

## Biological therapy at-home administration support for patients with severe asthma: BioCart©

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In Spain, asthma affects about two million people (10% of children, 5% of adults) [1], 5% of whom have severe asthma. One of the therapeutic options available to uncontrolled severe asthma (SA) patients are biologic treatments, which can be administered in the hospital or, more recently, self-administered at home by the patient or else by a caregiver [2–4]. Medications self-administered at home offer several advantages, such as flexibility of administration or portability. They also potentially minimize healthcare costs by reducing hospital visits. However, home administration may raise practical concerns in patients regarding the administration of the medicine, the influence of concomitant medical conditions and/or the interpretation of possible adverse effects. In addition, treatment compliance is an important factor related to asthma control [5] and it is important that healthcare providers (HCPs) verify biologic treatment adherence and monitor the disease and its management between medical visits. Therefore, in this context, there is a need for a tool that helps SA patients and HCPs alike to manage self-administered treatment better, improving disease control and follow-up and communication related to the practical aspects of treatment.

The Spanish Society of Allergology and Clinical Immunology (SEAIC) created a scientific committee (SC) to develop a tool to help HCPs to monitor self-administration and adherence,

adverse events and asthma control parameters, while also educating patients in the management of their treatment. In order to ensure that all the health professionals involved in the specialized SA patient-care process were represented, the SC was comprised of three allergists, two pulmonologists, two asthma unit nurses and two hospital pharmacists with extensive experience in the management of patients with SA, including patients on home-based biologic therapies.

A bibliographic search in the relevant literature, as well as a guided discussion to identify the key information to be included, was performed to create the first version of the tool, officially named BioCart© Diary.

This first draft was submitted to eight cognitive debriefing interviews with native Spanish-speaking SA patients on biologic treatment (representing the different biologic treatments currently available in Spain, as well as people of different ages, genders, geographical origins and sociocultural backgrounds). After the patients' real understanding of all the questions and response options included in BioCart© had been evaluated, the proposed changes were implemented and the new version was submitted for validation to a panel of 101 experts (25 from each representative group) by using the modified Delphi methodology [6]. Specific questions to validate whether BioCart© covered the objectives for which it had been designed and was useful to patients and to HCPs were included. Finally, qualitative and quantitative information from the Delphi survey was collated and analysed to develop the final version of BioCart© that was reviewed and endorsed by the SC members.

A high consensus was achieved on all the items (consensus was defined as when at least 70% of the panellists gave an item the same score), confirming the theoretical utility of BioCart©

and also that it included all the essential information and sections to gather the necessary information to permit appropriate SA patient follow-up.

The final Spanish version of BioCart© contained 3 different sections (Figure 1):

- 1) Patient Information: containing general information about biologic treatments. The main topics covered were self-administration technique, correct transportation and storage of the medication and information on the most common adverse effects related to biologics and how to act if they occur.
- 2) Patient Data Record: designed as a tool to help patients to keep a record of biologic treatment administration (date, dose, number of injections and administration site). Additionally, the ACT™ questionnaire and a record of peak flow results were included, as they are recommended instruments that HCPs use to assess the patient's level of control.
- 3) Adverse Events and Asthma Attacks: to allow the patients to record the incidence of adverse effects and asthma attacks between visits. The information gathered may include the date on which it occurred, symptoms or any action taken.

The tool is presented in paper format to be given to patients at the HPCs' discretion, and will be exchanged among the stakeholders during the subsequent follow-up visits. A translated English version of BioCart© is available in Supplementary material Appendix 1.

To the best of our knowledge, BioCart© is the first well-structured tool for monitoring and supporting the self-management of biologic drugs in SA, with a high rate of consensus among experts and patients. BioCart© is intended to be a universal, simple and practical tool to

assess compliance in the self-administrated treatment of biologic drugs for severe asthma in a real-life setting, useful to both patients and HCPs in that it also helps to evaluate the clinical evolution of disease during follow-up. It can be particularly useful to patients monitored remotely by telephone or videocall.

Following the patients' recommendations, the first section focuses on patient needs, as it mainly contains useful information related to self-administration conveyed in clear and simple language. Conceived as a brief section to handle doubts or queries, it is intended to guide patients during the self-administration process, making them more comfortable with the injection process and fostering therapeutic adherence.

The other two BioCart© sections were designed to help HCPs to take better-informed therapeutic decisions, as they provide a comprehensive overview of the patient's condition and the degree of asthma symptom control. Although BioCart© should be evaluated in clinical practice, we truly believe that these sections could also be useful to the patients, as they empower them to self-manage their disease, allowing them to easily record all the relevant information and dates of follow-up visits, while also avoiding problems of forgetfulness.

In conclusion, once it has been implemented in routine clinical practice, BioCart© could help both patients and healthcare professionals, constituting an advantageous tool promoting a more efficient monitoring of self-administered biologics and treatment adherence, potentially facilitating the follow-up of their condition and treatment.

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Conflicts of interests available in [www.jiaci.org](http://www.jiaci.org).

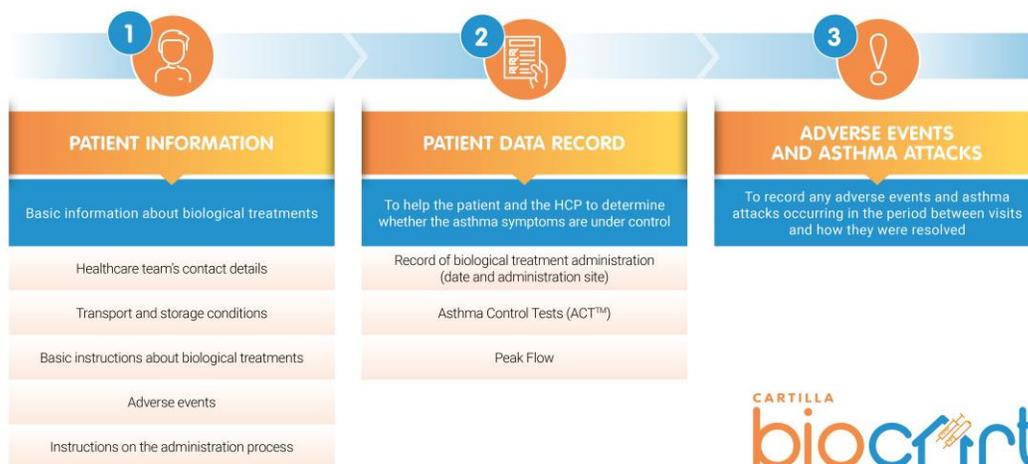
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**Figure. Diagram of the BioCart© Diary content.** BioCart© has 3 sections: 1) Patient information on self-administration of the drug (how to store, administer and dispose of it) and possible administration-related adverse effects 2) Recording of patient data prior to self-administration (ACT™ questionnaire, Peak flow and recording of the date and administration site) and 3) Recording of adverse reactions and asthma attacks.



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