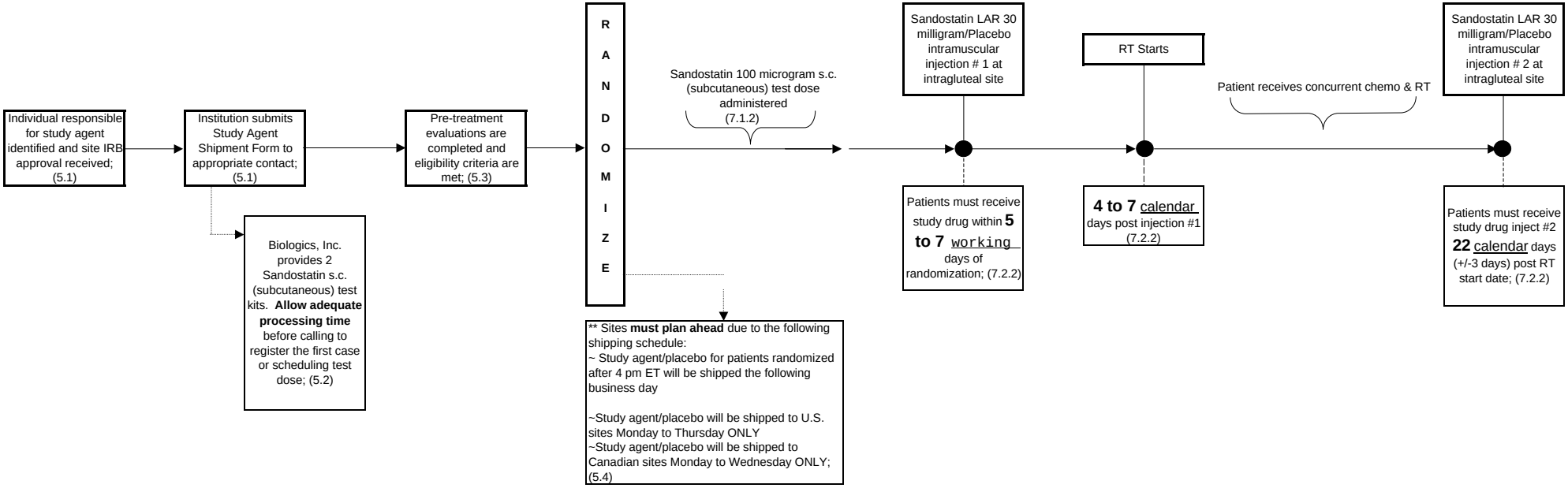
Individual responsible for study agent identified and site IRB approval received; (5.1)
Institution submits Study Agent Shipment Form to appropriate contact; (5.1)
Biologics, Inc. provides 2 Sandostatin s.c. (subcutaneous) test kits. **Allow adequate processing time** before calling to register the first case or scheduling test dose; (5.2)
Pre-treatment evaluations are completed and eligibility criteria are met; (5.3)
RANDOMIZE
Sandostatin 100 microgram s.c. (subcutaneous) test dose administered (7.1.2)
** Sites **must plan ahead** due to the following shipping schedule:
~ Study agent/placebo for patients randomized after 4 pm ET will be shipped the following business day
~Study agent/placebo will be shipped to U.S. sites Monday to Thursday ONLY
~Study agent/placebo will be shipped to Canadian sites Monday to Wednesday ONLY; (5.4)
Sandostatin LAR 30 milligram/Placebo intramuscular injection # 1 at intragluteal site
Patients must receive study drug within **5 to 7** working days of randomization; (7.2.2)
RT Starts
4 to 7 calendar days post injection #1 (7.2.2)
Patient receives concurrent chemo & RT
Sandostatin LAR 30 milligram/Placebo intramuscular injection # 2 at intragluteal site
Patients must receive study drug inject #2 **22** calendar days (+/-3 days) post RT start date; (7.2.2)