

CARTILLA

bioCart

Project BioCart[®]

Follow-up diary for the adult patient with severe asthma on home treatment with biologics

OPINION STUDY IN REAL CLINICAL PRACTICE

PRE and POST Patient Questionnaires

February 2022

Previous Note

This document includes two surveys to be completed by patients participating in the project:

1. Survey prior to starting your experience of using the BioCart® Diary (focused on expectations).
2. Post-use survey of the BioCart® Diary (focused on experience of use, not health impact).

Opinion survey for patients PRE use of the BioCart®

INTRODUCTION

Thank you very much for participating in the **BioCart® Diary project!**

Your feedback is very valuable to us, and we thank you for choosing to be part of this project to **assess the use and usefulness of the BioCart® by patients with severe asthma.**

This is the first of two surveys that we will give you. The **aim of this** first questionnaire is to **find out what your expectations and impressions of the expectations and impressions about BioCart® BEFORE you use it.**

Before proceeding, please read the following considerations carefully:

- Although your doctor has invited you to participate in this survey, your answers will be kept strictly confidential and anonymous. They will not be shared with any healthcare professional.
- Your answers will not affect the medical care you receive in any way.
- The survey is not linked to any promotional material, and you will not be contacted for marketing purposes based on your survey responses. Neither the survey sponsor nor its suppliers will sell or rent your information.
- If you have any questions not related to the survey, such as questions on how to fill in the BioCart®, please contact your doctor.

Clauses

In accordance with the provisions of the current regulations on Personal Data Protection LOPD, RGPD and LSSICE 34/2002, we inform you that your data will be incorporated into a data processing system owned by ADELPHI TARGIS, S.L. to attend to your participation in our project, as well as sending the cheque to your postal address, as well as other commitments arising from your participation. ADELPHI TARGIS, S.L. informs you that your data will not be transferred to third parties except in the legally established cases, as well as in those cases in which you expressly authorise such transfer. They will be kept for the period of time strictly necessary to comply with the aforementioned purposes, as well as the development of the project and to comply with the relevant legal obligations. The legitimacy for the processing of your data is given by the execution of the legal-business relationship with ADELPHI TARGIS, S.L., as well as by your own consent.

Exercise of rights. You may exercise your rights of access, rectification, deletion, limitation, portability and opposition, free of charge, by contacting the address at the bottom of the page. You may also contact the competent Control Authority (SPANISH DATA PROTECTION AGENCY) to submit any claims you deem appropriate.

- I declare that I have carefully read this document and I expressly consent and legitimise ADELPHI TARGIS, S.L. to process my personal data for the purposes indicated above.

The survey should take you no more than **5 minutes** to complete, so please **read the questions below carefully and answer as honestly as possible.**

CHARACTERISATION OF PARTICIPANTS																															
1.	At which hospital is your asthma monitored? <i>(please write the name of the hospital)</i>																														
2.	When were you diagnosed with severe asthma <i>(write the year and month if you remember)?</i>																														
3.	When did you start using a biologic/injectable treatment to treat your severe asthma <i>(write the year and month, if you remember)?</i>																														
4.	What biologic/injectable treatment do you currently use for severe asthma?																														
5.	This treatment is administered by: <i>(check ONLY one answer)</i> <ul style="list-style-type: none"> <input type="radio"/> At home, I administer it myself. <input type="radio"/> At home, it is administered by someone else <input type="radio"/> At the hospital / health centre <input type="radio"/> Other, please specify: ... 																														
6.	When is your next asthma control visit with your doctor scheduled <i>(write the approximate date: day, month, and year)?</i>																														
CURRENT VISITS WITH THE HEALTH PROFESSIONALS																															
7.	<p>Below are a series of statements related to your visits with the health professionals who have been caring for you since you were diagnosed with severe asthma.</p> <p>Please read them carefully and mark the option that best fits your answer, where 1 NOT AT ALL AGREE and 5 STRONGLY AGREE <i>(please mark only one answer for each statement)</i>.</p> <table border="1"> <thead> <tr> <th>DURING THE VISIT ...</th> <th>1 NOT AT ALL AGREE</th> <th>2</th> <th>3</th> <th>4</th> <th>5 STRONGLY AGREE</th> </tr> </thead> <tbody> <tr> <td>... I discuss with the health professional any questions or concerns I have about severe asthma.</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>... the support materials used (brochures, information sheets, etc.) have been useful to me</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>... I have the time and comfort to ask questions of the health professional. health professional</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>... I remember to consult all outstanding questions</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	DURING THE VISIT ...	1 NOT AT ALL AGREE	2	3	4	5 STRONGLY AGREE	... I discuss with the health professional any questions or concerns I have about severe asthma.						... the support materials used (brochures, information sheets, etc.) have been useful to me						... I have the time and comfort to ask questions of the health professional. health professional						... I remember to consult all outstanding questions					
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8.	<p>Below are a series of statements related to the period between follow-up visits with your healthcare professionals since you were diagnosed with severe asthma.</p> <p>Please read them carefully and mark the option that best fits your answer, where 1 NOT AT ALL AGREE and 5 STRONGLY AGREE <i>(please mark only one answer for each statement)</i>.</p> <table border="1"> <thead> <tr> <th>BETWEEN ONE FOLLOW-UP VISIT AND ANOTHER ...</th> <th>1 NOT AT ALL AGREE</th> <th>2</th> <th>3</th> <th>4</th> <th>5 STRONGLY AGREE</th> </tr> </thead> <tbody> <tr> <td>... I usually need additional information.</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>... I would need to have more follow-up/support from my doctor/nurse/ hospital pharmacy staff</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>... I usually make a note of the treatment schedule</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>... I usually make a note of all the issues I want to discuss at my next visit</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	BETWEEN ONE FOLLOW-UP VISIT AND ANOTHER ...	1 NOT AT ALL AGREE	2	3	4	5 STRONGLY AGREE	... I usually need additional information.						... I would need to have more follow-up/support from my doctor/nurse/ hospital pharmacy staff						... I usually make a note of the treatment schedule						... I usually make a note of all the issues I want to discuss at my next visit					
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<p>9.</p>	<p>Please indicate which of the following statements are true in your case (<i>tick all that apply</i>)</p> <p><i>During the time between visits and another ...</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> ... I remember to take the doses of my biological medicine at home on the day it is due. <input type="checkbox"/> ... it is clear to me how to inject the biological medicine. <input type="checkbox"/> ... I know what the side effects related to my medication are and what to do in each case. <input type="checkbox"/> ... I am clear about how I should deal with asthma attacks/seizures and have a written personal action plan. <input type="checkbox"/> ... I know when I should go to the emergency room because of my asthma.
<p>EXPECTATIONS WITH THE BIOCART® DIARY</p>	
<p>10.</p>	<p>At your last visit, your doctor / nurse / hospital pharmacy staff gave you the BioCart® (<i>tick ONLY one answer</i>)</p> <ul style="list-style-type: none"> <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> I do not remember <p>[For those who answer YES go to Q11].</p> <p>[Those who have answered "NO" or "I don't remember", thank them for their participation and end the survey. Message: "Before completing the survey any further, please contact your doctor"].</p>
<p>11.</p>	<p>In the previous question, you answered that the health care professional has given you the BioCart® together with this questionnaire and explained how to use it.</p> <p>BEFORE you start using it, please answer the following questions. You do not need to refer to the Diary to answer.</p> <p>Do you think you will use the BioCart® Diary (<i>tick ONLY one answer</i>)?</p> <ul style="list-style-type: none"> <input type="radio"/> I'm sure it is <input type="radio"/> It is likely to <input type="radio"/> It is likely that it will not <input type="radio"/> Surely not <input type="radio"/> I don't know

12. Carefully read the following statements regarding the BioCart® Diary and mark the option that best fits your answer, where **1 NOT AT ALL AGREE** and **5 STRONGLY AGREE** (*mark only one answer for each statement*).

BEFORE using the BioCart® Diary, what do you expect this material to be useful for?

	1 NOT AT ALL AGREE	2	3	4	5 STRONGLY AGREE
It will make it easier for me to remember when I need to take my treatment.					
It will make it easier for me to administer my treatment					
It will allow me to better monitor my treatment					
It will allow me to have better control of my asthma.					
It will allow me to have more effective follow-up visits					
It will enable me to communicate better with the health professional.					
It will allow me to feel more confident during the period between visits.					

13. Is there anything else you would like to add about what you expect from the use of this Diary? (*Optional: please write your answer*).

Opinion survey for patients POST use of the BioCart®

INTRODUCTION	
<p>Welcome back,</p> <p>To finalise your participation in the BioCart® Diary project, you need to fill in a second survey, the purpose of which is to evaluate your experience and collect your opinion AFTER USING the BioCart® Diary during the last months.</p> <p>Before proceeding, please read the following considerations carefully:</p> <ul style="list-style-type: none"> ▪ Although your doctor or nurse has invited you to participate in this survey, your answers will be kept strictly confidential and anonymous. They will not be shared with any healthcare professional. ▪ Your answers will not affect the medical care you receive in any way. ▪ The survey is not linked to any promotional material, and you will not be contacted for marketing purposes based on your survey responses. Neither the survey sponsor nor its vendors will sell or rent your information. <p>The survey should take you no more than 5 minutes to complete, so please read the questions below carefully and answer as honestly as possible.</p> <p>Thank you very much for participating in this project.</p>	
BIOCART® DIARY USE	
<p>1.</p>	<p>Have you used the BioCart® Diary in the last few months (<i>tick ONLY one answer</i>) <i>And remember that honesty is important, your answers will not affect your participation in the project.</i></p> <ul style="list-style-type: none"> <input type="radio"/> Yes, all the time indicated and I have filled in all the information. <input type="radio"/> Yes, all the time indicated and I have filled in some of the information. <input type="radio"/> Part of the time, filling in all information <input type="radio"/> Part of the time, filling in part of the information <input type="radio"/> I have not used it [<i>SKIP to P2</i>].
<p>2.</p>	<p>Question only for those who have indicated in Q1 that they have not used the Diary].</p> <p>You have indicated that you have not used the BioCart® Diary, could you please tell us why: (<i>tick all that apply</i>)</p> <ul style="list-style-type: none"> <input type="checkbox"/> I have lost my BioCart® <input type="checkbox"/> I forgot to complete the BioCart® <input type="checkbox"/> I didn't understand how to fill in the BioCart® <input type="checkbox"/> I haven't had time <input type="checkbox"/> I did not find it useful <input type="checkbox"/> I did not want to participate in this part of the project <input type="checkbox"/> Other reasons. Please give details of your response: _____

3. Overall, your experience of using the BioCart® Diary over the last few months has been... *(tick ONLY one answer)*

- Excellent
- Very good
- Good
- Acceptable
- Bad
- Very bad
- Don't know / No answer

4. Here are several statements related to the BioCart® Diary based on their experience of use.

Please indicate your level of agreement with each of the statements, **with 1 NOT AT ALL AGREE and 5 STRONGLY AGREE** *(please tick only one response for each statement)*.

The BioCart® Diary ...	1 NOT AT ALL AGREE	2	3	4	5 STRONGLY AGREE
... is easy to understand material					
... is an easy material to complete					
... contains useful information					
... includes all the necessary information					

5. Did you have any difficulties or doubts when filling in any of the sections of the Diary *(please tick ONLY one answer)*?

- YES
- NO

[Questions Q6, Q7 and Q8 are only for those who indicated in Q5 that they had difficulties using the Diary. Those who answered that they had no doubts/difficulties, skip to Q9].

6. You have answered that you had difficulties using the BioCart® Diary, in which sections did you have the most difficulties *(tick all that apply)*?

- Patient information section
- Patient Data Record - Asthma Control Test (ACT)™
- Patient data recording - Dose administration
- Adverse reaction register
- Asthma crises register

7. Please briefly explain why you found it difficult to complete the sections of the booklet you have indicated in the previous answer.

8. Were you able to discuss these questions with your doctor / nurse / hospital pharmacy staff and resolve them to your satisfaction (*tick ONLY one answer*)?

- YES
- NO
- I don't know

BIOCART® DIARY ASSESSMENT

9. Carefully read the following statements regarding the BioCart® Diary and mark the option that best fits your answer, where **1 NOT AT ALL AGREE** and **5 STRONGLY AGREE** (*mark only one answer for each statement*).

What did you find the BioCart® Diary useful for?	1 NOT AT ALL AGREE	2	3	4	5 STRONGLY AGREE
It has made it easier for me to remember when I need to take the treatment.					
It has made it easier for me to administer my treatment					
It has allowed me to better monitor my treatment					
It has allowed me to have better control of my asthma					
It has allowed me to have more effective follow-up visits					
It has enabled me to communicate better with the health professional					
It has allowed me to feel more confident during the treatment period.					

10. Which sections of the Diary did you find most useful? Please tick the option that best fits your answer, where **1 is NOT VERY USEFUL** and **5 is VERY USEFUL** (*tick only one answer for each statement*).

	1 NOT VERY USEFUL	2	3	4	5 VERY USEFUL
Patient information section					
Patient Data Record - Asthma Control Test (ACT) TM					
Patient data recording - Dose administration					
Adverse reaction register					
Asthma crisis register					

11. Please briefly describe your experience of using the BioCart® Diary and why you have or have not found it useful.

FUTURE USE OF THE BIOCART® DIARY

12. Would you continue to use the BioCart® Diary in the future (*tick ONLY one answer*)?

- YES
- NO
- Only if requested by my doctor or other health professional.
- I don't know

13.	Would you recommend the BioCart® to other patients as a tool to improve the control and monitoring of their asthma? <i>(tick ONLY one answer)</i> <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> I don't know
14.	Do you want to add anything else to what you expected from the use of this Diary? <i>(Optional: please write your answer).</i>