ARRIA

ARRIA NLG *for* CLINICAL STUDY REPORTING (CSR)

How Arria NLG for CSR is impacting the multi-billion-dollar clinical trial market

Bringing a drug to market is a drawn-out process. With Arria's AI technology, drug lifecycle data can now be analyzed instantly!

- Adverse affects can be spotted early
- Changes can be made early
- Much larger groups can be studied

This allows the safety of clinical trial participants to be radically improved as data can be analyzed instantly rather than 15 days following the end of each month.

Arria's Natural Language Generation (NLG) technology break-through enables scalable intelligent automation of drug data that lets Pharmaceutical companies bring drugs to market faster by:

- Automating medical reports, saving significant time and money while increasing scalability and efficiency
- Increasing innovation and digital transformation
- Enhancing your edge over the competition
- Improving compliance and safety

FDA VALIDATION ACHIEVED

Arria NLG for CSR received FDA validatation under Reg CFR21 Part 11

Arria is pleased to have achieved validation for its Clinical Safety Reporting application.

- **Dramatically accelerate clinical trial reporting**
- **Intelligently automate data-to-insight workflow**
- **Bring life-saving drugs to market faster**
- **Improve drug safety and efficacy**
- **Drive efficiency and scalability**
- **Remove mundane tasks from medical writers**

Arria's NLG-driven process helps to radically reduce time to market and, more importantly, improve best practices, standards and the overall safety and well-being of participants.

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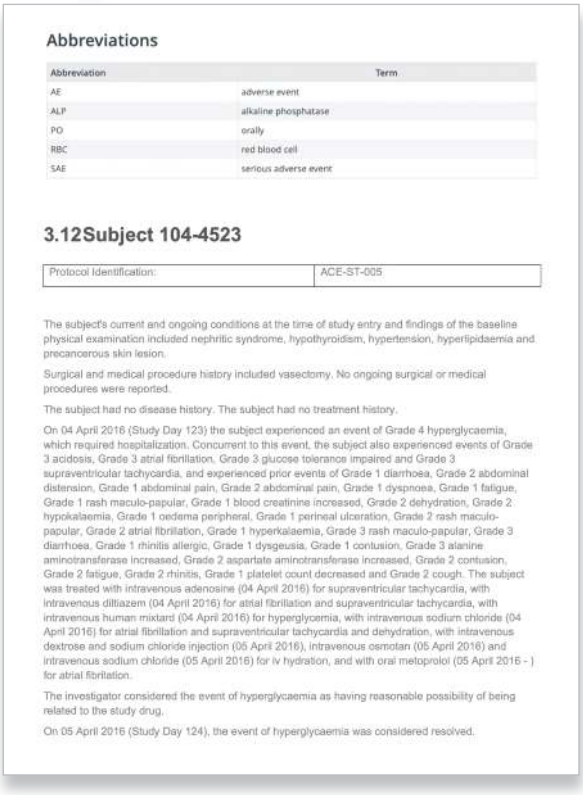
An absolute technology breakthrough for Pharmacovigilance and Clinical Safety Reports

COMPLEX DATA IN ..... Studio ..... **EXPERT NARRATIVES OUT**

Study Identifier	ABB	Unique Subject Identifier	#	Lowest Level Term	Term Code	Dictionary Term
MSY-ST-004	AE	MSY-ST-004-412-4501	1	Nausea	10028813	Nausea
MSY-ST-004	AE	MSY-ST-004-412-4501	2	Headache	10019211	Headache
MSY-ST-004	AE	MSY-ST-004-412-4501	3	Vomiting	10047700	Vomiting
MSY-ST-004	AE	MSY-ST-004-412-4501	4	Fever	10016558	Pyrexia
MSY-ST-004	AE	MSY-ST-004-412-4501	5	Vomiting	10047700	Vomiting
MSY-ST-004	AE	MSY-ST-004-412-4501	6	Hypotension	10021097	Hypotension
MSY-ST-004	AE	MSY-ST-004-412-4501	7	Unsteady gait	10046261	Gait disturbance
MSY-ST-004	AE	MSY-ST-004-412-4501	8	Vomiting	10047700	Vomiting
MSY-ST-004	AE	MSY-ST-004-412-4501	9	Depression aggravated	10012379	Depression
MSY-ST-004	AE	MSY-ST-004-412-4502	1	Diaphoresis	10012703	Hyperhidrosis
MSY-ST-004	AE	MSY-ST-004-412-4502	2	Back pain	10003988	Back pain
MSY-ST-004	AE	MSY-ST-004-412-4502	3	Unilateral leg pain	10052410	Pain in extremity
MSY-ST-004	AE	MSY-ST-004-412-4502	4	Intermittent headache	10059296	Headache
MSY-ST-004	AE	MSY-ST-004-412-4502	5	Memory loss	10027176	Amnesia
MSY-ST-004	AE	MSY-ST-004-412-4502	6	Blurred vision	10005886	Vision blurred
MSY-ST-004	AE	MSY-ST-004-412-4502	7	Cough	10011224	Cough
MSY-ST-004	AE	MSY-ST-004-412-4502	8	Dry throat	10013789	Dry throat
MSY-ST-004	AE	MSY-ST-004-412-4502	9	Dyspnea exertional	10013966	Dyspnoea exertional
MSY-ST-004	AE	MSY-ST-004-412-4502	10	Smell alteration	10041215	Parosmia
MSY-ST-004	AE	MSY-ST-004-412-4502	11	Constipation	10010774	Constipation
MSY-ST-004	AE	MSY-ST-004-412-4502	12	Fatigue aggravated	10048415	Fatigue
MSY-ST-004	AE	MSY-ST-004-412-4502	13	Nausea	10028813	Nausea
MSY-ST-004	AE	MSY-ST-004-412-4502	14	Anorexia	10002646	Decreased appetite
MSY-ST-004	AE	MSY-ST-004-412-4502	15	Acute kidney injury	10069339	Acute kidney injury
MSY-ST-004	AE	MSY-ST-004-412-4502	16	Urethral burning on micturition	10046429	Dysuria
MSY-ST-004	AE	MSY-ST-004-412-4502	17	Lightheadedness	10024492	Dizziness
MSY-ST-004	AE	MSY-ST-004-412-4502	18	Dizziness aggravated	10048324	Dizziness
MSY-ST-004	AE	MSY-ST-004-412-4502	19	Weight loss	10047900	Weight decreased
MSY-ST-004	AE	MSY-ST-004-412-4502	20	Bruising	10006504	Contusion
MSY-ST-004	AE	MSY-ST-004-412-4502	21	Diarrhea	10012727	Diarrhoea
MSY-ST-004	AE	MSY-ST-004-412-4502	22	Vomiting aggravated	10048356	Vomiting
MSY-ST-004	AE	MSY-ST-004-412-4502	23	Fall	10016173	Fall
MSY-ST-004	AE	MSY-ST-004-412-4503	1	Peripheral neuropathy aggravated	10034608	Neuropathy peripheral
MSY-ST-004	AE	MSY-ST-004-412-4503	2	Edema of penis	10014242	Penile oedema
MSY-ST-004	AE	MSY-ST-004-412-4503	3	Edema of penis	10014242	Penile oedema
MSY-ST-004	AE	MSY-ST-004-412-4503	4	Fatigue	10016256	Fatigue
MSY-ST-004	AE	MSY-ST-004-412-4503	5	Fever	10016558	Pyrexia
MSY-ST-004	AE	MSY-ST-004-412-4503	6	Urine flow decreased	10046640	Urine flow decreased
MSY-ST-004	AE	MSY-ST-004-412-4503	7	Abdominal pain	10000081	Abdominal pain
MSY-ST-004	AE	MSY-ST-004-412-4503	8	Feeling cold	10016326	Feeling cold
MSY-ST-004	AE	MSY-ST-004-412-4503	9	Rectal discharge	10049101	Rectal discharge
MSY-ST-004	AE	MSY-ST-004-412-4503	10	Pain in limb	10033447	Pain in extremity
MSY-ST-004	AE	MSY-ST-004-412-4503	11	Defecation urgency	10012114	Defaecation urgency
MSY-ST-004	AE	MSY-ST-004-412-4503	12	Joint pain	10023222	Arthralgia
MSY-ST-004	AE	MSY-ST-004-412-4503	13	Buttock pain	10048677	Musculoskeletal pain
MSY-ST-004	AE	MSY-ST-004-412-4503	14	Dyspnea	10013963	Dyspnoea
MSY-ST-004	AE	MSY-ST-004-301-4501	1	Fatigue aggravated	10048415	Fatigue
MSY-ST-004	AE	MSY-ST-004-301-4501	2	Anorexia	10002646	Decreased appetite
MSY-ST-004	AE	MSY-ST-004-301-4501	3	Hepatic failure	10019663	Hepatic failure
MSY-ST-004	AE	MSY-ST-004-301-4501	4	Abdominal pain	10000081	Abdominal pain
MSY-ST-004	AE	MSY-ST-004-301-4501	5	Confusion aggravated	10048321	Confusional state
MSY-ST-004	AE	MSY-ST-004-301-4501	6	Hypocalcemia	10020949	Hypocalcaemia
MSY-ST-004	AE	MSY-ST-004-301-4501	7	Urinary tract infection	10046571	Urinary tract infection
MSY-ST-004	AE	MSY-ST-004-301-4501	8	Hypotension	10021097	Hypotension
MSY-ST-004	AE	MSY-ST-004-301-4501	9	Urinary retention	10046555	Urinary retention
MSY-ST-004	AE	MSY-ST-004-301-4503	1	Nausea	10028813	Nausea
MSY-ST-004	AE	MSY-ST-004-301-4503	2	Fever	10016558	Pyrexia
MSY-ST-004	AE	MSY-ST-004-301-4503	3	Hyperhidrosis	10020642	Hyperhidrosis

Millions of trial data points are analysed by an army of clinical writers once every 30 days. There are not enough human experts to write the reports.



Abbreviations

Abbreviation	Term
AE	adverse event
ALP	alkaline phosphatase
PO	orally
RBC	red blood cell
SAE	serious adverse event

3.12Subject 104-4523

Protocol Identification:	ACE-ST-005

The subject's current and ongoing conditions at the time of study entry and findings of the baseline physical examination included nephritic syndrome, hypothyroidism, hypertension, hyperlipidaemia and precancerous skin lesion.

Surgical and medical procedure history included vasectomy. No ongoing surgical or medical procedures were reported.

The subject had no disease history. The subject had no treatment history.

On 04 April 2016 (Study Day 123) the subject experienced an event of Grade 4 hyperglycaemia, which required hospitalization. Concurrent to this event, the subject also experienced events of Grade 3 acidosis, Grade 3 atrial fibrillation, Grade 3 glucose tolerance impaired and Grade 3 supraventricular tachycardia, and experienced prior events of Grade 1 diarrhoea, Grade 2 abdominal distension, Grade 1 abdominal pain, Grade 2 abdominal pain, Grade 1 dyspnoea, Grade 1 fatigue, Grade 1 rash maculo-papular, Grade 1 blood creatinine increased, Grade 2 dehydration, Grade 2 hypokalaemia, Grade 1 oedema peripheral, Grade 1 perineal ulceration, Grade 2 rash maculo-papular, Grade 2 atrial fibrillation, Grade 1 hyperkalaemia, Grade 3 rash maculo-papular, Grade 3 diarrhoea, Grade 1 rhinitis allergic, Grade 1 dysgeusia, Grade 1 contusion, Grade 3 alanine aminotransferase increased, Grade 2 aspartate aminotransferase increased, Grade 2 contusion, Grade 2 fatigue, Grade 2 rhinitis, Grade 1 platelet count decreased and Grade 2 cough. The subject was treated with intravenous adenosine (04 April 2016) for supraventricular tachycardia, with intravenous diltiazem (04 April 2016) for atrial fibrillation and supraventricular tachycardia, with intravenous human mixtard (04 April 2016) for hyperglycaemia, with intravenous sodium chloride (04 April 2016) for atrial fibrillation and supraventricular tachycardia and dehydration, with intravenous dextrose and sodium chloride injection (05 April 2016), intravenous osmotan (05 April 2016) and intravenous sodium chloride (05 April 2016) for iv hydration, and with oral metoprolol (05 April 2016 -) for atrial fibrillation.

The investigator considered the event of hyperglycaemia as having reasonable possibility of being related to the study drug.

On 05 April 2016 (Study Day 124), the event of hyperglycaemia was considered resolved.

300+ page detailed FDA validated Clinical Safety Reports (CSRs) are now **created instantly** by Arria's CSR NLG software application.

AstraZeneca

"Dramatically improve the speed and efficiency of reporting"

"Arria NLG Studio's BI analytical and linguistic capabilities provide us with the technology to dramatically improve the speed and efficiency of our reporting. A key benefit for us is that we can use this powerful platform to create our own NLG applications within our department."

– **Brian O'Connor**, *Lead Director, Advanced Analytics Global Business Services, AstraZeneca*