Evaluating the benefit of Gene Expression Profiling (GEP) in early breast cancer

WBCR manual



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1. Modes of data delivery to the Belgian Cancer Registry

For the project 'Evaluating the benefit of Gene Expression Profiling (GEP) in early breast cancer' or 'GEP Breast', there are two ways to deliver the registrations to the Belgian Cancer Registry (BCR):

- via the Web-Based Cancer Registration (WBCR) application of the BCR or
- via structured batch deliveries.

This manual only concerns the first delivery mode: via the **WBCR** application.

For **more information** on this project and both modes of delivery, please consult the section '1. General project information' in the **project-specific GEP manual**. All documents related to this registration can be consulted on our **website**: <u>https://kankerregister.org/GEPBreast</u>.

2. What is Web-Based Cancer Registration (WBCR)?

The **Web-Based Cancer Registration (WBCR) application** is an online application developed and managed by the BCR. It allows to fill out, save and send patient registration data to the BCR in a secure and user-friendly manner.

The benefits of using WBCR are plenty:

- The **access** to WBCR is **strictly regulated and secure**, requiring login through the eHealth platform of the Belgian government.
- It is possible to **save** your (in)complete **registrations before sending** them. The saved registrations can be modified or completed at any time, allowing to follow up patients over time.
- Help functions and **internal validation checks** have been built into the WBCR to guarantee a high quality of the transferred data.
- Users have **access to their own registration data**. The application offers multiple options to consult your saved or sent registrations
- Patient registrations are **easily and securely sent to the BCR** through the WBCR application.

Please note that, although the 'GEP Breast' registration project is provided in English, the WBCR application itself is only available in Dutch or French, but not in English.



3. Access to WBCR (to be arranged once)

The WBCR **access** should be **arranged within your hospital itself** via the eHealth platform. This platform is managed by the Belgian government and guarantees patient privacy and data protection.

Please contact the (Main) Access Manager (Dutch: "(Hoofd)Toegangsbeheerder" / French: "Gestionnaire d'Accès (Principal)") of your hospital to arrange this access. For your information, the Access Manager was formerly known as the "Lokale Beheerder" or "Gestionnaire Local". This person will be responsible for creating new user profiles and setting up the correct hierarchical relationships between doctors and their administrative personnel.

Information for the Access Manager:

- Application to be used: Access Management for Enterprises and Organizations
 - o Dutch: Toegangsbeheer voor Ondernemingen en Organisaties
 - French: Gestion d'accès pour Entreprises et Organisations

Within this application a login name and password must be chosen for each new user. The user does not need this login name and password to log in to the WBCR.

- For each user there is the choice between three different user functions:
 - WBCR-Geneesheer Specialist / WBCR-Médecin Spécialiste (type A)
 - → have access to their own WBCR registrations and those made by their hierarchical linked administrative personnel within the hospital
 - WBCR-Oncologisch Coördinator / WBCR-Coordinateur Oncologique (type B)
 - → have access to all WBCR registrations of the entire hospital (not only GEP Breast), should only be given to effective oncologic coordinators
 - Administratief / Administratif
 - \rightarrow must always work under the responsibility of one (or more) doctor(s)
 - → have access to all registrations made by and for the responsible doctor (= in WBCR they have the same rights as the responsible doctor)
 - → the link (hierarchical relationship) with the responsible doctor(s) should be set up via the application tab "Hierarchy of responsibilities"
- The following website (and manual) can be consulted for more information:
 - Dutch: <u>https://www.ehealth.fgov.be/nl/egezondheid/hoe-krijgt-u-toegang-tot-het-portaal-egezondheid//gebruikers-en-toegangsbeheer</u>
 - French: <u>https://www.ehealth.fgov.be/fr/esante/acceder-au-portail-</u> esante/gestion-des-utilisateurs-et-des-acces



4. WBCR login procedure

Once the necessary user profiles and hierarchical relationships have been set up, you can log in to the WBCR application. The easiest route of access is by following the link: <u>https://www.kankerregistratie.be/wbcr</u>.

- Choose a method to log in to the eHealth application
 <u>Note:</u> If you use your electronic identity card (eID), you will need a card reader and the PIN code of your eID.
- Choose your preferred language (Figure 1, red box) <u>Note:</u> Only Dutch or French are possible
- Indicate the organisation (hospital) for which you will register
- Confirm your profile to enter the WBCR application

user NAME Nederlands v Aanmelden voor Kanker Registratie	USER NAME Français v Se connecter pour Enregistrement du cancer
Kies uw profiel:	Choisissez votre profil:
Ik wil me aanmelden	Je souhaite me connecter
Binnen de organisatie:	Au sein de l'organisation:
Kies een profiel 🔹	Choisissez un profil
Profiel bevestigen	Confirmer le profil
> Hulp nodig	> Besoin d'aide ?

Figure 1. Access to WBCR is granted through logging in via the eHealth platform. Please indicate the preferred language here and select the correct hospital.



5. How to access the project 'GEP Breast' in WBCR?

5.1 WBCR homepage

Once you have successfully logged in to the eHealth platform to access the WBCR application, it is necessary to agree to the WBCR terms of use (Figure 2). If you have an administrative profile, you need to indicate for which doctor you will register (Figure 3).

Afterwards, you arrive at the WBCR homepage.

startpagina					afmelden
Belgian Cancer R	egistry U gaat naar een en personen die gebruiker weet kwaitieits- en sc U bent verantwi Door deze gegei door u gedownlo Door deze gegei gedownloade ge Door op de knoj <u>Webtoepassing M</u> Ik ga akkoor	gevoelige toepassing met vertrouw zijn aangesteld door een medisch i en aanvaardt dat alle transacties w reeningdoeleinden. sordelijk voor uw gebruik van deze rens te downloaden, bevestigt u dat iade gegevens. vens te exporteren, ontslaat u de Si gevens dat plaatsvindt buiten deze t p 'lk ga akkoord' hierna te klikken o <u>(ankerregistratie - Gebruiksvoorwaar</u> rd Ik ga niet akkoord	elijke medische gegev nstituut dat erkend is vorden geregistreerd e toepassing en voor de t u alleen verantwoord tichting Kankerregister ioepassing. of door verder toegan rden heeft gelezen en	ens. Enkel erkende gebruikers, m.a.w. j door de Stichting Kankerregister, moger n dat daaruit resulterende informatie privacy en vertrouwelijkheid van de ge elijk bent voor het daaropvolgende geb van elke aansprakelijkheid ten gevolge g te nemen tot en gebruik te maken va begrepen en dat u ze zult naleven (recer	personeel van de Stichting Kankerregister i toegang tot deze toepassing krijgen. De kan worden gebruikt voor waarnemings-, egevens die u in deze toepassing plaatst. ruik, de beveiliging en de privacy van de e van het daaropvolgende gebruik van de an deze toepassing, bevestigt u dat u de tiste wijziging: 25/05/2010).
page d'accueil Belgian Cancer R	Conditions d'utilisations legistry Vous accédez à Fondation Regis accéder. Par ce Vous êtécharge vous télécharge En télécharge En télécharge En télécharge En télécharge	on sélection de la mutuelle une application sensible contenar tre du Cancer et les personnes dés texte, les utilisateurs sont informés nsable de l'utilisation que vous faite z ces données, vous reconnaissez êtr z. It des données, vous déchargez la l argées hors du cadre de cette applic le bouton "J'accepte" ci-dessous c	contactez-nou nt des données média ignées par une institu et acceptent que tout is de cette application re le seul responsable Fondation Registre du ation.	s aide tales confidentielles. Seuls les utilisate tion médicale approuvée par la Fondat es les transactions soient consignées et ainsi que du secret et de la confidentia de l'utilisation consécutive, de la sécuri Cancer de toute responsabilité qui pou céder et à utiliser cette application,	se déconnecter eurs autorisés, cà-d. le personnel de la ion Registre du Cancer, sont autorisés à y suivies à des fins de sécurité. lité des données que vous y introduisez. Si té et de la confidentialité des données que irrait découler l'utilisation consécutive des vous reconnaissez avoir lu et compris les

J'accepte Je n'accepte pas



startpagina	gebruiksvoorwaarden	moc-deelnemers	contact	help	
Belgian Cancer Re	gistry Kies een dokter		V		
page d'accueil					
Belgian Cancer Re	Veuillez choisi	r le médecin pour leque	el vous souhait	ez travailler	 ~

Figure 3. Choose the doctor for which you will perform registrations.



On the WBCR homepage, all available registration modules are listed (Figure 4).

- This includes the 'standard cancer registration' of malignant indications, which is obliged since 2003 for all oncological care programs and care programs for basic oncological care. This module is the first one displayed in the list of registration modules on the homepage. With this module, the Annexe 55/Bijlage 55 is filled out. This registration needs to be included with the project-specific registration of 'GEP Breast'.
- The rest of the list consists of specific registration projects, in which additional variables related to a certain condition are requested. As the available modules for project-specific registrations are listed alphabetically, the module for GEP Breast can be found in the middle of the list.

In every registration module, several **actions** can be performed. By clicking on the question mark next to the title of the 'standard cancer registration' (see the red box in Figure 4), a legend pops up explaining the action that corresponds to each icon displayed in every registration module (see Figure 5). Please be aware that the actions linked to these symbols are restricted within the specific registration module you are active in. A description of the various actions is provided in Table 1.

	voorwaarden selecteer een ziekenfonds contact help	page d'accueil con	ditions d'utilisation sélection de la mutuelle contactez-nous aide
Belgian Cancer Registry	Wekom USER NAME Bron Onbekend Standaard kankerregistratie	Belgian Cancer Registry	Bonjour USER NAME Source Inconnu Enregistrements généraux
	Antal beward: 7		Nonbre sauvés: 7 Nonbre envoyés: 21 Mais
	Projecten		Projets
	BE-RFA (Barrett Esophagus - RadioFrequency Ablation)		BE-RFA (Barrett Esophagus - RadioFrequency Ablation)
	By using this module you are not participating in the legally obliged registration of new Meer		By using this module you are not participating in the legally obliged registration of new <u>Pus</u>
	Aantal bewaard: 5 <u>Meer</u>		Nombre sauvés: 5 <u>Plus</u>
	+ + 🗁 👒 🔅 🐻		+ + = +
	Complex Surgery Oesonbagus		Complex Surgery Oesophagus
	By using this module you are not participating in the legally obliged registration of new		By using this module you are not participating in the legally obliged registration of new
	Aantal bewaard: 3 Meer		Nombre sauvés: 3 <u>Plus</u>
	+ 🗁 👒 🔅 🐻		+ 🗁 👒 🔅 🐻
	Complex Surgery Pancreas		Complex Surgery Pancreas

Figure 4. Homepage of the Web-Based Cancer Registration, WBCR. The module for the 'standard cancer registration' is the first registration module displayed in the list. Beneath that, all specific registration project modules are listed alphabetically. The meaning of the icons displayed in each registration module is explained by the 'Help' function near the 'standard cancer registration' module (see red box).





Figure 5. The legend, explaining the different actions that are available for each registration module, pops up after clicking the 'help' icon next to the 'standard cancer registration'.

lcon	Description	Additional info
÷	A new registration can be started	
f	If follow-up registrations are possible, a second 'plus' icon is available with an 'F' inside	Not applicable for the project 'GEP Breast'
	A saved or sent registration can be searched, viewed, downloaded or printed. Saved registrations can be modified and sent.	Searches can be performed based on INSZ/NISS number (or other). There are separate tabs for saved and sent registrations. For saved registrations, their status is included. When a green check is present, it means that the registration has been validated and is ready to be sent to BCR. When consulting the data that has been sent to BCR for a certain patient, there might be a second list of sent registrations, that have been submitted to BCR by another doctor or hospital. You might not have access to these registrations. Here, the name of the physician or the source that submitted the registration will be displayed.
	Saved registrations can be sent (in bulk or by making a selection).	
	Saved or sent registrations can be downloaded (in bulk)	Both saved and sent registrations can be downloaded (through separate searches). It is only possible to download those data for which access has been granted. For saved registrations, a search is performed based on

Table 1. An overview of the various actions that are available for each registration module.



the date the registration was last modified. For 'sent' registrations, it is only possible to search on the date of submission, not on date of incidence, as this variable is not included in the project-specific 'GEP Breast' dataset. It is included in the standard cancer registration
(bijlage/annexe 55).

5.2 Starting a new 'GEP Breast' registration

5.2.1 Administrative patient data

Click on the blue 'plus' icon within the registration module for the project 'GEP Breast'.

First, the administrative patient data need to be filled out (Figure 6). The required data are:

- Health insurance institution (option "Unknown" is available and may be indicated)
- National number for social security (INSZ/NISS) *
 - o Last name
 - o First name
 - o Zip code
 - o Town
 - Country
 - Date of birth
 - o Sex

* The web service 'IdentifyPerson' (managed by eHealth) has been built into the WBCR application to **autocomplete the requested patient data** when the **INSZ/NISS number** of the patient has been filled out. In case the administrative patient data is not automatically filled out, there could be two possible explanations:

- 1. The INSZ/NISS number is not correct
- 2. The eHealth web service is temporarily out of order

Patiënt		Patient	t		
Bronnen		Sources			
Ziekenhuis Ziekenfonds	Onbekend		Hôpital Mutuelle	Inconnu	
Vul de patiëntgegevens in		Introduisez	les coordonnées du pati	ent	
INSZ			Numéro de sécurité sociale		
Familienaam			Nom de tamile		
Voornaam			Prénom		
Postcode			Code postal		
Gemeente			Commune		
Land	Belgium	~	Pays	Belgium	~
Ziekenfondsnummer			N° organisme assureur		
Geboortedatum	dd/mm/jjjj		Date de naissance		jj/mm/aaaa
Sterftedatum	dd/mm/jjjj		Date de décès		🤨 jj/mm/aaaa
Geslacht	○ Mannelijk ○ Vrouwelijk		Sexe	○ Masculin ○ Féminin	
Bewaar Volgen	nde		Sauvegarder	uivant	





In case registrations have already been saved or sent for a certain patient (i.e. based on INSZ/NISS number) in the project module in WBCR, a notification will appear when the INSZ/NISS number is filled out, including a link to access these registrations directly (Figure 7).

Introduisez les coordonnées du patient

Il existe déjà une ou des tumeurs enregistrées pour ce patient. Vous pouvez continuer ou choisir une action. Consulter/reprendre un enregistrement conservé, cliquez <u>'Reprendre un enregistrement'</u> Consulter les enregistrements envoyés, cliquez <u>'Consulter les enregistrements envoyés'</u>.

Vul de patiëntgegevens in

Voor deze patient bestaat er reeds een registratie. U kan verder doen met deze registratie of één van volgende acties kiezen. Om de bewaarde registraties te bekijken/editeren, klik <u>'Bewerk registraties'</u> Om verzonden registraties van deze patiënt te bekijken, klik <u>'Bekijk verzonden registraties'</u>.

Figure 7. Pop-up warning if registrations have already been performed for a patient within the registration module (based on INSZ/NISS number).

5.2.1.1 What if a patient does not have an INSZ/NISS number?

In case a patient does not have an INSZ/NISS number, please follow the next steps:

1. The patient is domiciled in Belgium

EU-citizens are not obliged to request an INSZ/NISS number, but often they will receive one when registering at their municipality. This can be used to register the patient. When this is not the case, the patient can be registered based on his/her health insurance number or another unique identification number. To do so:

- Fill out the health insurance number or another unique identification number in the 'health insurance number' field.
- When clicking 'Next', a warning will appear (in orange) indicating that the INSZ/NISS number is required. When a comment is provided in the general 'Comments' field, indicating that this registration concerns a patient without INSZ/NISS number, who is registered in Belgium, it will be possible to proceed with the registration.

2. <u>The patient is not domiciled in Belgium</u>

- Fill out the foreign zip code and country, in which the patient is domiciled.
- Fill out the (temporarily assigned) health insurance number or another unique identification number in the 'health insurance number' field.



5.2.2 Registration form for GEP Breast

When the required fields of the administrative patient data have been filled out, click 'Next' to enter the project-specific registration form for GEP Breast.

All variables are required to be filled out unless stated otherwise (e.g. 'if applicable'). For 'single-select variables' (\bigcirc) only one answer can be selected, for 'multi-select variables' (\square) one or more answers can be selected. For additional information on the requested variables, please consult the project-specific manual for GEP Breast, which can be found on our website: <u>https://kankerregister.org/GEPBreast</u>.

5.2.3 Completing a registration: validation, error messages and sending it to BCR

Once a registration has been completed, click 'Next'. The **data will be validated** and a **summary of the registration** will be presented. If erroneous data have been filled out (according to the application) or if a registration was incomplete, an **error message** (in red) will appear at the top of the page, numbering the errors/blanks and indicating the type of error. An example of such a message could be: "*The date of the postoperative consultation cannot precede the date of surgery*", when a mistake was made when entering the date of surgery or the date of the postoperative consultation.

Several options are available to you on the bottom of this summary page:

- Go to the <u>previous</u> page (=project-specific registration form)
- Go to the patient administrative data
- Go to <u>1st page characteristics</u> (=project-specific registration form)
- <u>Save</u> the registration
- <u>Send</u> the registration
- <u>Send and Print</u> the registration (creation of a pdf file)
- <u>Print</u> the registration (creation of a pdf file)

Please note that a registration can be saved <u>at any time</u>, to be completed, modified or send to BCR later in time!

Only complete and **validated registrations** without errors **can be send** to BCR. You can check the status of saved registrations by going to the homepage and clicking on the 'envelop' icon. A green check will appear in the column 'status' if registrations have been correctly validated and can be sent. Two statuses are possible for saved registrations:

- Solution : "validated without errors"
 - : "not yet validated"

Please note that you can send in registrations in bulk, by going to the homepage and clicking on the 'envelop' icon, where you will find an overview of the saved registrations, which can be send in to the BCR at once. Alternatively, a selection of registrations can be made.

5.2.4 Changes to registrations are not possible after sending

Once a validated registration has been sent to BCR, it is no longer possible to modify the data. However, if you would like to **modify a sent registration** (e.g. because erroneous



information was included or because additional information about the patient has become available), we advise you to do the following:

- Start **a new registration** for the patient and enter the necessary corrections or additional data.
- Indicate in the <u>general 'Comments' field</u>: "**Corrected version**". This field can be found at the bottom of the project-specific registration form.
- Please also indicate the WBCR reference number of the first registration and specify the variables for which the changes have been made or additional information has been added.

6. Signing out

It is stronly recommended to **actively sign out** from the WBCR application (even for a break). In any case, you will be logged off automatically after 1 hour of inactivity in WBCR. To sign out, click on 'afmelden' or 'se déconnecter' in the upper right corner of the task bar (Figure 8).

					afmelden
page d'accueil	conditions d'utilisation	sélection de la mutuelle	contactez-nous	aide	se déconnecter

Figure 8. It is advised to actively sign out from WBCR.

7. Problems: Safety settings

For a proper functioning of the WBCR application, it might be necessary to change some safety settings of your network/computer.

- 1. Enable cookies
 - Go to 'Start', 'Control panel'
 - In 'Network and Internet', select 'Internet options'
 - In the tab 'Privacy', select 'Sites'
 - Copy/paste the URL of the WBCR application into the text field and click 'Allow' (<u>https://www.kankerregistratie.be/wbcr/)</u>
 - Click 'OK'
- 2. Add the WBCR site to your trusted sites
 - Go to 'Start', 'Control panel'
 - In 'Network and Internet', select 'Internet options'
 - In the tab 'Security', select 'Trusted sites'
 - Click on 'Sites'
 - Copy/paste the URL of the WBCR application into the text field and click 'Add' (<u>https://www.kankerregistratie.be/wbcr/</u>)
 - Click 'OK'