

USDM and Expanding the Timeline Logic

Typical SoA

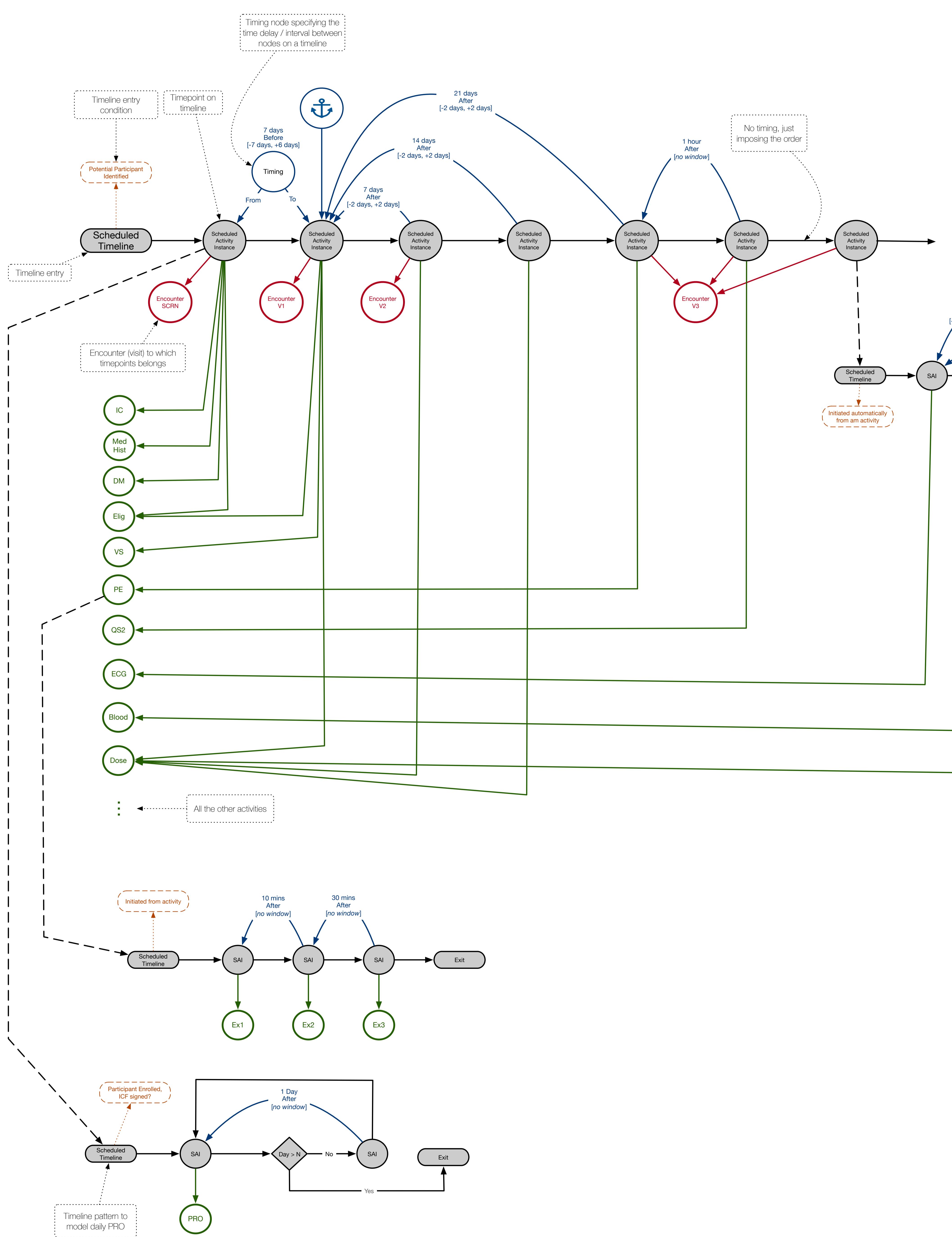
If this timeline logic were presented in a typical SoA, this is what we would probably see. Note the footnotes containing timing logic.

	SCRN(s)	V1	V2	V3
7 Days	Day 1	7 Days	21 Days	
-7...+6 Days	X	X	-2...+2 Days	-2...+2 Days
IC				
Med Hist				
DM				
Elig	X	X		
VS		X		
PE			X	X
QS2			X(b)	
ECG			X	
Blood				X(c)
Dose				
Dosing shall take place every 7 days				

- a) A daily diary shall be completed by the participant every day until day N once the ICF and been signed
- b) QS2 shall be performed before ECG
- c) Bloods shall be performed 2 hrs after the ECG

USDM Timelines

Study logic encoded into USDM providing precise timing and ordering.



Expanded Timeline

The timelines expanded into the study logic. Note the windows allowed within the design are not applied because this is what is planned for a participant.

