

If a Preferred Term (PT) comes up more than once in the list of reactions, please remove one of the reactions. You can then type all the reactions related to that PT in the Reported Reaction field under the PT left.

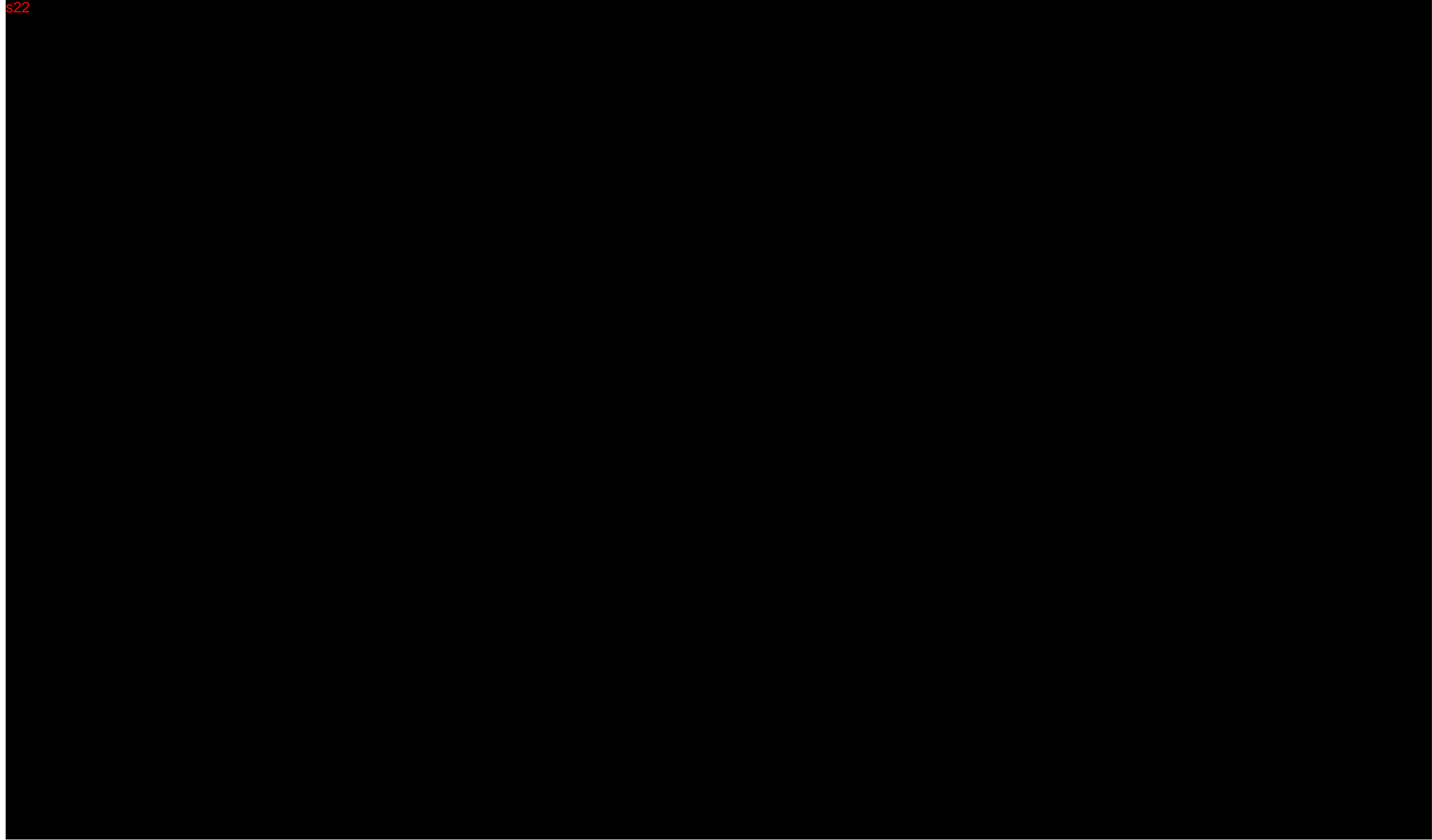
Reported As	Code As	Codes to Preferred Term (PT)
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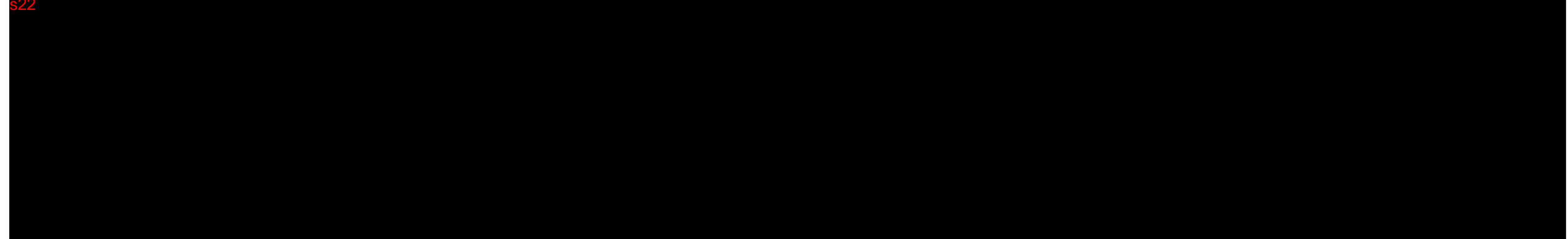


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General Disorders		
They had symptoms, but didn't specify what they were	Adverse event following immunisation	Adverse event following immunisation

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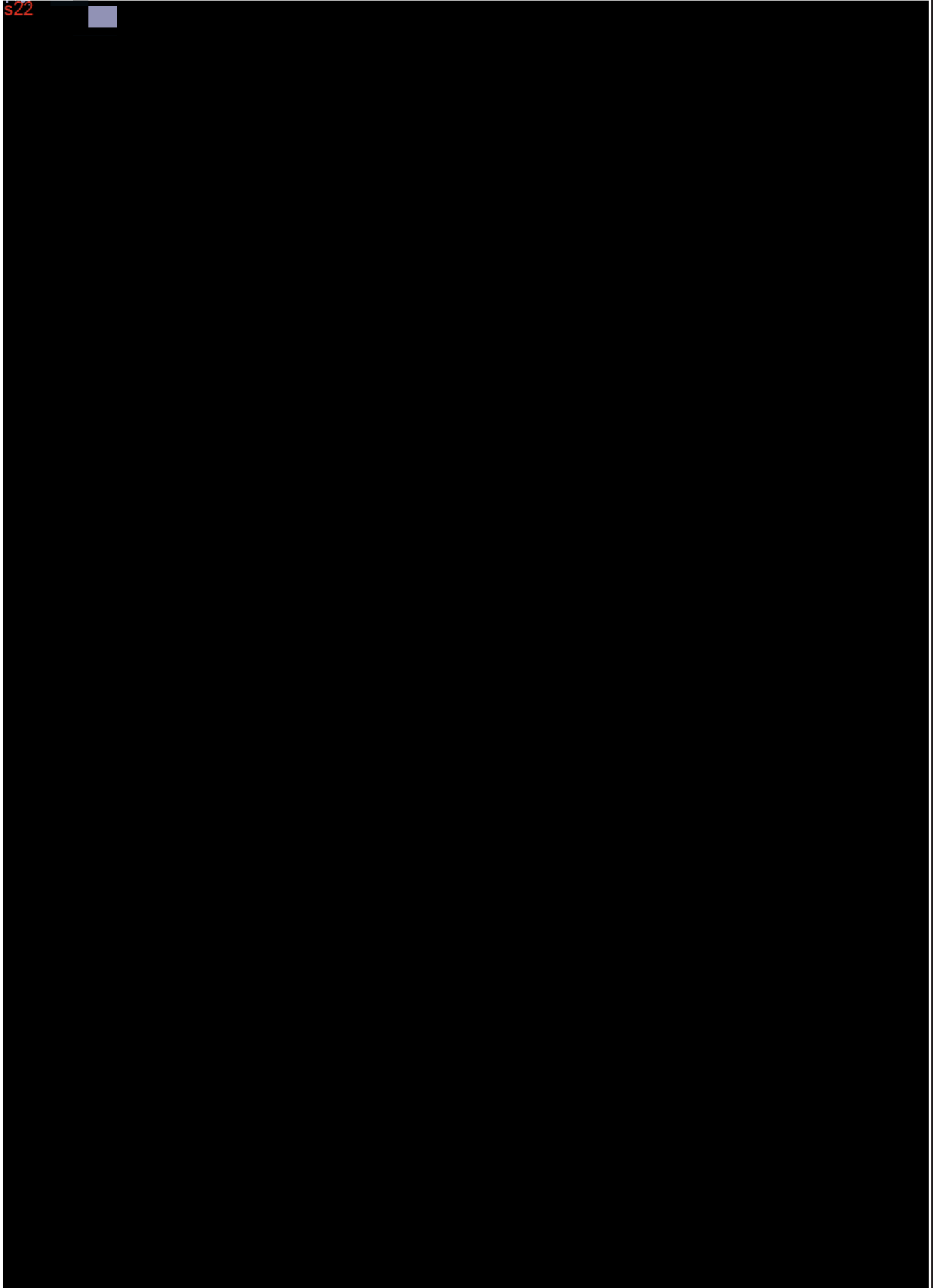


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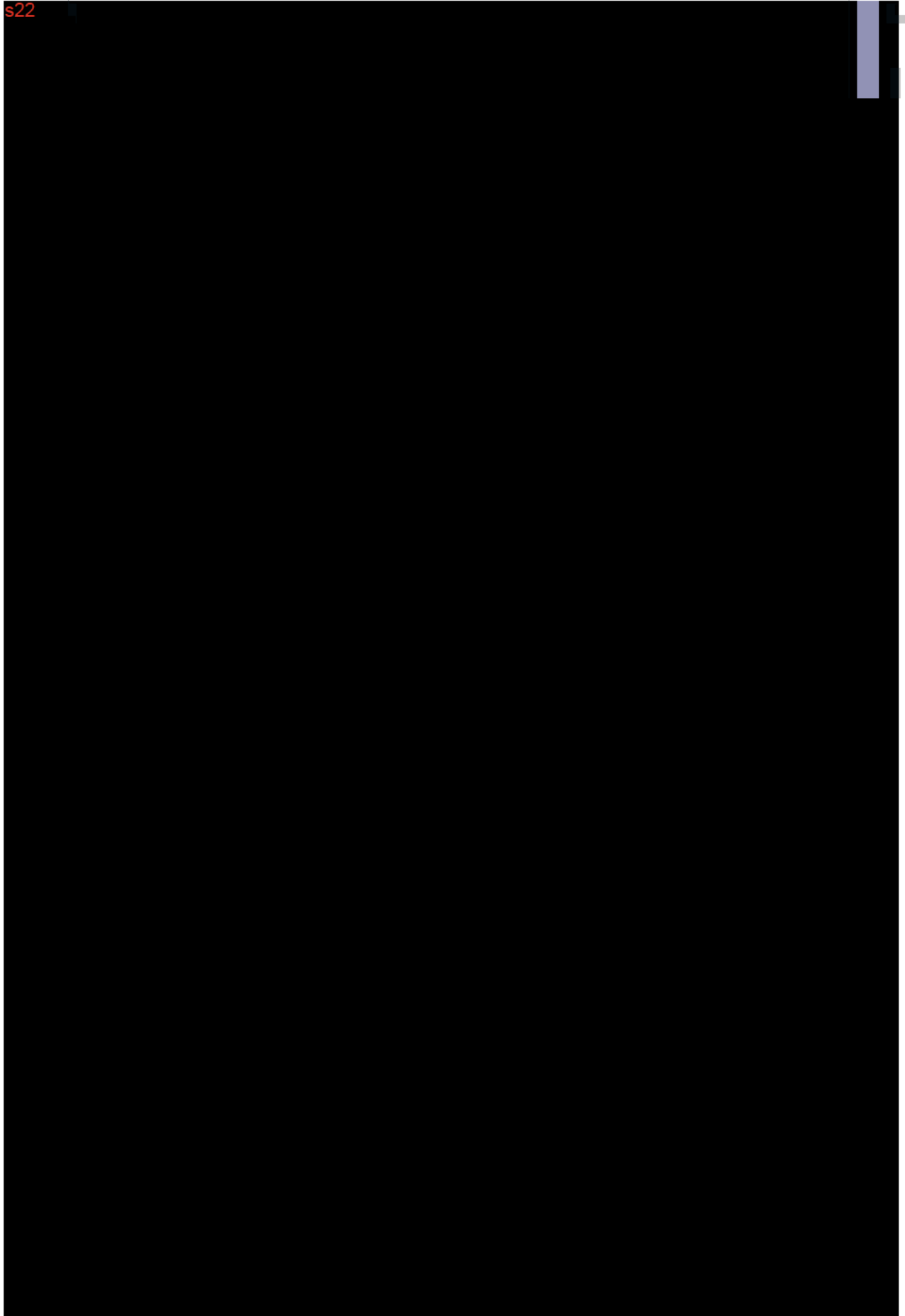
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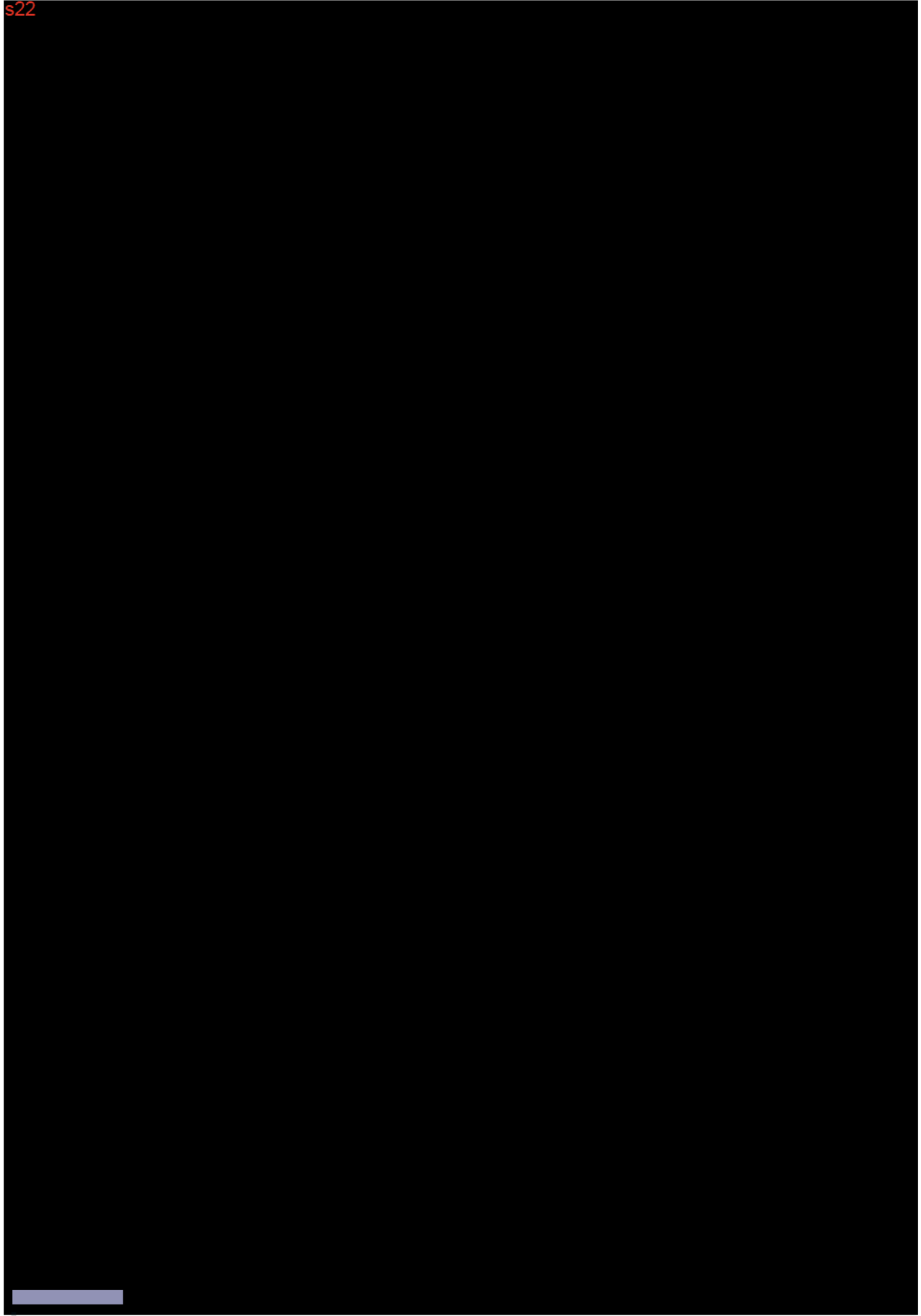
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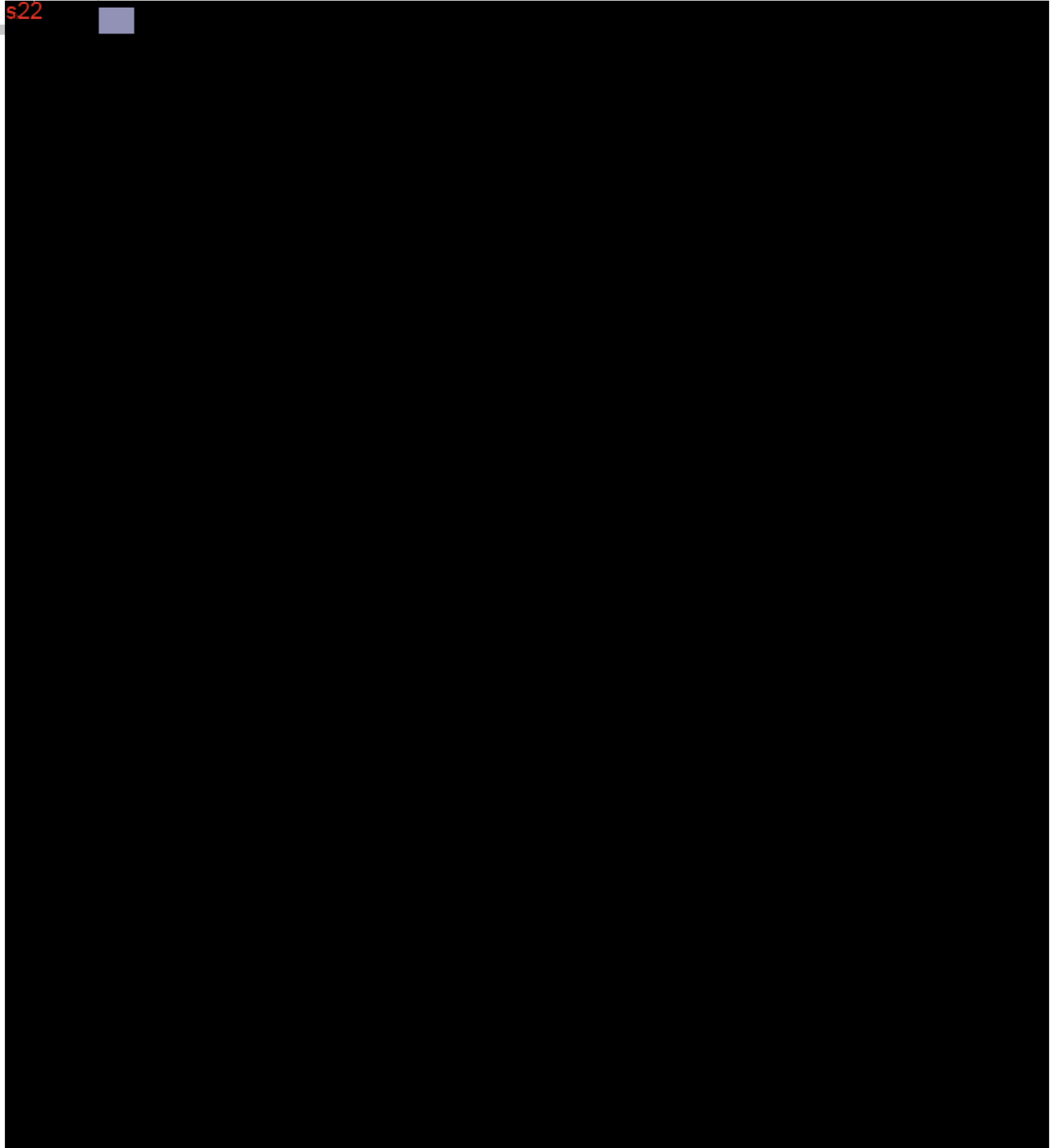
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### General advice and preferences for coding

- Always refer to the MedDRA Term Selection: Points to Consider document
- A single Preferred Term (PT) should appear only once as a reaction term in a case. If a Preferred Term (PT) appears more than once in the list of selected reactions for a case, please select only one of the relevant LLT/reaction terms that map to that PT and remove the additional reactions terms to avoid duplicating the PT. You can type all the reactions related to that PT in the 'Reported Reaction' field within the remaining reaction entry.
- **Do not code** 'death' as a reaction – the reaction term should be selected according to the reported adverse event, with 'Outcome' listed as fatal, and seriousness criteria correctly selected. If there is insufficient information regarding the adverse event, please code 'adverse event NOS' or 'adverse event following immunisation' as appropriate.
- **Do not code** 'hospitalisation' as a reaction – the reaction term should be selected according to the reported adverse event, with seriousness criteria reflecting the hospitalisation. If there is insufficient information regarding the reported adverse event, please code 'adverse event NOS' or 'adverse event following immunisation' as appropriate.
- Where both a diagnosis and characteristic signs or symptoms are reported: It is acceptable to select both the reported diagnoses AND all reported signs/symptoms as reaction terms in the case. If you are completely certain that the reported individual signs/symptoms are clinically consistent with the reported final diagnosis, then you may select only the final or definitive diagnosis if it has been clearly reported. **DO NOT assume a diagnosis based on reported signs/symptoms.**

Please note that according to the MedDRA guidelines, the preference is to only select a term for the reported final diagnosis. However, depending on the report, or the clinical understanding and experience of the coder, it may not always be clear what signs or symptoms are consistent with a particular diagnosis. Where there is any uncertainty, it is acceptable and preferred to include the reported diagnosis AND any reported signs or symptoms.

Any uncertainties or coding questions – please reach out to your supervisor or another Database Team manager and/or send the case up for review (including a note outlining the question/issue).

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