

Screen Log Codelist (Worksheet) and CRF

General Information :

- All subjects screened for this study should be included on this log.
- Include only those subjects who are actively screened (criteria for screening : Diabetes known for more than 2 years, foot lesion Wagner 2-4 persisting for more than 12 weeks , no obvious revascularisation possibility)
- This form will be collected and entered into the database. The data will be summarized throughout the trial and as part of the final report / regulatory submission.
- Only the codelist provided should be used.
- No more than 3 reasons (codes) as to why the subject was not enrolled should be listed.
- List the primary reason (code) first.
- If the code requests to « specify », record the information in the « Specify » column on the Screen Log.
- The study coordinator requests this form to be periodically faxed to him (every 3 months).

Reasons for Screen Failure :

- Only the codelist provided should be used.
- No more than 3 reasons (codes) as to why the subject was not enrolled should be listed.
- List the primary reason (code) first.
- If the code requests to « specify », record the information in the « Specify » column on the Screen Log.

Screen numbers and Patient initials :

- How to record screening numbers :
 - ◆ All screening numbers begin with « 9 ».
 - ◆ The « 9 » has been hard coded into the screening number boxes
 - ◆ Example :

9	0	4	6	0	0	0	1
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9	0	4	6	0	0	0	2
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9	0	4	6	0	0	0	3
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Site #
- If enrolled, enter the subject number given at randomization.
- Patient initials : any code allowing the investigator to retrieve the patient case report.

Date Screened :

- Provide date the subject was screened

HBO in the traitement of diabetic foot lesion

CODELIST : SCREEN LOG (Worksheet)

Reasons for Screening Failure

Inclusion criteria :

1. Foot lesion currently healing when compared with pre inclusion visit (3 weeks ago)
2. Revascularization possibility
3. Incorrect treatment
 31. Diet not followed
 32. Weigh bearing measures unapplied
 33. Incorrect surgical debridement
 34. Study protocol. Dressing unapplied
4. Subject is less than 18 years of age
5. Patient or family refused consent
6. Physician or IRB refused patient enrollment
199. Other (specify in last column of Screen Log)

Exclusion criteria :

7. Secondary diabetes
8. Planned revascularization procedure
9. Vascular reconstruction less than 12 weeks ago
10. Urgent amputation needed
11. Contra indication to HBO :
 111. Acute respiratory disease
 112. History of spontaneous pneumothorax
 113. Acute ENT infection
 114. Non stabilized epilepsy
 115. Non stabilized HTA
 116. Non stabilized heart failure
 117. Others
12. Renal failure (creatinine $> 250 \mu\text{mol/L}$ [2.8 mg / dL]) or patient requiring dialysis
13. Associated therapy by steroids or chemotherapy.
14. Patient unable or not willing to be followed for 1 year at the foot clinic
15. Ethic criteria (pregnancy, children under 18, end of life, etc)
16. Patient participating in another trial or having been enrolled in another trial within 6 months
17. Informed consent not obtained
18. Presence of an underlying disease/injury which is clearly irreversible and is anticipated to be rapidly fatal within 3 months
299. Other (specify in last column of Screen Log).