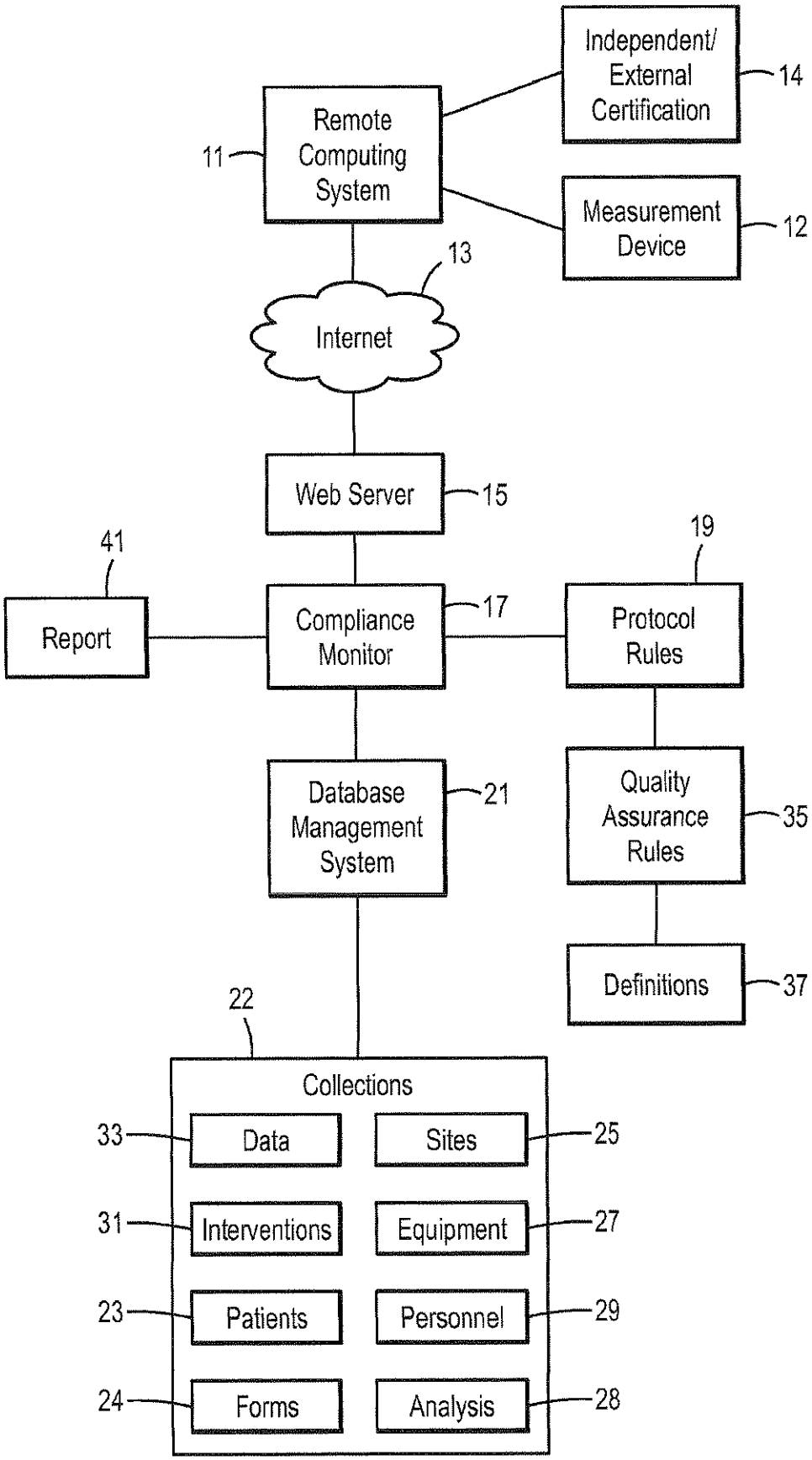
FIG. 1


Independent/ External Certification
14
Remote Computing System
11
Measurement Device
12
13
Internet
Web Server
15
41
19
Report
Compliance Monitor
17
Protocol Rules
Database Management System
21
Quality Assurance Rules
35
Definitions
37
22
Collections
33
Data
Sites
25
31
Interventions
Equipment
27
23
Patients
Personnel
29
24
Forms
Analysis
28

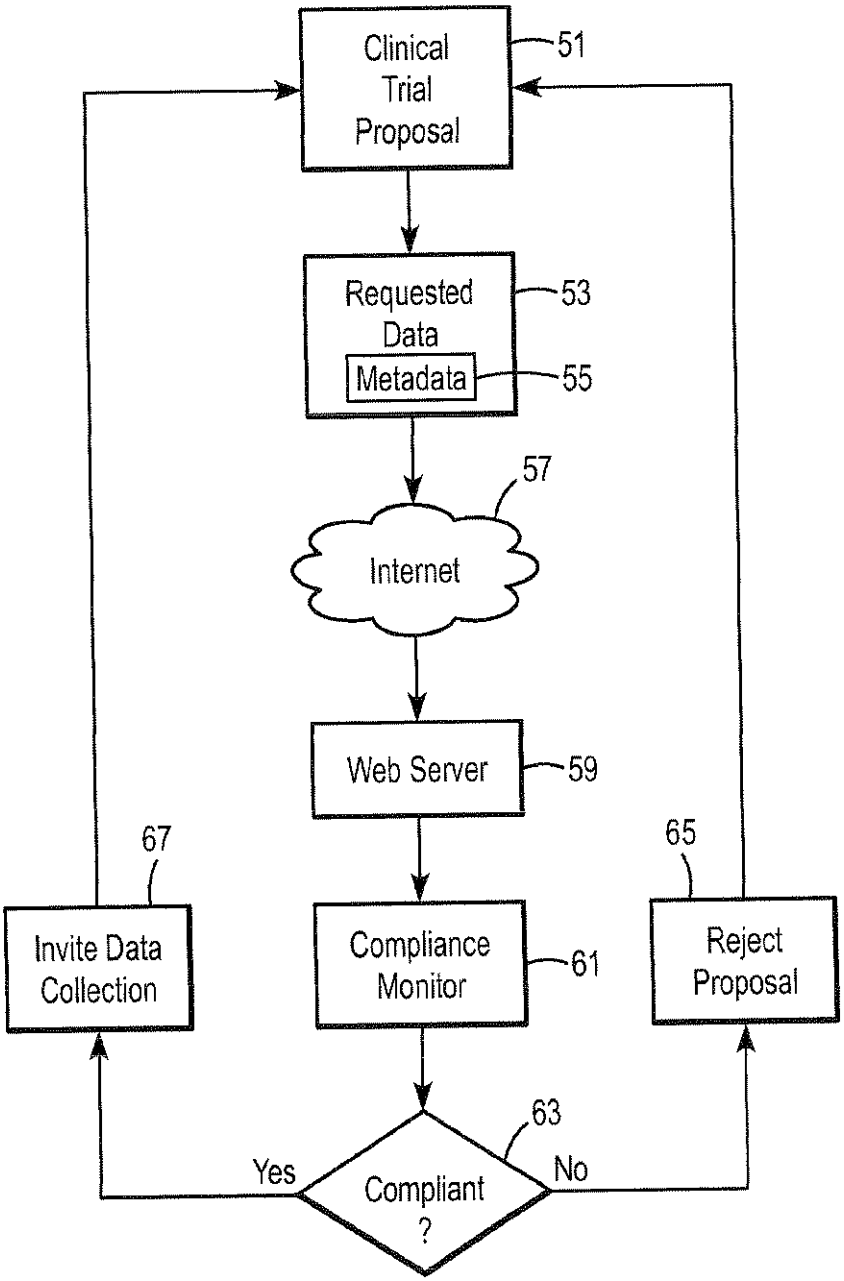

Clinical Trial Proposal
51
Requested Data
Metadata
53
55
57
Internet
Web Server
59
67
65
Invite Data Collection
Compliance Monitor
61
Reject Proposal
63
Yes
Compliant ?
No

FIG. 2

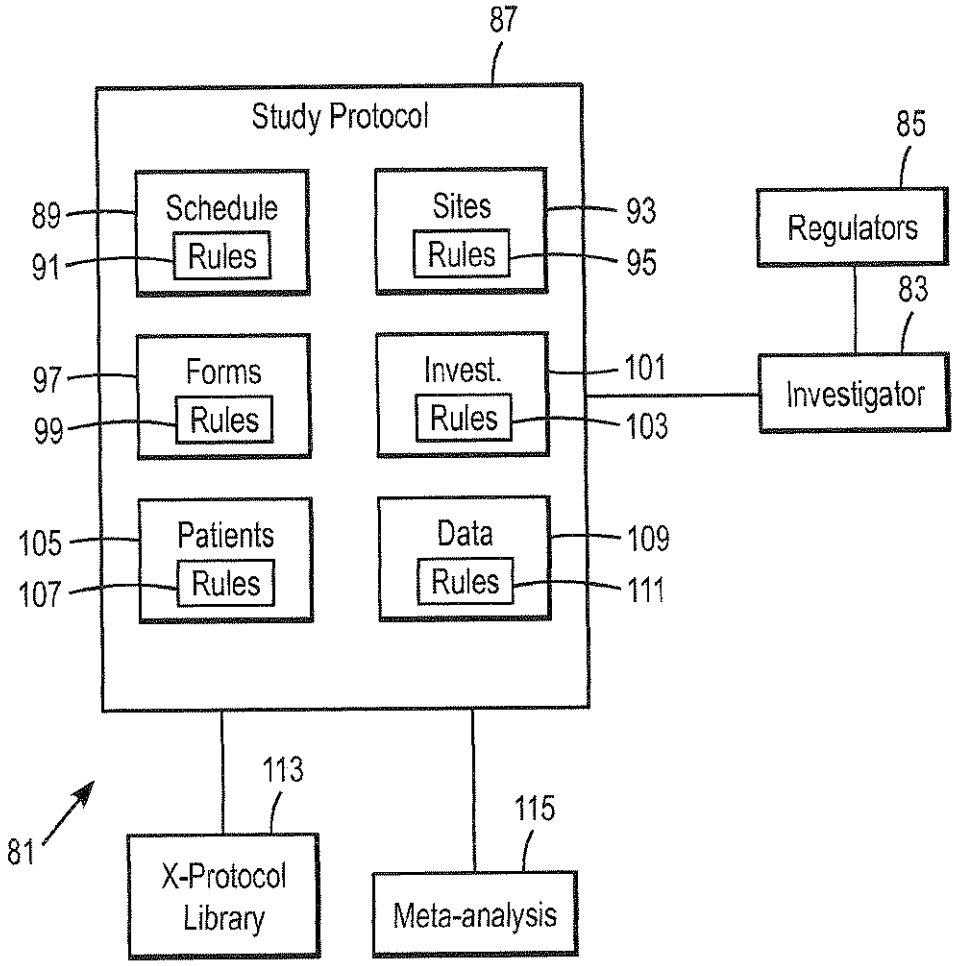

87
Study Protocol
85
Regulators
83
Investigator
89
91
Schedule
Rules
Sites
Rules
93
95
97
99
Forms
Rules
Invest.
Rules
101
103
105
107
Patients
Rules
Data
Rules
109
111
81
113
X-Protocol Library
115
Meta-analysis

FIG. 3

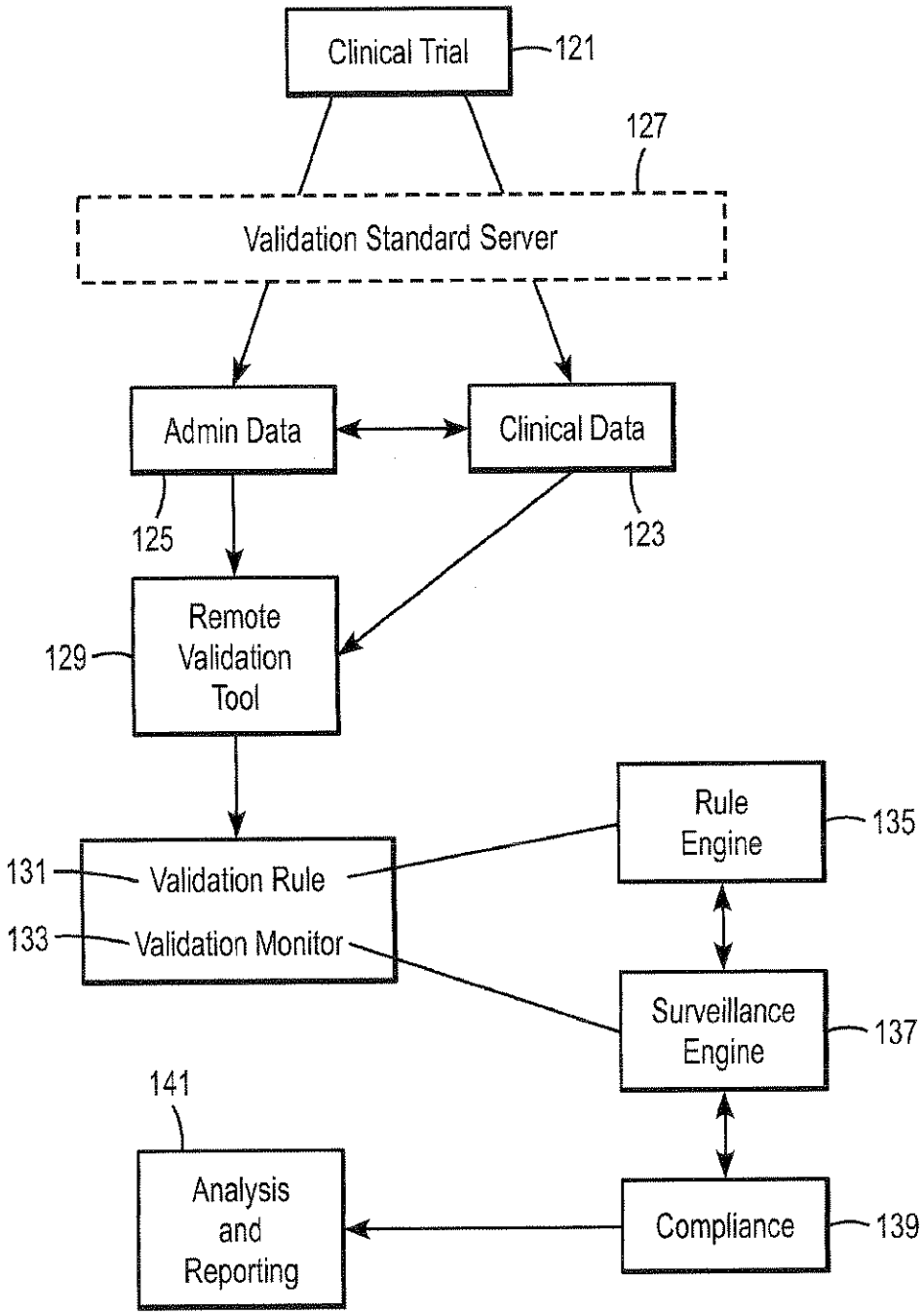

Clinical Trial
121
127
Validation Standard Server
Admin Data
Clinical Data
125
123
Remote Validation Tool
129
Rule Engine
135
131
Validation Rule
133
Validation Monitor
Surveillance Engine
137
141
Analysis and Reporting
Compliance
139

FIG. 4