**Supplemental Digital Content 1.** Solicited injection site reactions: terminology, definitions, and intensity scales

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| **CRF term (MedDRA lowest level term [LLT])** | **Injection site pain\*** | **Injection site erythema** | **Injection site swelling** |
| **Diary card term** | Pain | Redness | Swelling |
| **Definition** |  | Presence of a redness including the approximate point of needle entry | Swelling at or near the injection site  Swelling or edema is caused by a fluid infiltration in tissue or cavity and, depending on the space available for the fluid to disperse, swelling may be either soft (typically) or firm (less typical) to touch and thus can be best described by looking at the size of the swelling |
| **Intensity scale\*** | Grade 1: Easily tolerated  Grade 2: Sufficiently discomforting to interfere with normal behavior or activities  Grade 3: Incapacitating, unable to perform usual activities | Grade 1: > 0 to < 25 mm  Grade 2: ≥ 25 to < 50 mm  Grade 3: ≥ 50 mm | Grade 1: > 0 to < 25 mm  Grade 2: ≥ 25 to < 50 mm  Grade 3: ≥ 50 mm |

\*For the subjective reaction of pain, subjects or parents / guardians will record the intensity level (Grade 1, 2, or 3) in the diary card. For the measurable reactions of redness and swelling, they will record just the size of the reaction, and the classification as Grade 1, 2, or 3 will be assigned at the time of the statistical analysis.