S36r0 Chelation Therapy Complication

Ad Hoc Event ID _____

Visit Date (yyyy/mm/dd): _____

Correction: _____

1. Patient's current weight (xxx.x Kg): _____

2. Height (xxx.x cm): _____

3. Deferoxamine dose (xxxx mg/Kg): _____

3A. Frequency - hours/day (xx): _____

3B. Frequency: - days/week (x): _____

3C. Route (if ORAL, skip to Item 5):
- ☐ IV
- ☐ SQ
- ☐ ORAL

4. Did the patient receive Hydrocortisone? If NO, skip to Item 6.
- ☐ Yes
- ☐ No

4A. Hydrocortisone dose (xxxx mg/Kg): _____

4B. Frequency - hours/day (xx): _____

4C. Frequency - days/week (x): _____

4D. Route:
- ☐ IV
- ☐ SQ

5. Oral chelating agent: _____

5A. Dose: _____

5B. Frequency: _____

Complications

Form S25r1, Adverse Event Report (NonCVA), must also be completed for this chelation therapy complication.

6. Pain at injection site:
- ☐ Yes
- ☐ No
- ☐ NA

6A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

6B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

7. Allergic reaction:
- ☐ Yes
- ☐ No
- ☐ NA

7A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

7B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

8. Tachycardia:
- ☐ Yes
- ☐ No
- ☐ NA

8A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

8B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

9. Urticaria:
- ☐ Yes
- ☐ No
- ☐ NA

9A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

9B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

10. Abdominal pain:
- ☐ Yes
- ☐ No
- ☐ NA

10A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

10B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

11. Acquired respiratory distress syndrome:
- ☐ Yes
- ☐ No
- ☐ NA

11A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

11B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

12. Visual disturbances, i.e., blurred vision, trouble seeing at night or trouble seeing colors:
- ☐ Yes
- ☐ No
- ☐ NA

12A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

12B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

13. Decreased hearing:
- ☐ Yes
- ☐ No
- ☐ NA

13A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

13B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

14. Tinnitus:
- ☐ Yes
- ☐ No
- ☐ NA

14A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

14B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

15. Edema:
- ☐ Yes
- ☐ No
- ☐ NA

15A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

15B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

16. Dysphasia:
- ☐ Yes
- ☐ No
- ☐ NA

16A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

16B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

17. Leg cramps:
- ☐ Yes
- ☐ No
- ☐ NA

17A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

17B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

18. Hypotension:
- ☐ Yes
- ☐ No
- ☐ NA

18A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

18B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

19. Fever within 24 hours of administration:
- ☐ Yes
- ☐ No
- ☐ NA

19A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

19B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

20. Hypovolemia:
- ☐ Yes
- ☐ No
- ☐ NA

20A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

20B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

21. Lethargy/malaise:
- ☐ Yes
- ☐ No
- ☐ NA

21A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

21B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

22. Loss of consciousness:
- ☐ Yes
- ☐ No
- ☐ NA

22A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

22B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

23. Vertigo:
- ☐ Yes
- ☐ No
- ☐ NA

23A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

23B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

24. Seizure:
- ☐ Yes
- ☐ No
- ☐ NA

24A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

24B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

25. Constipation:
- ☐ Yes
- ☐ No
- ☐ NA

25A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

25B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

26. Dysuria:
- ☐ Yes
- ☐ No
- ☐ NA

26A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

26B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

27. Decreased urine output:
- ☐ Yes
- ☐ No
- ☐ NA

27A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

27B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

28. Diarrhea:
- ☐ Yes
- ☐ No
- ☐ NA

28A. If Yes, describe onset, duration, treatment, and assessment for residual effects: _____

28B. Study relationship:
- ☐ Not related
- ☐ Possible
- ☐ Probable
- ☐ Definite

Staff I.D. #: _____