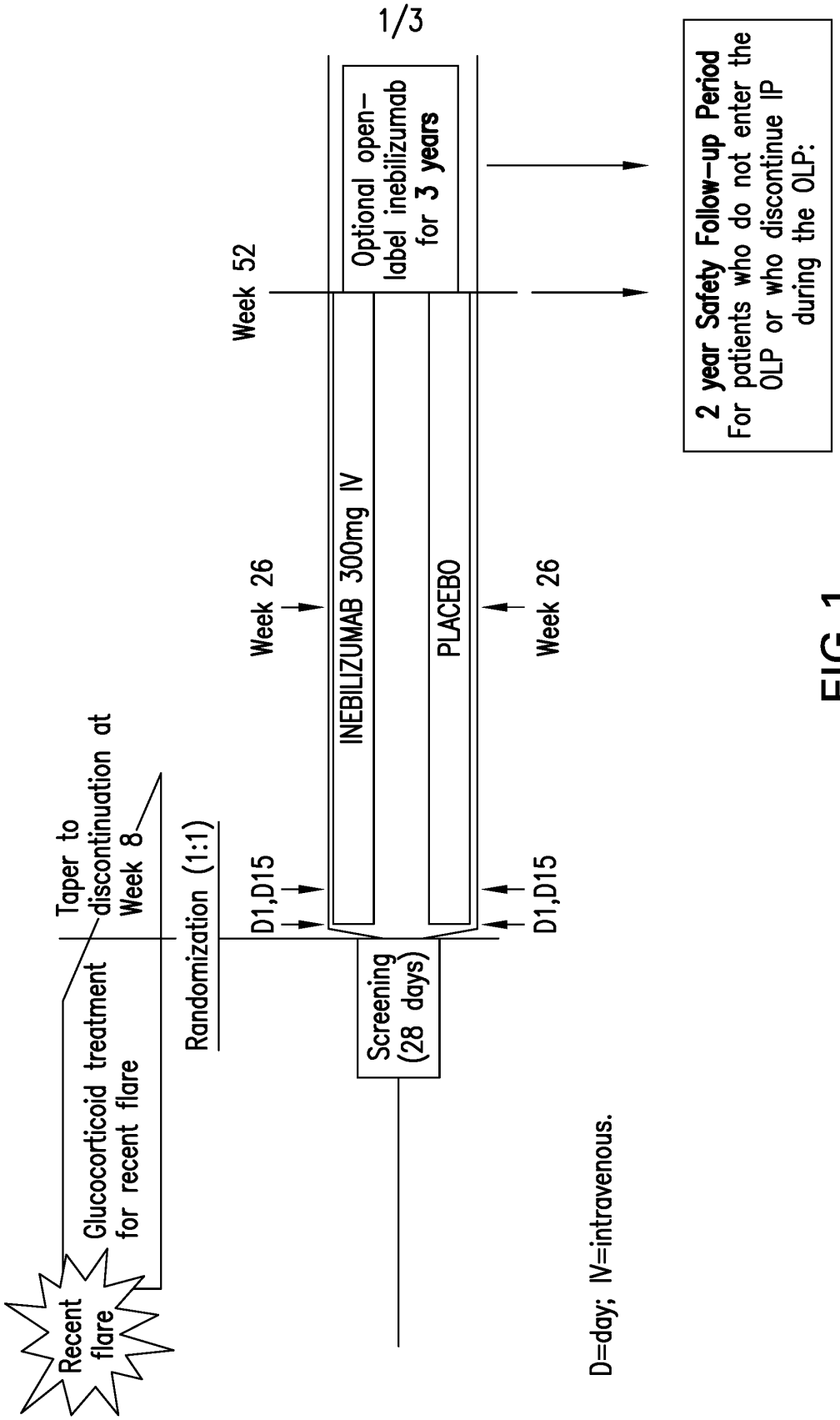
Recent flare
Glucocorticoid treatment for recent flare
Taper to discontinuation at Week 8
Randomization (1:1)
Screening (28 days)
D1,D15
INEBILIZUMAB 300mg IV
PLACEBO
Week 26
Week 26
D1,D15
Week 52
Optional open-label inebilizumab for 3 years
2 year Safety Follow-up Period
For patients who do not enter the OLP or who discontinue IP during the OLP:
D=day; IV=intravenous.

FIG. 1

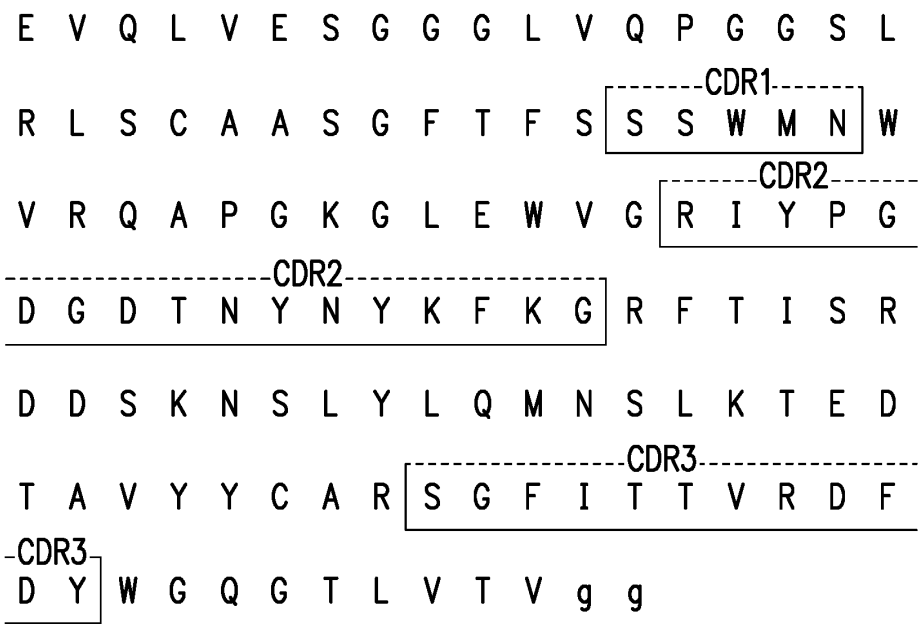
E V Q L V E S G G G L V Q P G G S L
CDR1
R L S C A A S G F T F S S S W M N W
CDR2
V R Q A P G K G L E W V G R I Y P G
CDR2
D G D T N Y N Y K F K G R F T I S R
D D S K N S L Y L Q M N S L K T E D
CDR3
T A V Y Y C A R S G F I T T V R D F
CDR3
D Y W G Q G T L V T V g g

FIG.2A

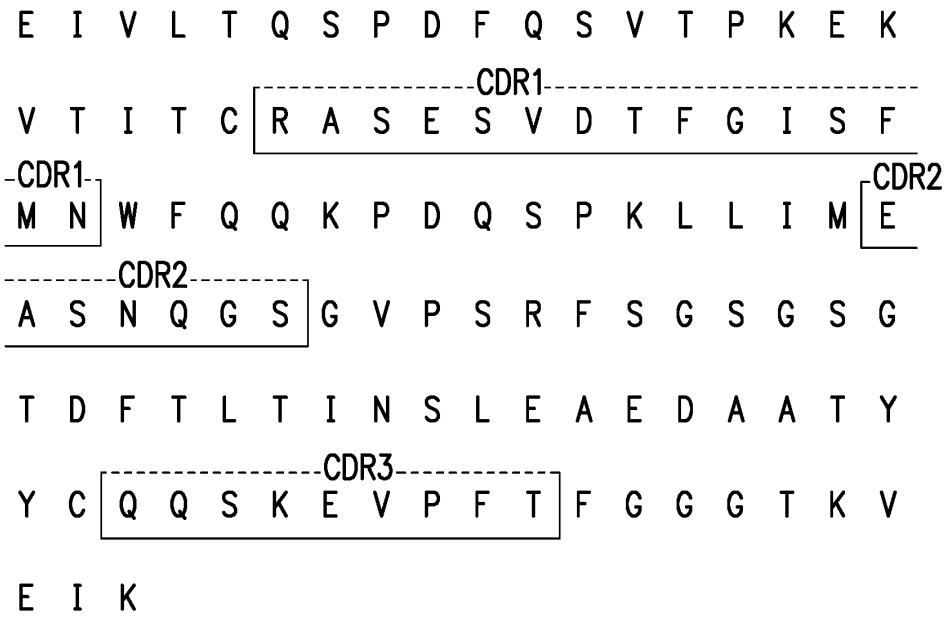
E I V L T Q S P D F Q S V T P K E K
CDR1
V T I T C R A S E S V D T F G I S F
CDR1
CDR2
M N W F Q Q K P D Q S P K L L I M E
CDR2
A S N Q G S G V P S R F S G S G S G
T D F T L T I N S L E A E D A A T Y
CDR3
Y C Q Q S K E V P F T F G G G T K V
E I K

FIG.2B

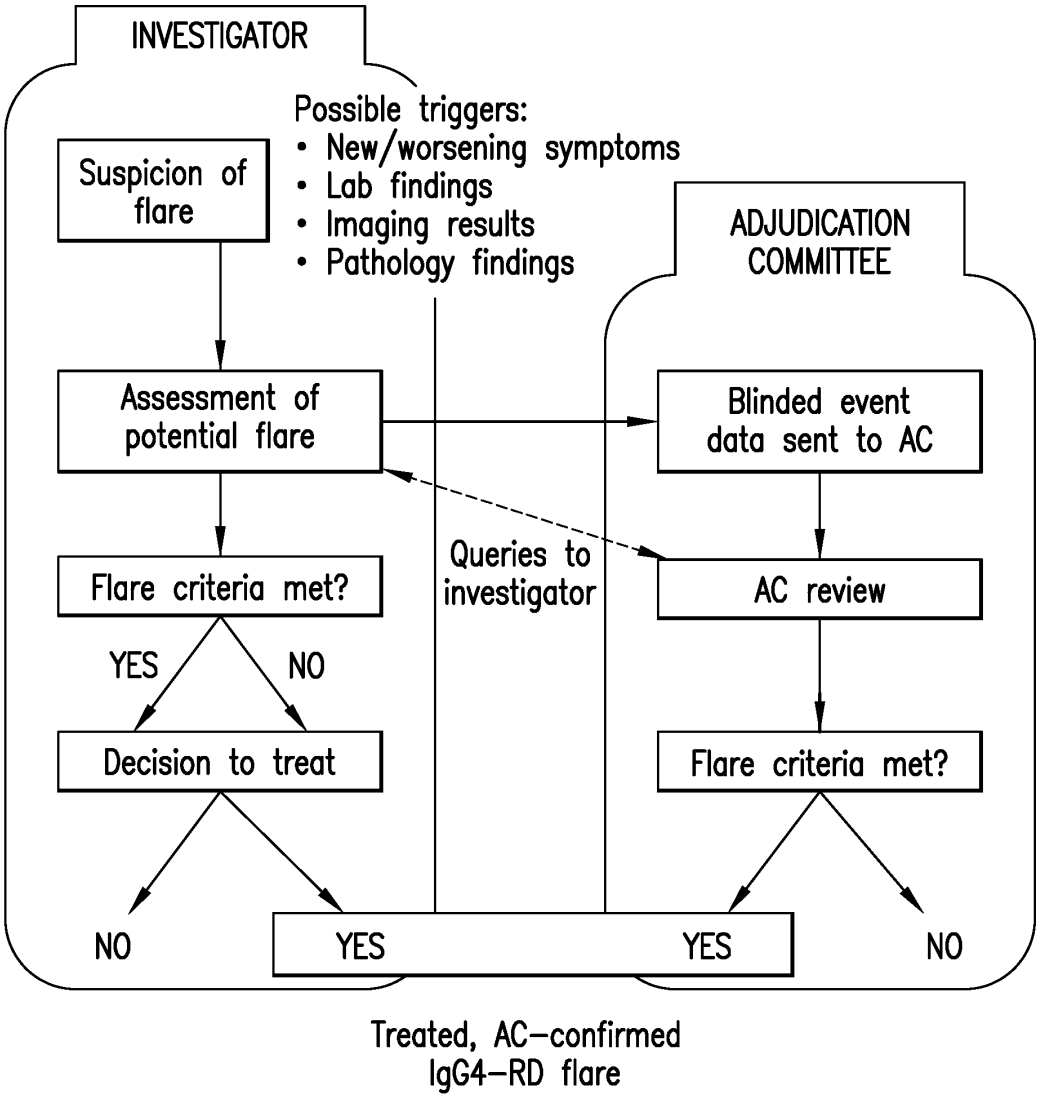
INVESTIGATOR
Possible triggers:
• New/worsening symptoms
• Lab findings
• Imaging results
• Pathology findings
Suspicion of flare
ADJUDICATION COMMITTEE
Assessment of potential flare
Blinded event data sent to AC
Queries to investigator
Flare criteria met?
AC review
YES
NO
Decision to treat
Flare criteria met?
NO
YES
YES
NO
Treated, AC-confirmed IgG4-RD flare

FIG.3