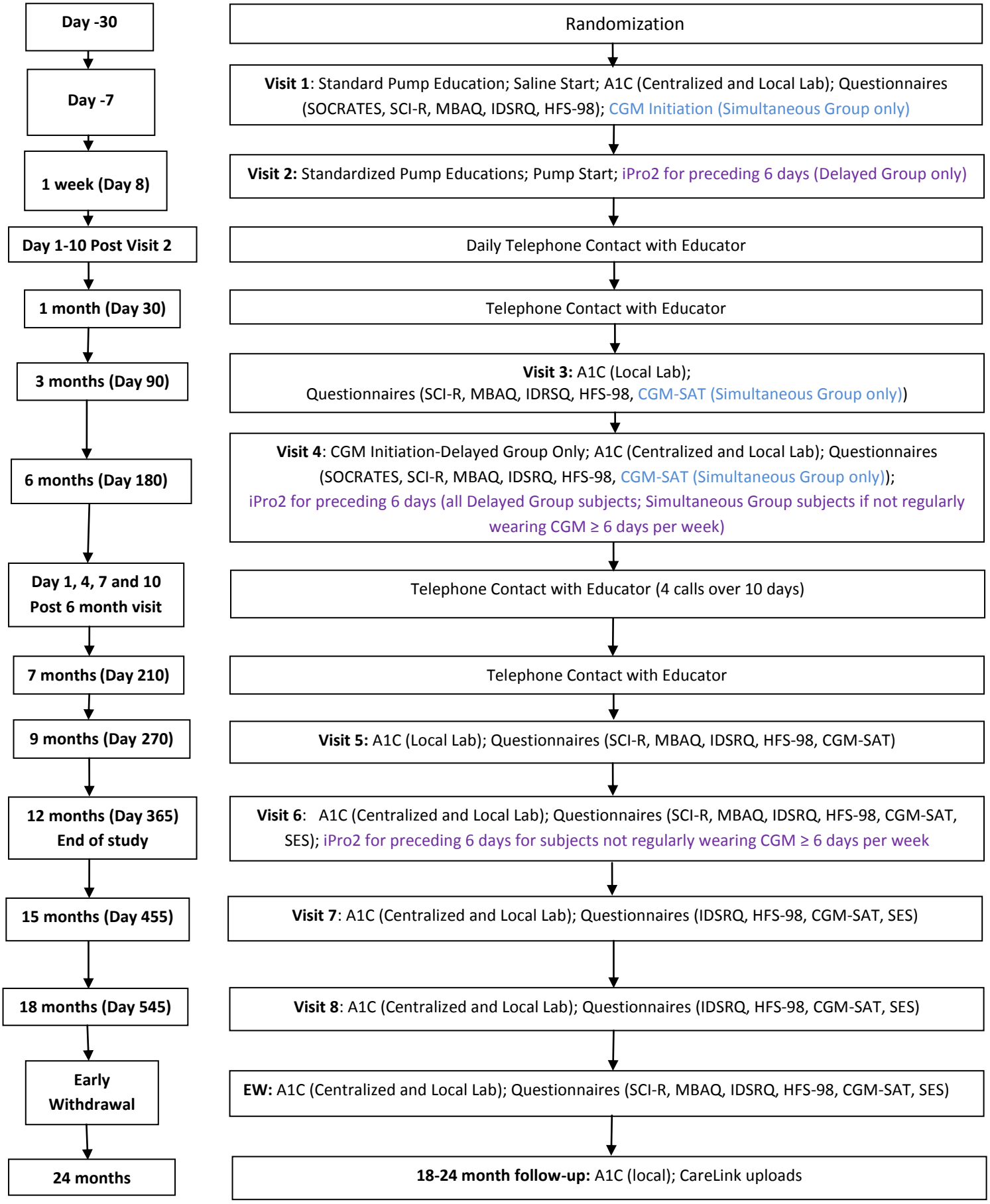Additional File 3: Schedule of Study Visits, Telephone Contacts, and Outcome Assessments