

# LAPS - Female patients with breast cancer treated with lapatinib in the context of an expanded access program (ATU): description of the care trajectory and clinical course

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## Général

### Identification

Nom détaillé Female patients with breast cancer treated with lapatinib in the context of an expanded access program (ATU): description of the care trajectory and clinical course

Sigle ou acronyme LAPS

Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.) CNIL : 1213267

### Thématiques générales

Domaine médical Cancer research

Autres, précisions Breast cancer

Mots-clés HER2+, Tyverb

### Responsable(s) scientifique(s)

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Laboratoire Laboratoire GSK

### Collaborations

### Financements

Financements Private

Précisions GSK laboratory

### Gouvernance de la base de

## données

Organisation(s) responsable(s)  
ou promoteur

Laboratoire GSK

Statut de l'organisation

Secteur Privé

Contact(s) supplémentaire(s)

## Caractéristiques

Type de base de données

Type de base de données

Study databases

Base de données issues  
d'enquêtes, précisions

Not-repeated cross-sectional studies (except case control studies)

Origine du recrutement des  
participants

A selection of health institutions and services

Critère de sélection des  
participants

Medication(s) taken

Le recrutement dans la base de  
données s'effectue dans le  
cadre d'une étude  
interventionnelle

No

Informations complémentaires  
concernant la constitution de  
l'échantillon

One hundred centers have filed at least one TUA request as of July 31, 2007 (about 3 months before the initiation of the study): about thirty of these are centers of substantial size (at least 5 patients, 10 patients on the average), the other 70 are small centers (less than 5 patients, 4 patients on the average).

The study will be proposed to 80% of the centers in each stratum (center size). The random drawing will make it possible, as such, to retain 56 small centers and 25 large centers. Based on an estimated response rate of 70%, 40 small centers and 18 large centers will in the end participate in the study:

Random drawing and number of patients expected: Based on the eligibility criteria retained, an additional CRF will have to be completed for all of the patients of a center. No random drawing will be carried out at this level.

Approximately 570 patients received a treatment via lapatinib over the period of the study retained. Based on participation of 58 of the 81 centers that had requested a TUA, to which this study will be proposed, 330 completed dossiers can be

expected.

## Objectif de la base de données

Objectif principal	Describe the care pathways of patients with breast cancer who have received and/or are receiving treatment with lapatinib under Temporary Use Authorization (TUA)
Critères d'inclusion	Patient who has received lapatinib for the treatment of breast cancer within the framework of a TUA between January 1, 2007 and 3 months prior to the beginning of the study

## Type de population

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
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Population concernée	Sick population
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Sexe	Woman
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Champ géographique	National
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Détail du champ géographique	France
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## Collecte

### Dates

Année du premier recueil	2008
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Année du dernier recueil	2010
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## Taille de la base de données

Taille de la base de données (en nombre d'individus)	< 500 individuals
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Détail du nombre d'individus	198
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## Données

Activité de la base	Data collection completed
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Type de données recueillies	Clinical data
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Données cliniques, précisions	Direct physical measures
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## Medical registration

Existence d'une bibliothèque	No
Paramètres de santé étudiés	Health event/morbidity Health event/mortality Health care consumption and services
Consommation de soins, précisions	Hospitalization Medical/paramedical consultation Medicines consumption
<b>Modalités</b>	
Mode de recueil des données	The investigating centers (prescribing doctor) that have accepted to carry out the study will receive a CRF for all of their patients eligible for the study: patient number, sex, age and treatment start date will be pre-completed in order to identify the patients. Prescribing doctors will complete the CRF using the medical doctor, based on the information available, and will return it to the logistics center
Suivi des participants	No
Appariement avec des sources administratives	No
<b>Valorisation et accès</b>	
<b>Valorisation et accès</b>	
<b>Accès</b>	
Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	Abstract (ISPOR 2009) Publication in progress
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only