

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 Questionnaires for Health Professionals

February 2022

Previous Note

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

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

Opinion survey for Healthcare Professionals PRE use of BioCart®

INTRODUCTION

Dear participant:

First, we would like to thank you for agreeing to participate in this BioCart® continuity project. Your feedback is very valuable to us.

This project aims to **collect useful feedback to assess the use and usefulness of the BioCart® in the context of real clinical practice.**

This is the first questionnaire we will ask you to complete, and it will help us to **understand what your expectations are for using the BioCart® as a healthcare professional.**

We would like to inform you that:

- The survey is not related 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 use the information outside the context of the project.
- Participation is anonymous. At no time will your answers be linked to the name of the respondent. The analysis of results will be carried out on an aggregate basis.

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.**

DAILY CLINICAL PRACTICE																																																																															
<p>1</p> <p>To begin with, we would like to know the reality of patients with severe asthma who start biologic therapy at home.</p> <p>Please indicate the percentage of patients who initiate in any of the following situations (if none, please indicate 0%) <i>(enter the % in each box. Must add up to 100%)</i></p>	<table border="1"> <thead> <tr> <th></th> <th>of total number of patients starting biological treatment at home</th> </tr> </thead> <tbody> <tr> <td>% of patients starting self-administered biological treatment at home after years (more than 12 months) of biological treatment in hospital setting</td> <td></td> </tr> <tr> <td>% of patients starting self-administered biologic treatment at home after 6-12 months of biologic treatment in the hospital setting</td> <td></td> </tr> <tr> <td>% of patients starting self-administered biologic treatment at home after less than 6 months of biologic treatment in the hospital setting</td> <td></td> </tr> <tr> <td>% of patients who directly initiate biological treatment on a self-administered basis at home after first administration education without going through the administration phase in a hospital setting</td> <td></td> </tr> <tr> <td>Other cases, specify and indicate % Other cases, specify and indicate % Other cases, specify and indicate % Other cases, specify and indicate</td> <td></td> </tr> </tbody> </table>		of total number of patients starting biological treatment at home	% of patients starting self-administered biological treatment at home after years (more than 12 months) of biological treatment in hospital setting		% of patients starting self-administered biologic treatment at home after 6-12 months of biologic treatment in the hospital setting		% of patients starting self-administered biologic treatment at home after less than 6 months of biologic treatment in the hospital setting		% of patients who directly initiate biological treatment on a self-administered basis at home after first administration education without going through the administration phase in a hospital setting		Other cases, specify and indicate % Other cases, specify and indicate % Other cases, specify and indicate % Other cases, specify and indicate																																																																			
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<p>2</p> <p>Below are several statements related to possible situations that could pose a problem in the management of patients with severe asthma on home treatment with biologics.</p> <p>Please read them carefully and rate them from 1 to 5 according to your opinion, where 1 IS NOT A PROBLEM and 5 IS A VERY COMMON PROBLEM <i>(please tick only one answer for each statement)</i>.</p>	<table border="1"> <thead> <tr> <th></th> <th>1 IS NOT A PROBLEM</th> <th>2</th> <th>3</th> <th>4</th> <th>5 IS A VERY COMMON PROBLEM</th> </tr> </thead> <tbody> <tr> <td>The patient's failure to follow the instructions given by the health professional</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Non-adherence to prescribed biological treatment</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Lack of persistence to the prescribed biological treatment (time during which the patient complies with the agreed prescription).</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>The patient's low awareness of their biological treatment</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Poor patient knowledge of how to store and transport biological treatment</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Incorrect self-administration of biological treatment at home by the patient</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Poor patient knowledge of the instructions for self-administration of the biologic drug</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Possible errors leading to a lack of therapeutic adherence to biological treatment</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Lack of knowledge to identify asthma attacks by the patient</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Poor control and management of asthma attacks by the patient</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>The patient does not remember, in the consultation, all the information that the health professional asks him/her (e.g. how many crises he/she has suffered in the inter-consultation period, if he/she has visited the emergency department, if he/she has been prescribed a course of antibiotics, adverse effects after the administration of the biologic, etc.).</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>The patient does not remember, in consultation, the additional information he/she wants to discuss with the health professional.</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		1 IS NOT A PROBLEM	2	3	4	5 IS A VERY COMMON PROBLEM	The patient's failure to follow the instructions given by the health professional						Non-adherence to prescribed biological treatment						Lack of persistence to the prescribed biological treatment (time during which the patient complies with the agreed prescription).						The patient's low awareness of their biological treatment						Poor patient knowledge of how to store and transport biological treatment						Incorrect self-administration of biological treatment at home by the patient						Poor patient knowledge of the instructions for self-administration of the biologic drug						Possible errors leading to a lack of therapeutic adherence to biological treatment						Lack of knowledge to identify asthma attacks by the patient						Poor control and management of asthma attacks by the patient						The patient does not remember, in the consultation, all the information that the health professional asks him/her (e.g. how many crises he/she has suffered in the inter-consultation period, if he/she has visited the emergency department, if he/she has been prescribed a course of antibiotics, adverse effects after the administration of the biologic, etc.).						The patient does not remember, in consultation, the additional information he/she wants to discuss with the health professional.					
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3	<p>We would like to know if the hospital provides any support material for patients with severe asthma on self-administered biologic therapy <i>(please tick ONLY one answer)</i></p> <ul style="list-style-type: none"> <input type="radio"/> Yes <input type="radio"/> No
<p>[Questions Q5, Q6 and Q7 are only for those who have answered YES in Q4. The rest skip to question Q8]</p>	
4	<p>You have replied that patients are given support material. Which health professionals deliver this material <i>(tick all that apply)?</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Allergist <input type="checkbox"/> Nursing <input type="checkbox"/> Hospital Pharmacy <input type="checkbox"/> Pneumologist <input type="checkbox"/> Other/s. Please specify: _____
5	<p>You have replied that patients with severe asthma and on home biological therapy are given support material. Can you tell us when it is delivered and what type of material <i>(please tick all that apply)?</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Information material at the time of diagnosis <input type="checkbox"/> Information material when starting biologic therapy <input type="checkbox"/> Information material at the time of initiation of home biological therapy <input type="checkbox"/> Section for adhesion monitoring <input type="checkbox"/> Other. Please specify: _____
6	<p>In addition to physical or digital material, do you have any other support systems available for these patients with severe asthma <i>(tick all that apply)?</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Contact telephone number from the unit or from the hospital pharmacy <input type="checkbox"/> E-mail handled from the unit or from hospital pharmacy <input type="checkbox"/> Other/s. Please specify: _____ <input type="checkbox"/> No additional support systems

EXPECTATIONS WITH THE BIOCART® DIARY																																																					
7.	<p>We would now like to focus on the BioCart® Diary. To begin with, we would like to hear your first impressions of the BioCart® Diary before you use it.</p> <p>Read each of the statements carefully and indicate your level of agreement with each statement, where 1 NOT AT ALL AGREE and 5 STRONGLY AGREE (<i>please tick only one answer for each statement</i>).</p> <table border="1"> <thead> <tr> <th>The BioCart® Diary looks like a material...</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>...easy to use for the healthcare professional</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>...easy to explain to the patient</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>...easy for the patient to understand</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>...easy to fill in by the patient</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>...easy to analyse (once filled in) by the healthcare professional</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	The BioCart® Diary looks like a material...	1 NOT AT ALL AGREE	2	3	4	5 STRONGLY AGREE	...easy to use for the healthcare professional						...easy to explain to the patient						...easy for the patient to understand						...easy to fill in by the patient						...easy to analyse (once filled in) by the healthcare professional																					
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<p>10.</p>	<p>Do you think the BioCart® will help to improve the management of your patients with severe asthma on home biologic therapy? <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 don't know
<p>11.</p>	<p>Do you think the BioCart® will help improve adherence to treatment? of your patients with severe asthma on home biological therapy? <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 don't know
<p>12.</p>	<p>What profile of patients with severe asthma do you think will benefit from the use of the BioCart® Diary <i>(tick all that apply)?</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Any patient on biologic home treatment <input type="checkbox"/> Patient on home biologic therapy with low/poor compliance <input type="checkbox"/> Patient on home biologic therapy with frequent seizures <input type="checkbox"/> Other/s. Please specify: _____
<p>13.</p>	<p>What profile of healthcare professionals do you think will benefit from the use of the BioCart® Diary <i>(tick all that apply)?</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Allergist <input type="checkbox"/> Pneumologist <input type="checkbox"/> Nursing <input type="checkbox"/> Hospital Pharmacy <input type="checkbox"/> Other/s. Please specify: _____

Opinion survey for Healthcare Professionals POST use of BioCart®

INTRODUCTION																																					
<p>Dear participant:</p> <p>You are about to finish your participation in the BioCart® project, thank you for your involvement.</p> <p>You now need to complete a second opinion survey, the purpose of which is to learn about your experience and to collect your opinion as a healthcare professional after using the BioCart® during the last months.</p> <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>																																					
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It has helped to improve communication with the patient																																																											
It has helped patients feel more confident about self-care and management of their disease																																																											
It has been used to monitor the condition of patients with severe asthma																																																											
<p>6. Which sections of the BioCart® Diary did you find most useful (<i>tick all that apply</i>)?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Patient information section <input type="checkbox"/> Patient Data Record - Asthma Control Test (ACT)™ <input type="checkbox"/> Patient data recording - Dose administration <input type="checkbox"/> Adverse reaction register <input type="checkbox"/> Asthma crises register 																																																											

7.	<p>Would you say that the use of the BioCart® has improved the adherence of your patients with severe asthma (<i>tick ONLY one answer</i>)?</p> <ul style="list-style-type: none"> <input type="radio"/> Yes, they have been more compliant with the Diary (therapeutic attachment). <input type="radio"/> As compliant as before using the Diary (therapeutic adherence). <input type="radio"/> No, they have been less compliant than before using the Diary (therapeutic adherence). 																																				
8.	<p>In general, have your patients reported a favourable opinion of the BioCart® Diary (<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 don't know 																																				
9.	<p>In general, have your patients experienced any difficulties in completing the BioCart® Diary (<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 don't know 																																				
10.	<p style="color: red;">[Question Q10 is only for those who have answered YES in Q9. The rest skip to question Q11]</p> <p>Please note down the most frequent problems your patients have experienced using the BioCart® diary:</p>																																				
FUTURE USE OF THE BIOCART® DIARY																																					
11.	<p>Based on your experience with the BioCart®, how likely is it that you would use it again for your patients with severe asthma on home biologic therapy? (<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"/> Maybe or maybe not <input type="radio"/> It is likely that it will not <input type="radio"/> Surely not 																																				
12.	<p>Thinking about the future use of the BioCart®, which patients would you consider giving the BioCart® to?</p> <p>Please carefully read the patient profiles described below and indicate the answer that best fits your opinion, with 1 being SURE NO and 5 being SURE YES (<i>please tick only one answer for each statement</i>):</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 10%; text-align: center;">1 <i>SURE NO</i></th> <th style="width: 10%; text-align: center;">2</th> <th style="width: 10%; text-align: center;">3</th> <th style="width: 10%; text-align: center;">4</th> <th style="width: 10%; text-align: center;">5 <i>SURE YES</i></th> </tr> </thead> <tbody> <tr> <td>Any patient on biologic home treatment</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Patient with whom home biological therapy is being initiated</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Patient on home biological treatment with poor compliance (therapeutic adherence).</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Patient on home biologic therapy with frequent seizures</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Other/s. Please specify: _____</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		1 <i>SURE NO</i>	2	3	4	5 <i>SURE YES</i>	Any patient on biologic home treatment						Patient with whom home biological therapy is being initiated						Patient on home biological treatment with poor compliance (therapeutic adherence).						Patient on home biologic therapy with frequent seizures						Other/s. Please specify: _____					
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<p>13.</p>	<p>What profile of healthcare professionals do you think will benefit in the future from the use of the BioCart®? <i>(tick all that apply)</i></p> <ul style="list-style-type: none"> <input type="checkbox"/> Allergist <input type="checkbox"/> Pneumologist <input type="checkbox"/> Nursing <input type="checkbox"/> Hospital Pharmacy <input type="checkbox"/> Other/s. Please specify: _____
<p>14.</p>	<p>Based on your experience with the BioCart® Diary, would you recommend it to a colleague <i>(tick ONLY one answer)?</i></p> <ul style="list-style-type: none"> <input type="radio"/> For sure <input type="radio"/> It is likely to <input type="radio"/> Maybe or maybe not <input type="radio"/> It is likely that it will not <input type="radio"/> Surely not