice guidelines, enabling an automatic generation of a preliminary Care Plan that can be modified by a late effects specialist.

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Demographic

The data collection process begins with demographic information, requiring the input of personal data: first name, last name, date and place of birth, sex, and survivor's or parent's telephone or e-mail contacts. After filling out this form, the system opens the tabs to insert detail on the first tumor.

First Tumor

This section is composed by different forms, to collect data about diagnosis, treatments received and all other relevant information needed to create the passport file/document to be delivered to the survivor

Diagnosis

Within this form, users are prompted to input specific details about the tumor and the survivor's condition (including hereditary syndromes and additional medical conditions). International classifications such as ICD-O-3, used for describing the morphology and topography of the tumor, and the ICCC classification play a pivotal role. Further tumor characteristics, including genetic and/or immunological markers, are also collected to provide an exhaustive record of the survivor's medical history.

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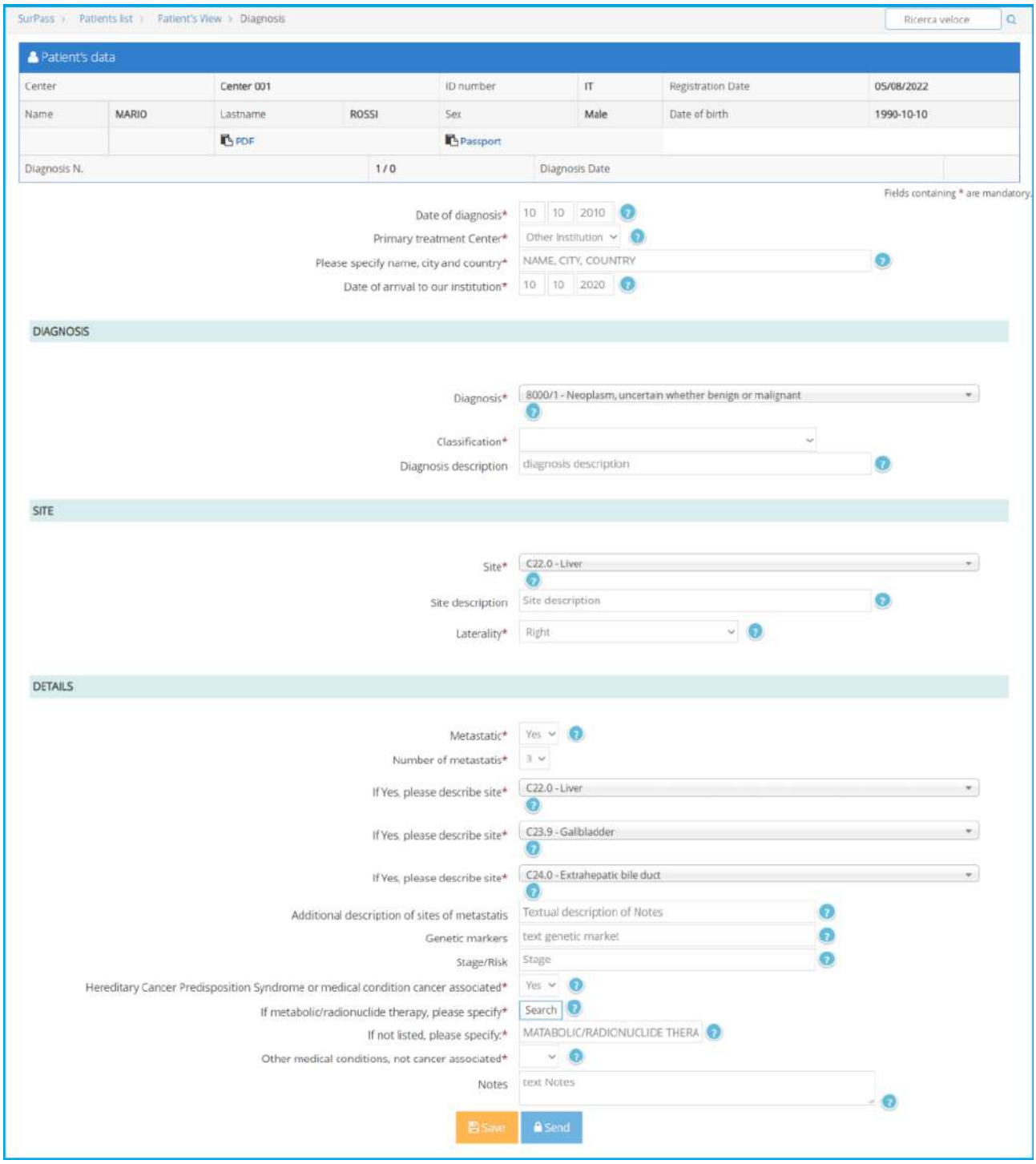
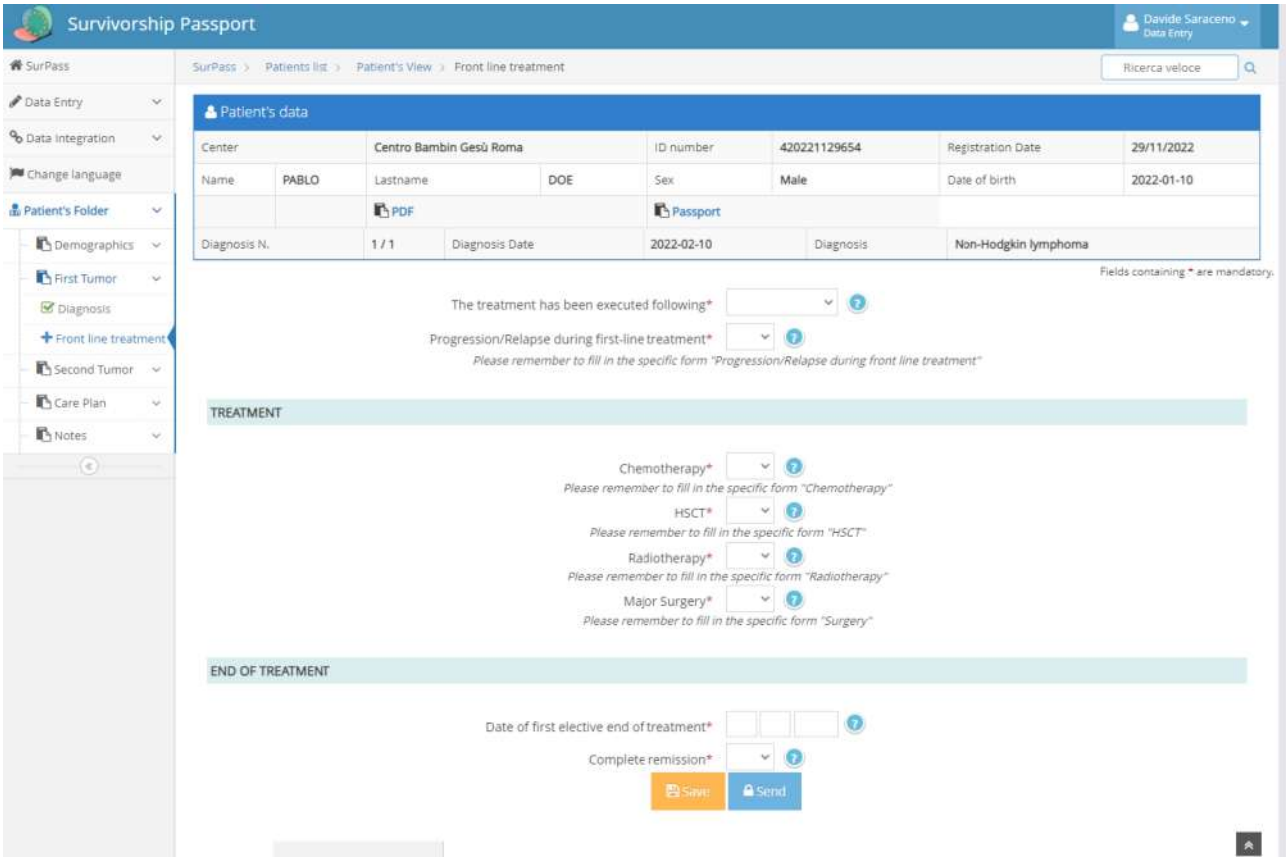


First-line treatment

This section requires entry of any treatment received by the survivor between the date of Tumor diagnosis and the date of the first elective end of treatment. It also includes treatments for progression/recurrence occurring before the date of the first elective end of treatment. It is asked what type of therapy the survivor underwent (chemotherapy, radiation therapy, surgery) before the first elective end of treatment. It is also asked whether progression/recurrence occurred before the first elective end of treatment, the date of the first elective end of treatment, and whether the survivor was in complete remission at that date.
Depending on the selected treatments (chemotherapy, radiotherapy, ...) the next forms are opened.



Progression/recurrence during first-line treatment:

This tab is opened only if progression or recurrence occurs in the first-line treatment tab before elective end of therapies.

Chemotherapy

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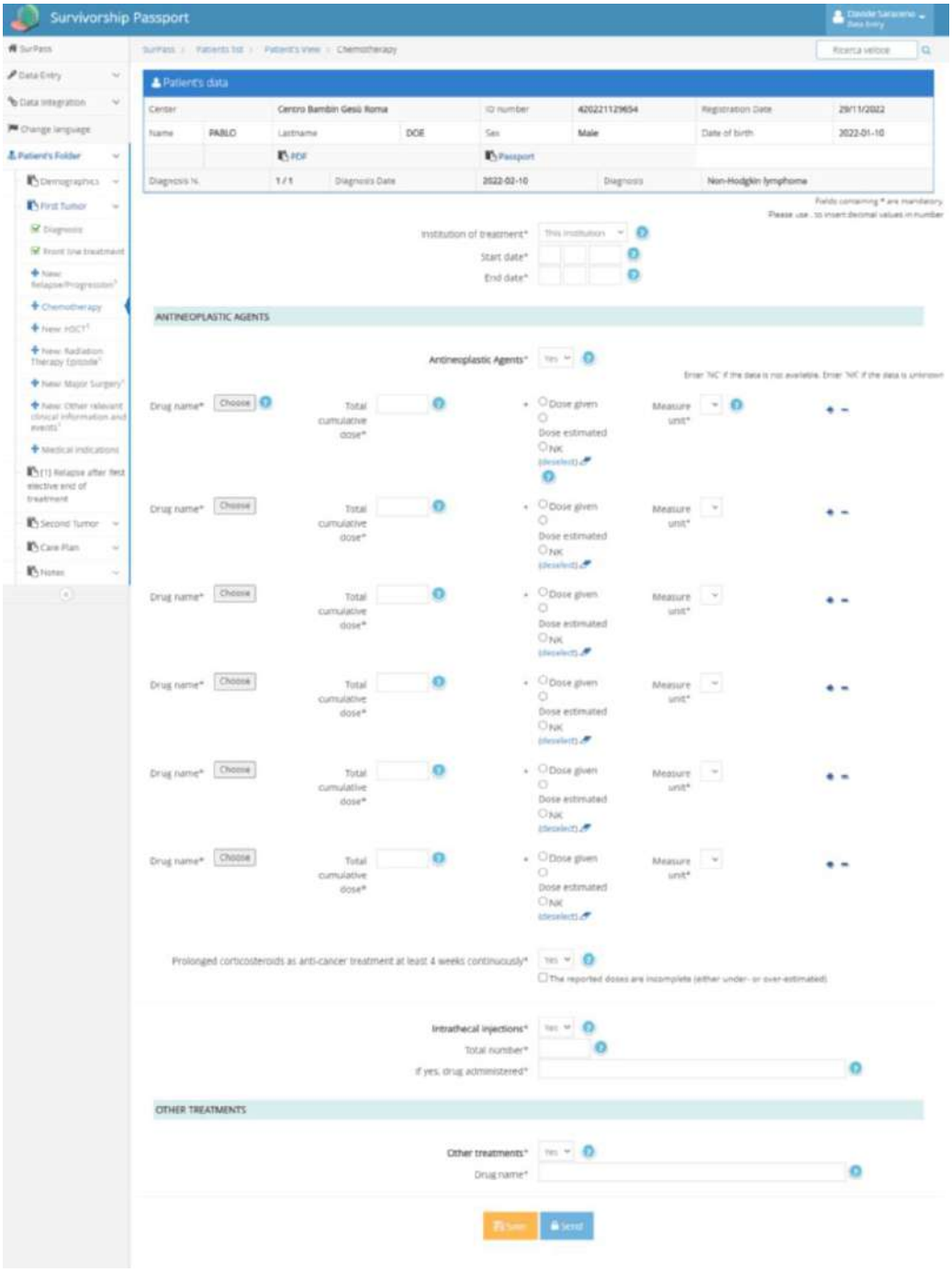
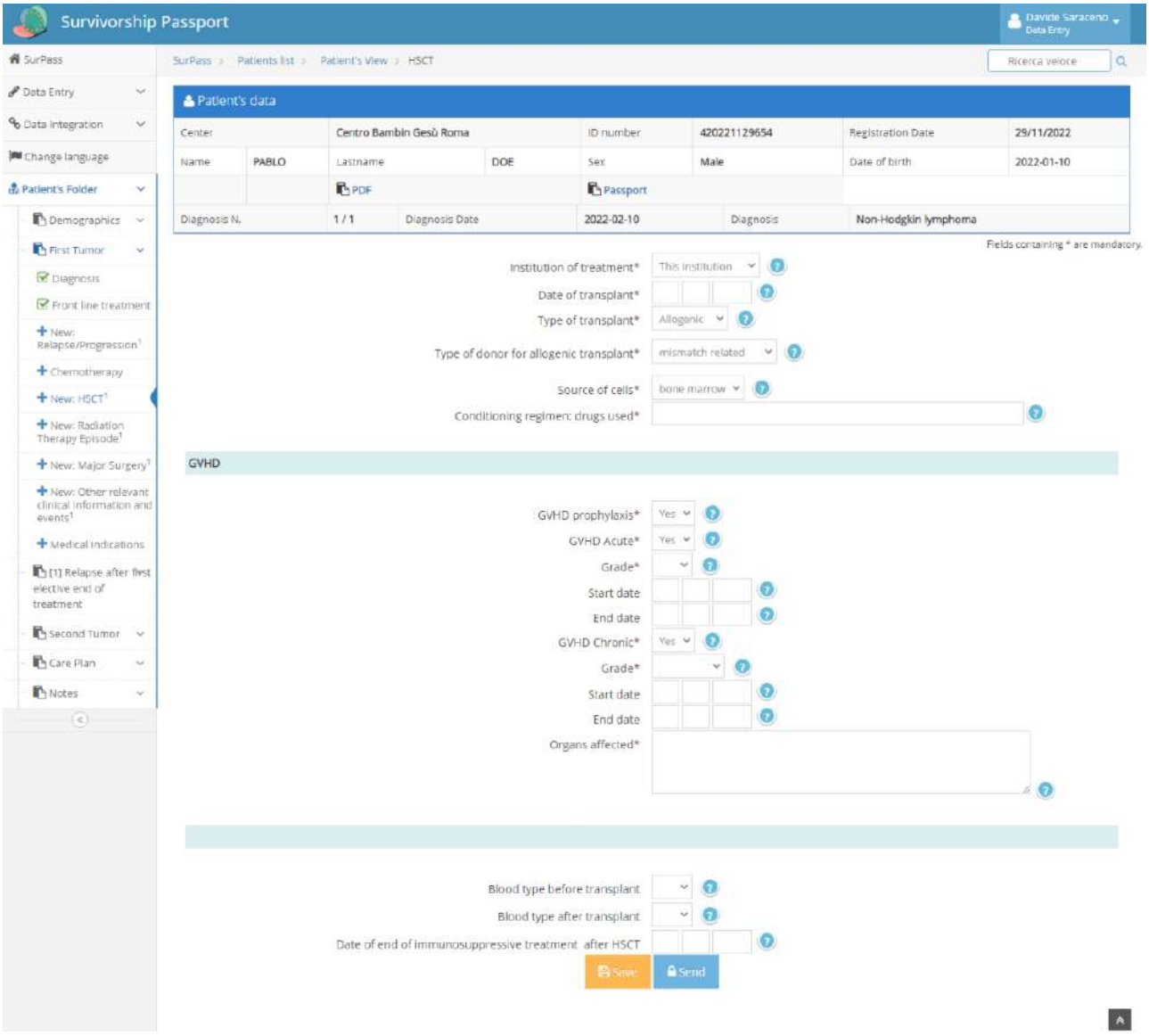
All antineoplastic and immunomodulatory chemotherapeutic agents that are used before or after the elective end of therapies or for the conditioning regimen for a hematopoietic stem cell transplant, if any, are listed in this tab. Steroids are not included among antineoplastic and immunomodulatory agents; only information on the duration of their use is requested.
Drugs are listed according to the Anatomical Therapeutic Chemical (ATC) classification and can be selected from predefined lists, and by typing the first few letters of the drug, the system will display all terms that match the word typed.
Either the name of the drug or a corresponding synonym can be selected, but the final document will display only the name of the drug. It is possible to enter more than one drug.
For each drug, the system also prompts for the total cumulative dose administered and the calculation method used.
It is also possible to indicate intrathecal injections and any other relevant treatment in a text box.



Stem Cell Transplantation

This form asks to enter data related to hematopoietic stem cell transplantation. In case the survivor has received more than one transplant, the form is repeatable, so more than one

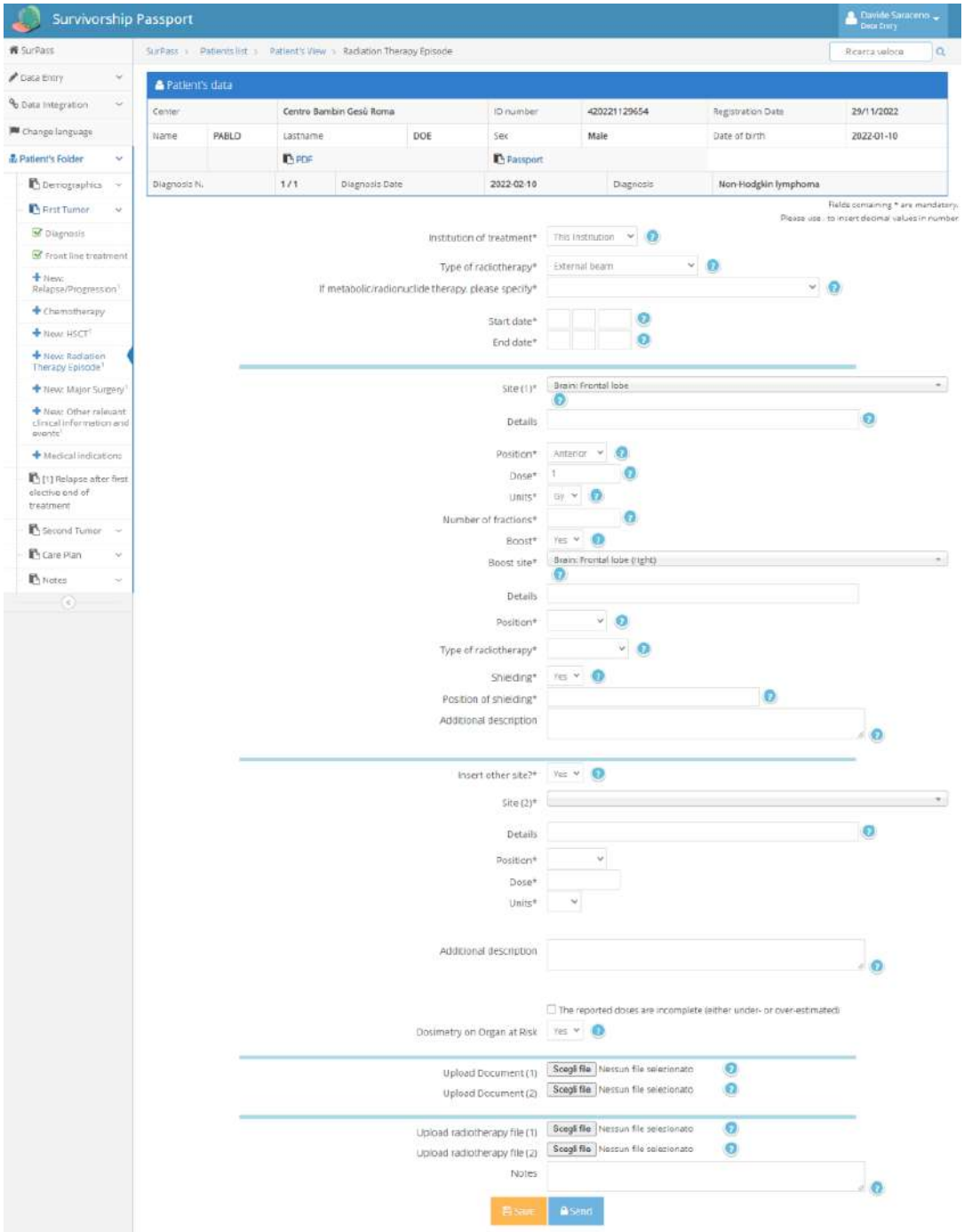
can be filled in. Information is requested on the type of transplant, type of donor, source of cells, and conditioning regimen.
Information on Graft versus Host Disease (GvHD), type of treatment before or after transplantation, and date of immunosuppressive treatment is requested only in the case of allogeneic transplantation.



Radiotherapy

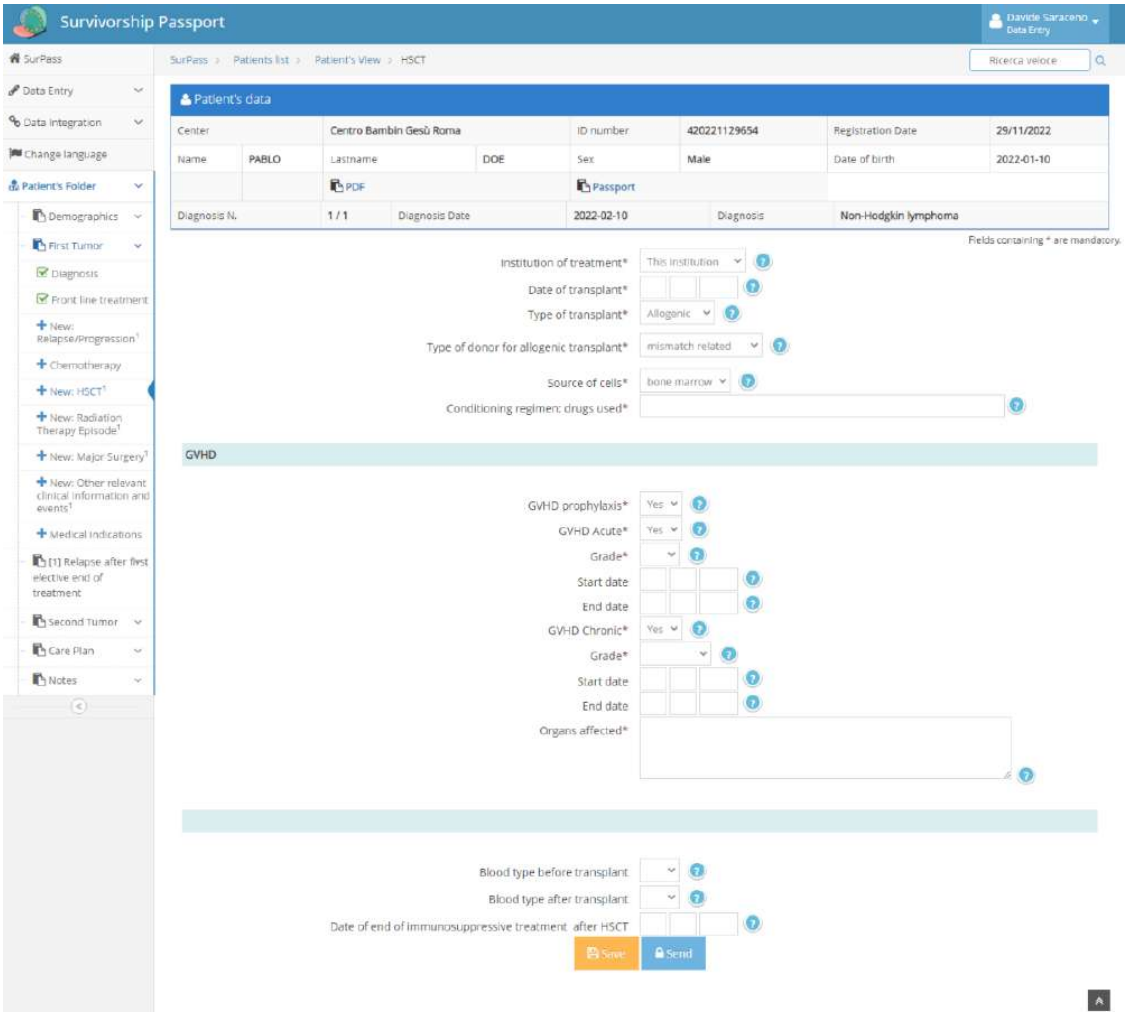
This form contains information regarding radiotherapy treatment. Information on the irradiation field, site, dates of administration, and cumulative doses administered must be

filled in on the form. The coding system used for radiation therapy areas and fields allows algorithms to suggest organ-specific recommendations for follow-up.
In the Radiotherapy form, it is also possible to upload the radiation therapy file.



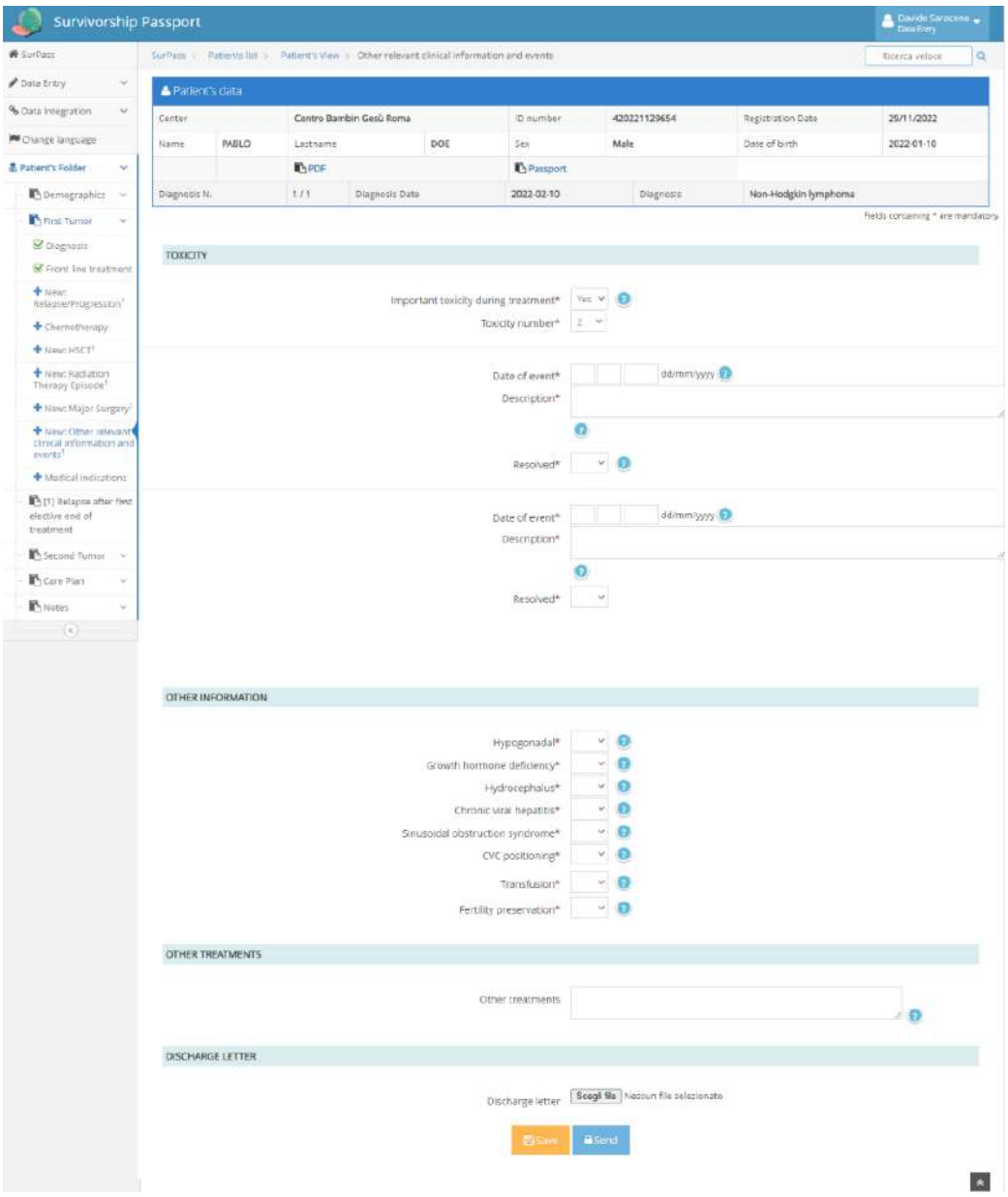
Major surgery

Major surgery data can be entered in this form. The form is repeatable, so if a survivor has had more than one major surgical procedure, multiple forms can be entered as needed. Only major surgical procedures are required to be reported, whether for therapeutic or diagnostic purposes. In the case of diagnostic procedures, only those performed after craniotomy, abdominal laparotomy or thoracotomy should be entered.
The description of the procedure should be entered as free text while specific listings are available for organs involved and organs scarred. This information is necessary to allow organ-specific follow-up recommendations to be made.



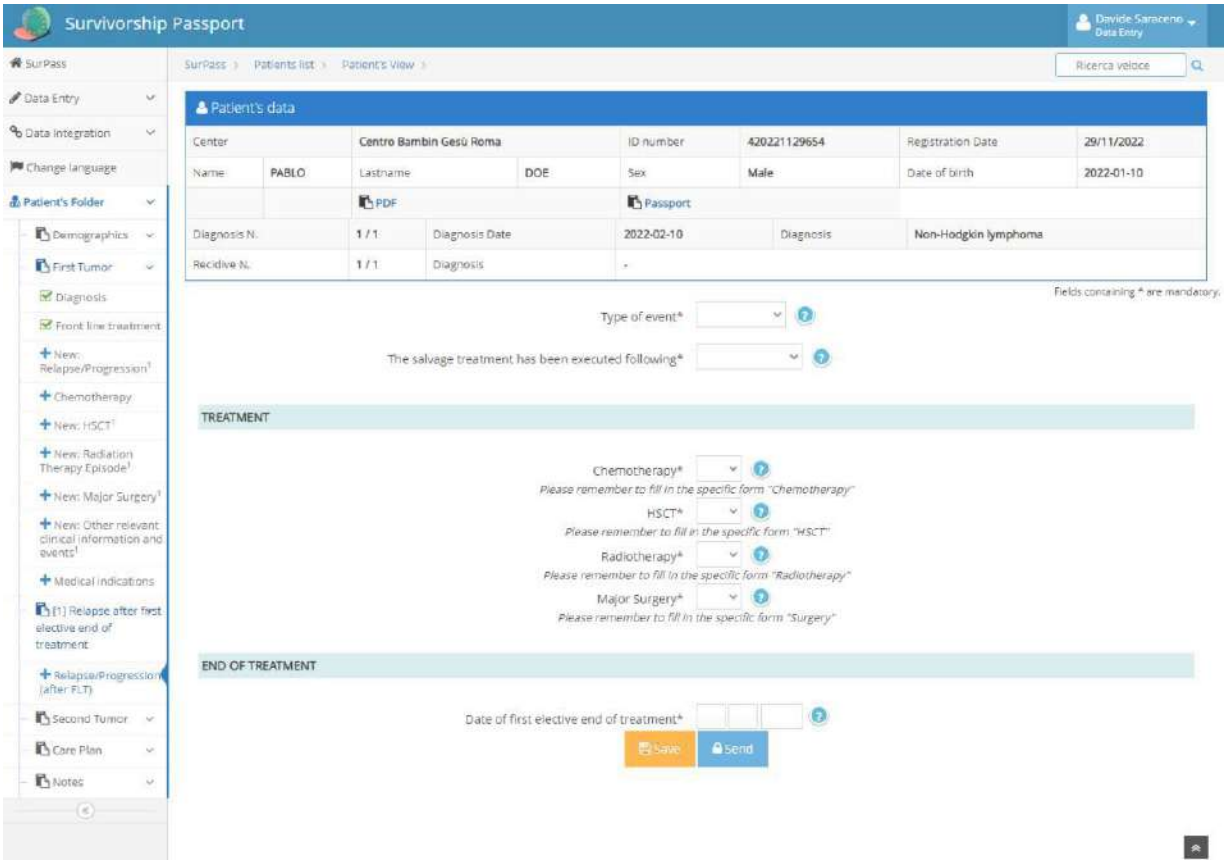
Other relevant information and clinical events

This form asks for information about relevant clinical events that occurred during treatment; serious toxicities should be described in a free text field while for other information is selectable from a list (e.g., previous transfusions, ..).
Information on other treatments (e.g., dexrazoxane) can also be provided in this section. In the form it is also possible to upload the discharge letter, if any.



Medical Suggestions

In this form it is possible to report any medical prescriptions or medical suggestions for the survivor when the Passport is delivered. This information will also be included in the Passport given to the survivor.



Relapse or progression after elective end of treatment

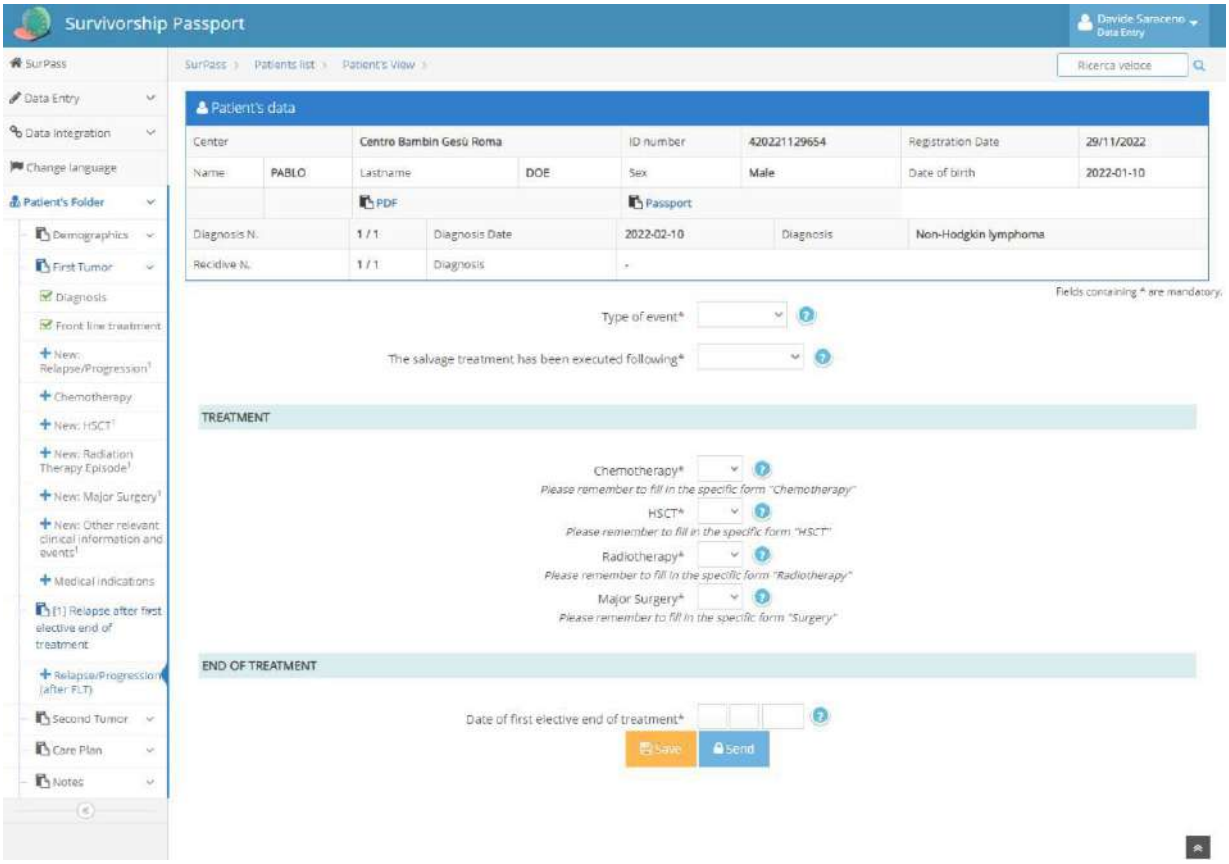
This section consists of several forms, to collect data in case of relapse after the first elective end of treatment.

In case of relapse, a new passport will have to be issued at the end of the new treatment for relapse and previous passports will no longer be valid, however any organ-specific follow-up recommendation based on the treatment received prior to relapse will continue during treatment for relapse.

The system allows the completion of up to five relapses / progressions.

The form collects comprehensive data similar to first-line treatment details, including survivor-received therapies, event type (relapse or progression), onset date, and event classification. Subsequent forms tailored to specific treatments (e.g., chemotherapy,

radiotherapy, transplantation, surgery) will automatically appear, mirroring the information structure of initial Tumor forms.



Other Tumours

The system allows the opening of further sections to collect data on secondary tumours, up to a maximum of five total tumours.

Care Plan

This section allows the creation of the personalized screening recommendations to be delivered along with the treatment summary.
The treatment plan can be generated only after completing the forms regarding treatments. Using algorithms that link treatments performed to possible risks according to the guidelines, a personalized "suggested" treatment plan is generated. It will then be up to the physician to consider whether to delete some specific recommendations if, for example, a late complication has occurred that occurs before the passport is delivered.

The care plan is composed of a first part called "GUIDELINES" in which recommendations selected by the system are listed as they are linked to specific treatments performed by the survivor. In fact, the treatments performed are linked to specific risk factors that triggered the recommendation algorithm.
All complications will be displayed on the computer screen, but thanks to the built-in algorithms, the system will automatically highlight with a check mark those for which a recommendation is suggested for the survivor, based on his or her treatment summary.
It is not possible to add or remove risk factors within a specific recommendation, but if the physician feels it should not be present, he or she can uncheck the entire recommendation.
It is possible to supplement the information by adding it to the notes field in each recommendation and indicating when the screening associated with that recommendation is planned.
The second part of the care plan shows "RECOMMENDATIONS FOR MEDICAL PERSONNEL ONLY USE," which are displayed only by the physician to give him or her support in mentioning other possible complications. In case the physician wishes these recommendations to be printed as well, the specific "Print in Passport" box must be checked for each guideline the physician wishes to enter.
At the end of the care plan there is an opportunity to enter current chronic conditions and any additional notes.
The final Passport will be given to the survivor or parents only after submission of the proposed care plan and a shared decision with the survivor on future follow-up planning.

Follow-Up

The form allows the collection of information regarding pathological conditions identified during follow-up visits after off-therapy.
In this form, it will be collected the date of the first clinical follow-up visit after the end of treatment, clinical conditions potentially associated with increased incidence of cancer in which predisposing genetic syndromes or clinical conditions potentially associated with increased incidence of cancer diagnosed after the cancer diagnosis can be entered and pathological conditions, which arose during the period between off-therapy and the first visit.
The follow up forms are repeatable; when opening the second follow up form, it is possible to indicate whether the clinical condition has resolved, is unchanged, or is still present but has changed.

Passport document

The Passport is a pdf document consisting of:
a first section that contains all the data reported in the data collection forms: personal data, diagnosis, treatments, surgeries, ...
a second section reporting current chronic conditions
a third section reporting generic and specific recommendations
a fourth section listing the follow-up plan with tests and visits to be performed
a fifth section in which final notes are given.

SUMMARY OF CANCER TREATMENT

This Survivorship Passport is a short summary extracted from the information reported in the medical record. It describes the disease and its clinical course as well the treatments you received. This document does not replace the medical record which is always available at the treatment center in case of need

Passport Number: 120220930270

PERSONAL DATA			
Name	X PB GRAVIDANZA	**Lastname**	TEST RT UTERO
Date of birth	01/01/2001	**Sex**	Female
Place of birth	GENOVA		
Mobile phone	FIG		

DIAGNOSIS	
Date of diagnosis	01/01/2011
Institution	Center 001
Classification	1 - Uncertain behaviour
Diagnosis	Neoplasm, NOS
Diagnosis (morphology)	Neoplasm, NOS
Site	Upper lip, NOS
Laterality	NK
Metastatic	No

OTHER DISEASES	
Hereditary Cancer Predisposition Syndrome or medical condition cancer associated	No
Other medical conditions, not cancer associated	No

FIRST-LINE TREATMENTS		
The treatment has been executed following	Guidelines	
Summary of major treatments	Chemotherapy	No
	HSCT	No
	Radiotherapy	Yes
	Major Surgery	No
Progression/Relapse during first-line treatment	No	
Date of first elective end of treatment	01/01/2013	

RADIATION THERAPY EPISODE				
FIRST LINE				
Type of radiotherapy	External beam: Orthovoltage / kilovoltage usually 200 - 300kv X rays/photons			
Start date	21/02/2011	**End date**	21/03/2011	
Site (1)	Uterus		**Dose**	2 Gy
Position	Anterior			
Shieldin	NK			

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Survivor Private Area

The platform has the capability to generate survivor access credentials. Each issued Passport also includes a QR Code linking directly to the access platform.
Currently, within the dedicated survivor area, survivors can download their digital Passport in all available languages. They also have the option to download copies of their data and utilize within other apps.
Future updates may include additional features like emergency assistance communicate directly with their healthcare providers, appointment scheduling and medication reminders, further enhancing survivor care and engagement.

Non-functional requirements

GDPR Compliance

Cineca has achieved and maintains the following certifications: ISO 9001-2015 (Quality management systems), ISO 27017:2015 (Information technology — Security techniques — Code of practice for information security controls based on ISO/IEC 27002 for cloud services), ISO 27018 ("Security techniques – Code of practice for protection of personally identifiable information (PII) in public clouds acting as PII processors) and ISO 20000 (Information technology — Service management).
Furthermore, the company procedures have been updated to consider the GDPR requirements, and to state the effectiveness of the Information Security Management System (ISMS), Cineca has achieved the certification according to the ISDP © 10003: 2020 scheme.
Each center collecting data will be responsible for compliance with relevant national law and local institutional requirements. Process of personal data is also subject to European/international requirements:
General Data Protection Regulation 2016/679,
European Convention on Human Rights,
Charter on Fundamental Rights of the EU,
Helsinki Declaration.
Two documents will be produced together with the clinics to make the platform operational in the production environment and to be compliant with privacy and security requirements:
Data Protection Impact Assessment (DPIA), to define treatment description, security measures, risk assessment and transparency and traceability;

Data Processing Agreement (DPA), to define duration of processing, nature and purpose, type of data processed, categories of data subject involved.

eCRF User Access

Authorized personnel within centres are granted controlled access to the Electronic Case Report Form (eCRF). This structured access ensures that only designated individuals can input, modify, or retrieve survivor data, aligning with stringent privacy and data protection standards.

User profiles with varying privileges will be set up on the platform. A comprehensive listing of these user profiles can be found in next paragraph.

To access, an email will be sent to the user containing the link to access the eCRFs. The user will have to be told the userid to log in and will have to set a password that will expire after 90 days and must have the following characteristics:

be at least 8 characters long
contain at least one capital letter
contain at least one lowercase letter
contain at least one number
contain at least one special character
be different from the previous password

User Priviledges

Surpass platform-enabled users have different access profiles, with different privileges:

Data Entry (DE): is a profile for physicians and is used for new survivor registration and form filling. This profile is authorized to import/export FHIR data.

Data Manager (GDM): is an optional user type for health clinics that can manage and correct data.

Read-only (GRO): is an optional user type for health clinics that can view survivor data without personal data.

Survivor Profile: is a profile that through a QR code allows the survivor to access and download their passport.

Data Collection

A mechanism is in place to display only the pertinent information that needs to be filled.

To ensure accuracy and reliability, the forms are equipped with validation checks,

effectively minimizing errors, and upholding the integrity of the collected data. This contributes to the overall quality and consistency of the data gathered through the platform.

Audit Trail

All changes made to the data will be securely tracked and verified through an advanced audit trail system. This includes capturing the identity of each user accessing or modifying the protocol, along with the specific nature and timestamp of their actions. All data are backed up daily, with retention times of one month; therefore, a snapshot of the data for the past 30 days can be tracked.

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Technical Aspects

Platform Architecture

The solution includes:

- URL routing: a tool that allows accepting requests from outside and can be fully customized by the partner. Requests are protected by an encrypted channel and the server must be secured by an SSL certificate.

- Containers:

"Identity provider" that allows users to be authorized to access internal resources;

"Survivorship Passport" which contains the application for collecting and displaying processing forms and producing the passport;

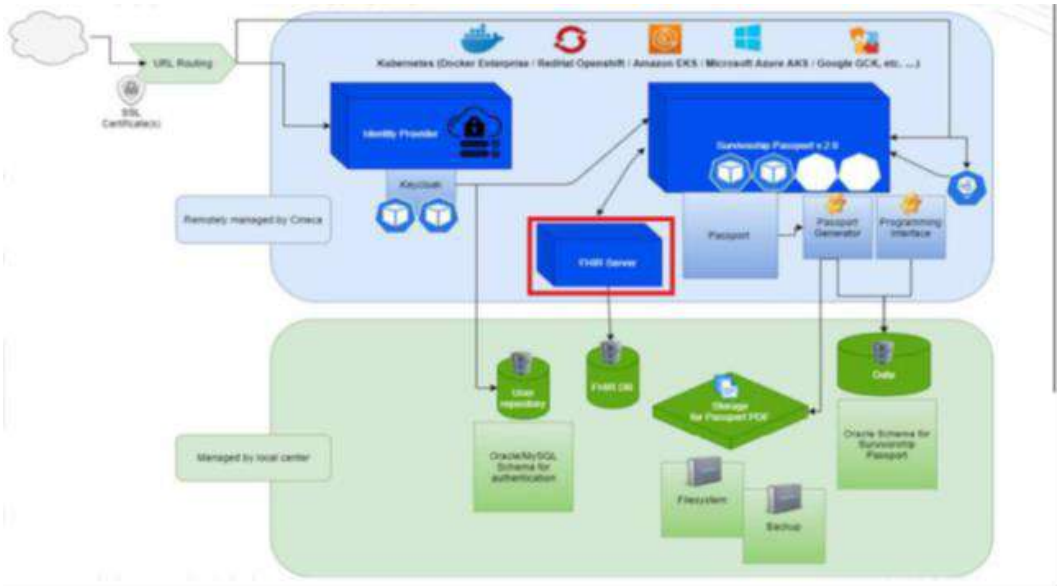
"FHIR server" which is based on HL7 FHIR HAPI and facilitates the exchange of health data.

-Physical repositories connected to the containers that are:

three different databases: one for users, one for HL7 FHIR resources, and one for Passport-related resources;

two filesystems to store Passport-related files.

The figure below represents the architecture of Passport.



SurPass involves the integration of the HL7 FHIR server into SurPass in accordance with the data model provided by HL7. Some clinics have provided HL7 FHIR examples and input useful for testing the capabilities of the platform.

To realize HL7 FHIR integration, the FHIR HAPI server was chosen as a scalable and open-source solution.

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User Interface

The top toolbar on the Home Page has quick links to the system's primary functions, appearing on every SurPass platform page.

It includes:

User Information: displays logged-in user's name, surname, and access profile. Clicking the profile opens a menu for password modification, logout, or contacting support. To contact support, users must select the desired support type and provide a free-text section to specify the required assistance.

Search: enables rapid searching of survivors by name, surname, and/or personal code.

The data entry menu, located on the left side of the homepage, provides quick access to data input functionalities across every SurPass page.

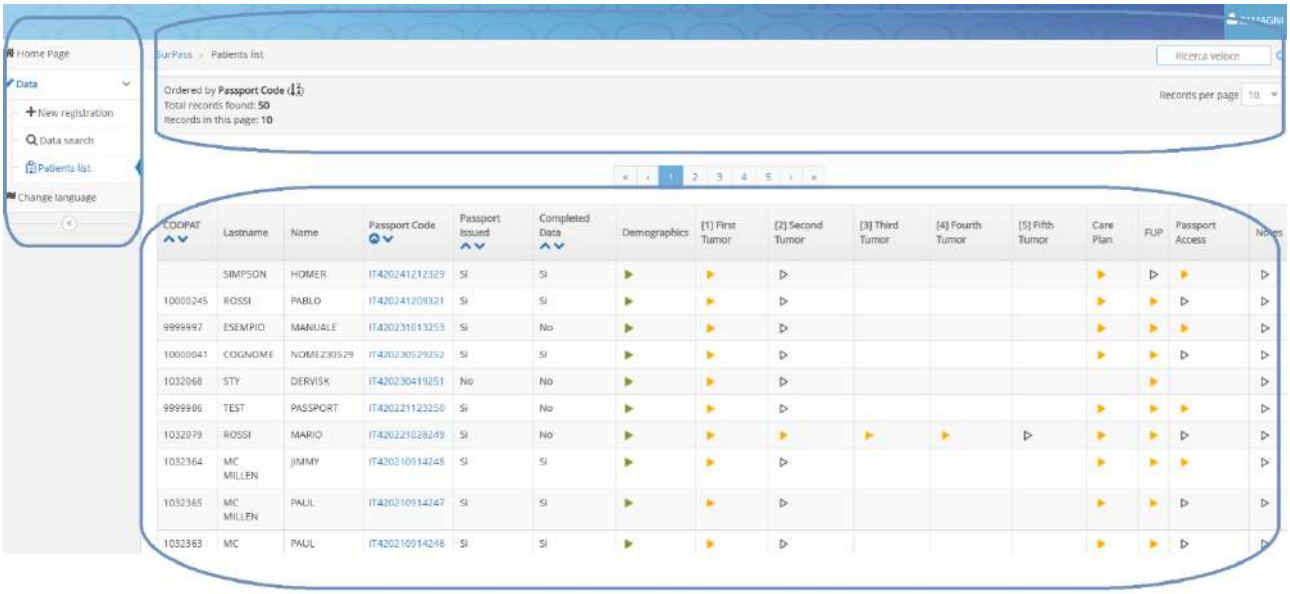
These include:

Register New Survivor: grants electronic module access for new survivor registration;

Advanced Search: allows searching for a survivor by name and/or passport number;

Survivors List: displays the list of registered survivors, with paginated results for extensive records.

Change Language: users can view and select available languages. The language can be switched at any time, and the Passport can be printed or displayed in different languages.



The central section on the screen changes based on the selected menu option. For instance, if "Survivors List" is chosen from the left-side menu, it will display the survivor list along

with completion status for each form and each survivor (e.g., demographic data, first tumor, second tumor).
Clicking the Survivor code users can view all forms. Green arrows indicate completed and sent forms, while orange arrows show partially completed forms. White arrows in the Survivors List enable users to select and access desired forms and initiate data entry.

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HAPI FHIR Server

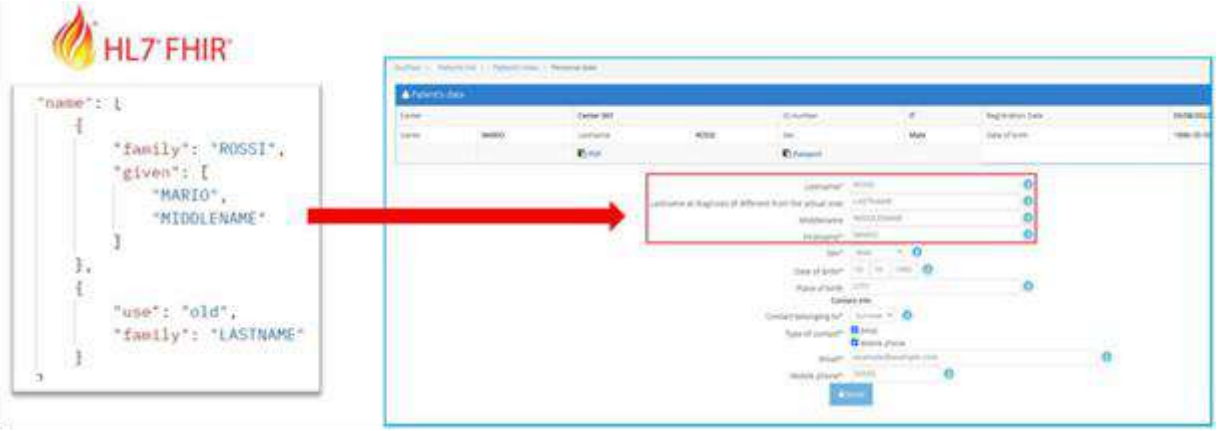
HAPI FHIR is a complete implementation of the HL7 FHIR standard for healthcare interoperability. HAPI defines model classes for every resource type and datatype defined by the FHIR specification and provides several mechanisms for building FHIR servers. Every resource type in FHIR has a corresponding class that has getters and setters for the basic properties of that resource.
The SurPass Data Integration Module was created to connect the HAPI FHIR Server; to convert the received HL7 FHIR resources; to feed the PCSP Database, to fetch and store resources and to let external applications access or change survivor data.

Keycloak: Credential Management and Authentication

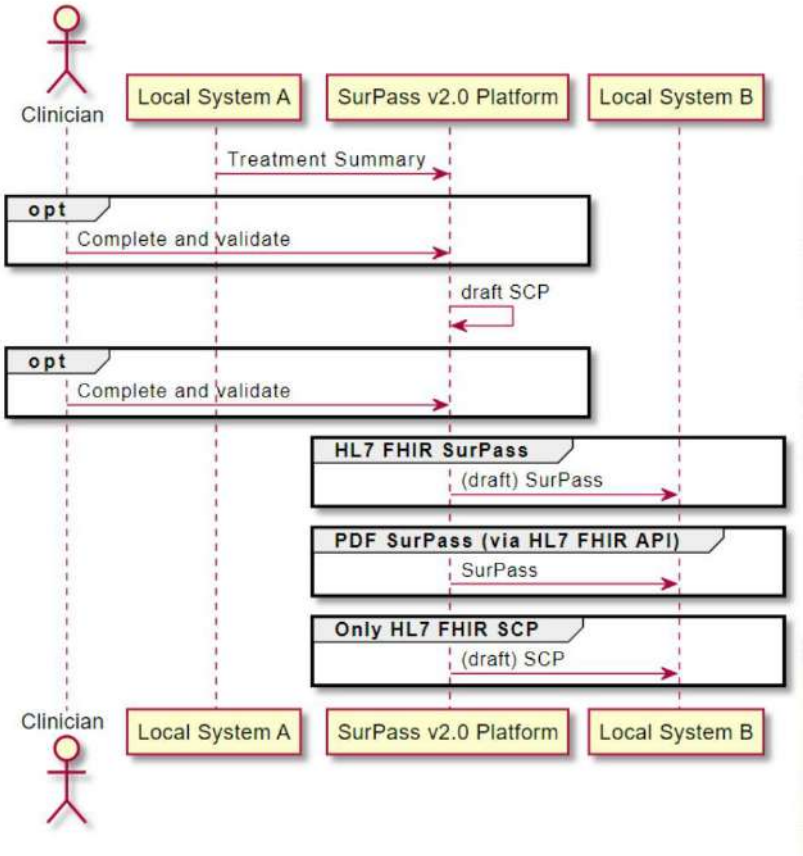
For user management, SurPass uses Keycloak, an open-source software platform for centralised and secure access management.
Keycloak provides a variety of authentication mechanisms by supporting different protocols, including social login, OAuth 2.0, SAML and OpenID Connect.
Keycloak supports Single Sign-On (SSO), which allows users to access multiple applications and services using the same credentials.
The platform also enables multi-factor authentication, thus providing an additional layer of security by asking users to provide additional authentication information before accessing resources, such as reading a code sent to a cell phone or generating a code via an app.

Interoperability

The SurPass platform implements interoperability features through its data integration module and HL7 FHIR interface.
The system has a centralized import process, where survivor information can be individually accessed and modified through an intuitive interface.



The platform's ETL (Extract, Transform, Load) capabilities handle various data transformations, including standardization of gender coding, date formats, and unit measurements. These transformations ensure consistency across different healthcare systems while maintaining data integrity. The platform can manipulate data with some tasks: filtering, joining multiple resources, and performing complex data validations.
SurPass Data Integration Module is able to performs ETL transformations:
Cleaning: Mapping "Male" to "1" and "Female" to "2," date format consistency, etc.
Format revision: Unit of measurement conversion, date conversion, etc.
Key restructuring: Establishing key relationships across tables
Derivation: Using business rules to apply new calculated values to existing data, such as a list of medications for a survivor. For example, multiple Medication Administration resources sent to the FHIR server will be combined in a single form to represent the list of medications of the survivor with the automatic calculation of total doses.
Filtering: Selecting only certain rows and/or columns
Joining: Linking data from multiple resources
Splitting: Splitting a single column into multiple columns
Data check: Simple and complex data check
Summarization: In some cases, the values are summarized to obtain totals



The platform currently provides three distinct methods for accessing medical information through the FHIR Server: retrieving a complete Treatment Summary with all associated resources, accessing an encapsulated PDF document, or obtaining a preliminary Care Plan in draft status.

Obtain a copy of Treatment Summary (Composition and all Resources)

Obtain a PDF encapsulated (DocumentReference Resource)

Obtain a Preliminary Care Plan (CarePlan Resource -> status: draft)

Other integration options may be possible, depending on the clinic's needs.

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Maintenance and Support

Training Material

The SurPass platform caters to a wide range of users through thorough documentation and support materials.

Tailored user manuals are available for both clinicians and survivors (private area). For technical implementation, an exhaustive interoperability guide is available, detailing API integration processes.

The Implementation Guide has specific instructions for HL7 FHIR (Fast Healthcare Interoperability Resources) implementation.

The API guide is also available and explains creation and management of Care Plans within external applications interacting with SurPass.

Online Support

To ensure users receive immediate assistance when needed, Cineca maintains a dedicated online support system where both technical and clinical users can access real-time help through a ticketing system and live chat feature. This support service is available during business hours and is staffed by experts.

Appendix 2

Languages tested for voice cloning. The final validation will be done by HCPs, as we need to ensure the scientific soundness and to limit potential discrepancies between the original scripts and the final results.

Languages tested – HeyGen solution (https://app.heygen.com/)	
Bosnian	*Hungarian*
Bulgarian	*Italian*
Croatian	*Norwegian*
Czech	*Polish*
Danish	*Portuguese*
Dutch	*Romanian*
English	*Slovak*
Finnish	*Spanish*
German	*Swedish*
Greek	*Ukrainian*
A wide range a language have been tested, with the idea behing it to be able to propose these optional language (not initially expected in the project) to be available beyong the countries engaged in the project.	