

Support for Home Administration of Biological Therapy in Patients With Severe Asthma: BioCart[®]

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In Spain, asthma affects about 2 million people (10% of children, 5% of adults) [1], of whom 5% have severe asthma (SA). One of the therapeutic options available to patients with uncontrolled SA is biologic treatments, which can be administered in the hospital or, more recently, self-administered at home by the patient or a caregiver [2-4]. Medications self-administered at home offer several advantages, such as flexibility of administration and portability. They also potentially minimize health care costs by reducing hospital visits. However, home administration may raise practical concerns regarding the administration technique itself, the influence of concomitant medical conditions, and/or the interpretation of possible adverse effects. In addition, adherence plays a key role in asthma control [5], and it is important that health care providers (HCPs) verify adherence to biologic treatment 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 and thus improve

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 to develop a tool to help HCPs to monitor self-administration, 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 committee comprised 3 allergists, 2 pulmonologists, 2 asthma unit nurses, and 2 hospital pharmacists with extensive experience in the management of patients with SA, including patients receiving home-based biologic therapies.

A literature search and a guided discussion to identify the key information to be included were undertaken to create the first version of the tool, which was officially named the BioCart[®] Diary.

This first draft was submitted to 8 cognitive debriefing interviews with native-speaking Spanish SA patients of both sexes receiving biologic treatment. These patients were representative of the different biologic treatments currently available in Spain, as well as of different ages, geographical origins, and sociocultural backgrounds. After the patients' real understanding of all the questions and response options included in BioCart had been evaluated, the changes proposed were implemented, and the new version was submitted for validation to a panel of 101 experts (25 from each representative group) 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 data from the Delphi survey were collated and analyzed to develop the final version of BioCart, which was reviewed and endorsed by the SC members.

A high consensus was achieved for all the items (consensus was defined as at least 70% of the panelists giving an item the same score), thus confirming the theoretical utility of BioCart and its inclusion of all the essential information and sections to gather the necessary data to enable appropriate follow-up of SA patients.

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

- Patient information, which contains 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.
- Patient data record, which is designed as a tool to help patients to keep a record of biologic treatment (date, dose, number of injections, and administration site). Additionally, the Asthma Control Test (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.
- Adverse events and asthma attacks, which enable 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, and action taken.

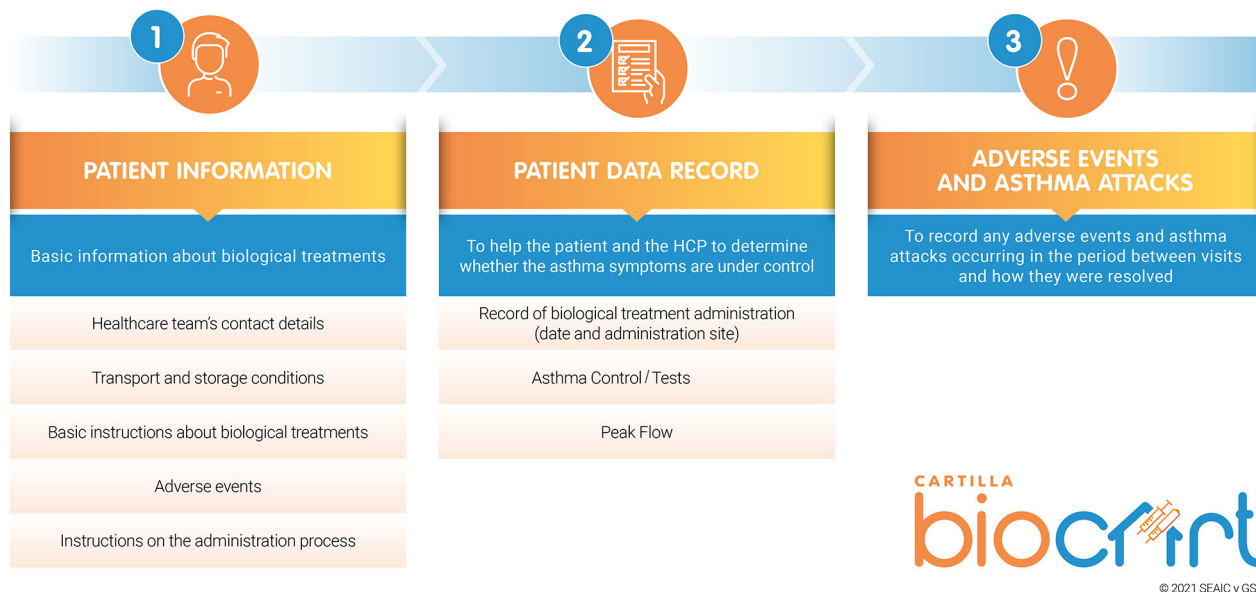


Figure. Diagram of the BioCart Diary content. BioCart has 3 sections: (1) Patient information on self-administration of the drug (how to store, administer, and dispose of it) and possible administration-related adverse effects; (2) A record of patient data prior to self-administration (Asthma Control Test questionnaire, peak flow, and recording of the date and administration site); and (3) A record of adverse reactions and asthma attacks.

The tool is presented in paper format to be given to patients at the HCP's discretion and is 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 adherence in the self-administered treatment of biologic drugs for severe asthma in a real-life setting. It is useful to both patients and HCPs in that it also helps to evaluate the clinical progress of disease during follow-up. It is particularly useful to patients monitored remotely by telephone or videocall.

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

The other 2 BioCart sections were designed to help HCPs to take better-informed decisions on therapy, 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 believe that these sections could also be useful to patients, as they empower them to self-manage their disease, enabling them to easily record all relevant information and dates of follow-up visits, while avoiding problems of forgetfulness.

In conclusion, once it has been implemented in routine clinical practice, BioCart could help both patients and HCPs.

BioCart is an advantageous tool that promotes more efficient monitoring of self-administered biologics and adherence and potentially facilitates follow-up and treatment.

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Conflicts of Interest

Available at www.jiaci.org.

References

- González-García JG, Chalela R, Carballo N, Ausín P. Mild Asthma and Life-threatening Exacerbations: Is it Time to Take Action? *Arch Bronconeumol*. 2020;56:395-6. doi: <http://doi.org/10.1016/j.arbr.2019.11.011>
- Melero Moreno C, Quirce S, Huerta A, Uría E, Cuesta M. Economic impact of severe asthma in Spain: multicentre observational longitudinal study. *J Asthma*. 2019;56:861-71. doi: <https://doi.org/10.1080/02770903.2018.1499035>
- Delgado J, Dávila JJ, Domínguez-Ortega J. Clinical recommendations for the management of biological treatments in severe asthma patients: A consensus statement. *J Investig Allergol Clin Immunol*. 2021;31:36-43. doi: <https://doi.org/10.18176/jiaci.0638>

4. Dávila I, Quirce S, Olaguibel JM. Selection of Biologics in Severe Asthma: A Multifaceted Algorithm. *J Investig Allergol Clin Immunol*. 2019;29:325-8. doi: <https://doi.org/10.18176/jiaci.0398>
5. González Barcala FJ, de la Fuente-Cid R, Álvarez-Gil R, Tafalla M, Nuevo J, Caamaño-Isorna F. Factors associated with asthma control in primary care patients: the CHAS study. *Arch Bronconeumol*. 2010;46:358-63. doi: <https://doi.org/10.1016/j.arbres.2010.01.007>
6. Dalkey NC, Brown BB, Cochran SW. The Delphi Method, III: Use of Self-Ratings To Improve Group Estimates. *Technological Forecast Soc Chang. RAND Corporation*. 1970;1:283-91. Available from: https://www.rand.org/pubs/research_memoranda/RM6115.html

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