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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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)
Population concernée	Sick population
Sexe	Woman
Champ géographique	National
Détail du champ géographique	France
Collecte	
Dates	
Année du premier recueil	2008
Année du dernier recueil	2010
Taille de la base de données	
Taille de la base de données (en nombre d'individus)	< 500 individuals
Détail du nombre d'individus	198
Données	
Activité de la base	Data collection completed
Type de données recueillies	Clinical data
Données cliniques, précisions	Direct physical measures

	Medical registration
Existence d'une biothèque	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
Modalités	
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
Valorisation et accès	
Valorisation et accès	
Accès	
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