GENERATING SEMI-AUTOMATED PATIENT NARRATIVES FOR REGULATORY SUBMISSION

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The goal of a medical writer is to create narratives for the Clinical Study Report (FDA Submission document) for Serious Adverse Events, Permanently Discontinued Subjects, Adverse Events of Special Interest and Adverse Events associated with Specific Standard MedDRA Queries (disease associated adverse events)
TRADITIONAL VS. JMP CLINICAL

**Traditional**
- Outsource to CROs, Medical Writing Services Companies
  - Price per study or subject population
- Performing In-house
- Time consuming
  - Requires quality review and validation with data sources
  - Requires access to sensitive data

**JMP Clinical**
- Generate 100s of narratives in seconds
- Modify text for Medical Writers Needs
- Keep Templates for Therapeutic Areas
- Limit Access to data
- Deploy Narratives with Interactive Patient Profiles to Writers
- Provide access to more safety and efficacy reports
Subject: 101004
Randomized Arm: NIC: 15
Investigator Name: 101A

Subject 101004 was a 48-year-old white female. Her medical history included focal deficit associated with SAH (1988), headache associated with SAH (1988), loss of consciousness associated with SAH (1988), vomiting associated with SAH (1988), other medical condition (1977), and allergies (start date unknown). She began and ended dosing with 30 mg/h of NIC: 15 on 28 JAN 1988 (Day 1).

The subject had the following abnormal laboratory test results at baseline: high CK [411 U/L, range = (15 - 195)], high CL [112 mmol/L, range = (97 - 107)], high WBC [21 U/L, range = (3 - 20)], low PCO2 [2394 Pa, range = (4655 - 5985)], and high PO2 [3154 Pa, range = (9975 - 13965)].

The subject discontinued the trial on 31 JAN 1988 (Day 4) due to death.

Other Adverse Event (coded term): BRAIN ODEMA

Drugs and Doses on Day of Event: Post Treatment

On 31 JAN 1988 (Day 4) the subject experienced a brain oedema (mild) which was considered a significant adverse event (AE). At the time of the event, the subject had completed study medication. The AE occurred 3 days after the last dose of any study medication. Trial medication had an action of unknown as a result of the event. It is not known from the case report form if therapeutic measures were administered to treat the event.

Adverse events that occurred within a +/- 3-day window of the onset of the AE included coma (severe), hydrocephalus (severe), hyperglycaemia (mild), hypotension (severe), intracranial pressure increased (severe), subarachnoid haemorrhage (severe), and vasoconstriction (severe).

Concomitant medications taken at the onset of the AE included: docetaxel sodium (stool softener), dopamine (elevated BP), phenobarbital (sedative), potassium supplements (fluids), and ranitidine (decrease acidity).

On the closest laboratory test results day on or prior to the start of the event (30 JAN 1988, Day 3), the subject had the following on-study laboratory test results with results different than baseline: low CO2 [82.612 mg/dL, range = (100.004 - 130.44)], BL = normal, low SODIUM [133 mmol/L, range = (136 - 144)], BL = normal, and normal WBC [18.4 U/L, range = (3 - 20)], BL = high. On the closest laboratory test results day subsequent to the start of the event, the subject had no on-study laboratory test results with results different than baseline.
PATIENT PROFILES

Demographics

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age</th>
<th>Sex</th>
<th>Race</th>
<th>Site</th>
<th>Arm</th>
<th>Start Date</th>
<th>End Date</th>
<th>Study</th>
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</thead>
<tbody>
<tr>
<td>101004</td>
<td>48</td>
<td>F</td>
<td>WHITE</td>
<td>10</td>
<td>NIC.15</td>
<td>1986-01-28T160000</td>
<td>1986-01-28T163300</td>
<td>NICSAH1</td>
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</tbody>
</table>

Profile

- Visit
- NIC.15
- Date of SAH
- Randomized
- Death
- Coma
- Hydrocephalus
- Hypoglycaemia
- Hypertension
- Intracranial pressure increased
- Vasodilatation
- Subarachnoid haemorrhage
- Brain oedema
- Docusate sodium
- Phenytoin
- Potassium supplements
- Ranitidine
- Dopamine

Medical History

- Allergies
  - Other medical condition
  - Focal deficit
  - Headache
  - Loss of consciousness
  - Vomiting

Legend

- Adverse Events
  - Mild
  - Moderate
  - Severe

- Laboratory Test Results
  - K
  - Sodium
  - AST
  - ALP
  - Bili
  - Gluc
  - Creat
  - Hct
  - Hgb
  - Rbc
  - Plat
  - Wbc
  - Aplt
  - Bun
  - Ca
  - CK
  - Cl
  - Co2
  - Ldh
  - Po2
  - Ph
  - Pno2
  - Po2
  - Prot