# **Additional file 8:** **Flowchart for Assessing and Reporting Adverse Reactions**

*(applies only to events which are deemed to be, or suspected of being, related)*

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| --- | --- | --- | --- | --- |
|  |  | **Event detected at study visit** |  | **Event suspected by parent/guardian** |
|  |  |  |  |  |
|  |  |  |  | **Childsmile or Fluoride varnish aftercare leaflets (phone numbers)** |
|  |  |  |  |  |
| **Assess seriousness, severity** |  |  | **Childsmile Study Staff** |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  | **Case Report Form** | **If serious, SAE report** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **Assess relatedness and severity. Re-assess seriousness** |  |  | **Principal Investigator** |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  | **Pharmaco - vigilance office** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| **Assess expectedness** |  |  | **Chief Investigator** |  |  |  | **If serious and unexpected, expedited reporting** |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  | **MHRA, ETHICS** |
|  |  |  |  |  |  |  |  |