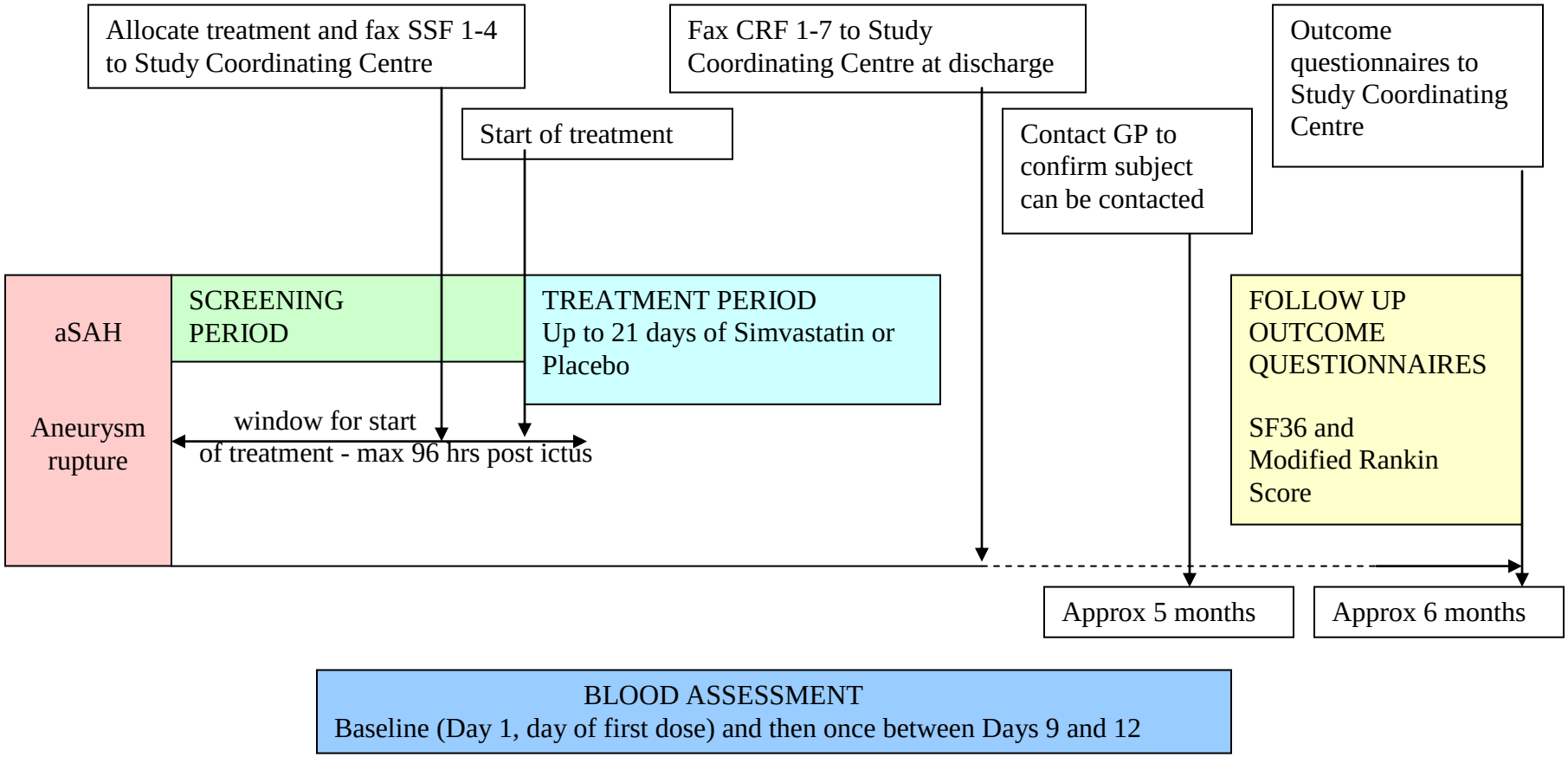STUDY DESIGN