

## Demo Clinical Trial Protocol

# Breast-001

**An Oncology Clinical Study for neoTrial System Demonstration Purposes with  
Demo-Drug-001 as Monotherapy in Fictional Patients with  
Metastatic Breast Cancer (MBC)**

**Version 1.0 – 18-Aug-2022**

---

*This document is not a real clinical study, but produced on the base of a real protocol of the (typical) oncology study in patients with breast cancer to reflect the study examinations/procedures which are possible to be managed in the **neoTrial** System.*

## ***Clinical Study Details***

Sponsor	Onco-Manufacturer LLC
Study Number	Breast-001
Version	1.0
Date Final	18-Aug-2022
Study Drug	Demo-Drug-001
Inclusion Criterion	Metastatic Breast Cancer (MBC) that is measurable or evaluable as defined by Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 criteria
Enrollment Point	Cycle 1 Day 1
Planned Enrollment	75 enrolled patients
Clinical Study Sites	5
Expected CT scan of the chest, abdomen, pelvis	375
Expected questionnaires BBQ	800
Study Periods	<ol style="list-style-type: none"><li>1. Screening – from 0 to 14 days</li><li>2. Study Treatment (Enrollment) – until disease progression or patient’s voluntary withdrawal</li><li>3. Survival Follow-Up</li></ol>

Table 1. Schedule of the Study Events

Procedures	Screening -14 days	Treatment, Cycle = 28 days Performing until disease progression						End of Treatment	Survival Follow-Up, Every 28d starting 28d after ET
		Cycle 1 Day 1	Cycle 2 and Every Other Subsequent Cycle (4, 6, 8, etc.) Day 1	Cycle 1 Day 8	Cycle 1 Day 15	Cycle 1 Day 22	Cycle 3 and Every Other Subsequent Cycle (5, 7, 9, etc.) Day 1		
<b>Tests and Observations</b>									
Informed Consent	X								
Medical history	X	X	X						
Physical examination, vital signs, height, weight	X	X	X	X	X	X		X	
ECOG Performance Status	X	X	X						
Brunnsviken Brief Quality of life scale (BBQ)	X	X	X				X	X	X
Adverse event evaluation (AE eDiary)		X	X	X	X	X	X	X	X
Concomitant medication review	X	X	X	X	X	X		X	
Study Drug Compliance assessment		X	X				X		
Dispense Study Drug		X	X				X		
<b>Laboratory tests</b>									
CBC, including 3-part differential and platelets	X	X	X						
CMP	X	X	X						
Fasting plasma glucose, insulin, c-peptide	X						X		
Serum Amylase/lipase	X	X	X						
Serum Hormones: estradiol, total and free testosterone, SHBG, ACTH, DHEA-S, and cortisol	X								
Pregnancy test (serum/urine)	X	X	X						
12-lead ECG	X						X		
ECHO/MUGA	X								
Urinalysis	X								
Archived tumor tissue	X								
<b>Disease Assessments</b>									
Computer Tomography scan of the chest, abdomen, pelvis <sup>1</sup>	X						X		
Bone scan <sup>1</sup>	X						X		
Magnetic resonance imaging of the brain <sup>1</sup>	X						X		

1. Response and progression will be evaluated in this study using the RECIST Version 1.1 (Eisenhauer et al. 2009). Lesions are either measurable or non-measurable using the it's criteria.

Table 2. Procedures to be collected on **neoTrial** System

Procedures	Screening -14 days	Treatment, Cycle = 28 days Performing until disease progression						End of Treatment	Survival Follow-Up, Every 28d starting 28d after ET
		Cycle 1 Day 1	Cycle 2 and Every Other Subsequent Cycle (4, 6, 8, etc.) Day 1	Cycle 1 Day 8	Cycle 1 Day 15	Cycle 1 Day 22	Cycle 3 and Every Other Subsequent Cycle (5, 7, 9, etc.) Day 1		
<b>Tests and Observations</b>									
Informed Consent	X								
Brunnsvikien Brief Quality of life scale (BBQ)	X	X	X				X	X	X
Adverse event evaluation (AE eDiary)	X	X	X	X	X	X	X	X	X
<b>Laboratory tests</b>									
12-lead ECG	X						X		
ECHO/MUGA	X								
<b>Disease Assessments</b>									
Computer Tomography scan of the chest, abdomen, pelvis <sup>1</sup>	X						X		
Bone scan <sup>1</sup>	X						X		
Magnetic resonance imaging of the brain <sup>1</sup>	X						X		

1. RECIST 1.1 Tracking required

**Appendix 1.** Brunnsviken Brief Quality of life scale (BBQ)

## Brunnsviken Brief Quality of life scale (BBQ)

The following 12 questions are about how you experience your quality of life. It covers six areas, how satisfied you are with these, and how important they are to you. Circle the number that best reflects your experience.

		Do not agree at all				Agree completely
1	I am satisfied with my leisure time: I have the opportunity to do what I want in order to relax and enjoy myself.	0	1	2	3	4
2	My leisure time is important for my quality of life	0	1	2	3	4
3	I am satisfied with how I view my life: I know what means a lot to me, what I believe in, and what I want to do with my life.	0	1	2	3	4
4	How I view my life is important for my quality of life.	0	1	2	3	4
5	I am satisfied with opportunities to be creative: to get to use my imagination in my everyday life, in a hobby, on the job, or in my studies.	0	1	2	3	4
6	Being able to be creative is important for my quality of life	0	1	2	3	4
7	I am satisfied with my learning: I have the opportunity and desire to learn new, exciting things and skills that interest me.	0	1	2	3	4
8	Learning is important for my quality of life	0	1	2	3	4
9	I am satisfied with friends and friendship: I have friends that I associate with and who support me (as many friends as I want and need).	0	1	2	3	4
10	Friends and friendship are important for my quality of life	0	1	2	3	4
11	I am satisfied with myself as a person: I like and respect myself.	0	1	2	3	4
12	My satisfaction with myself as a person is important for my quality of life	0	1	2	3	4