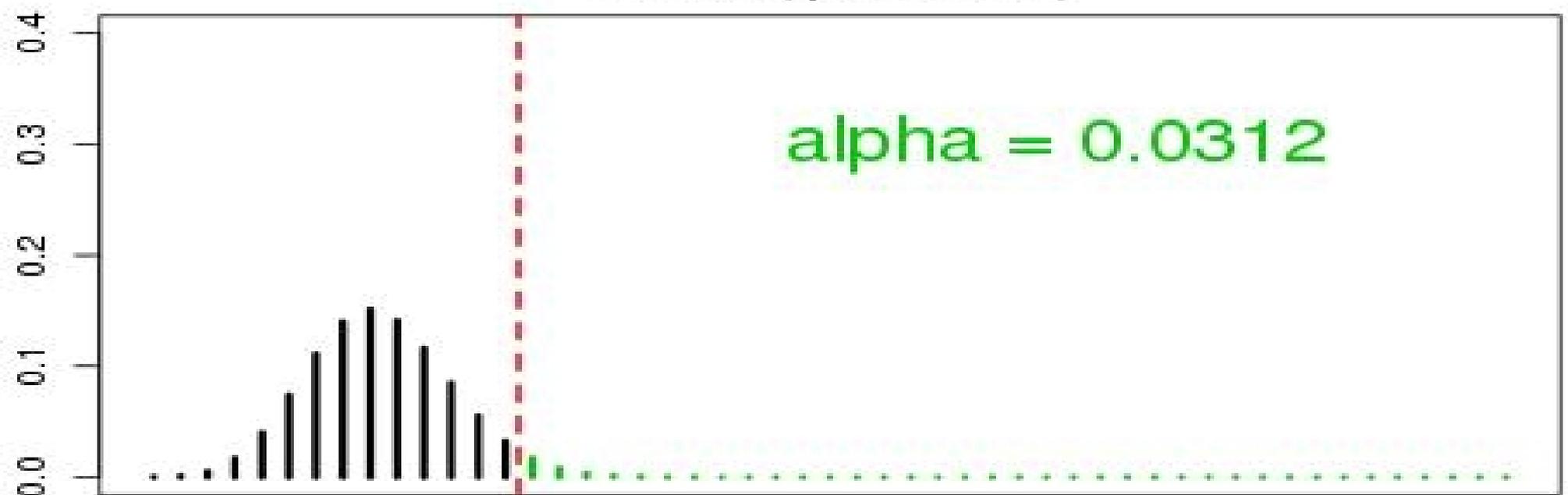
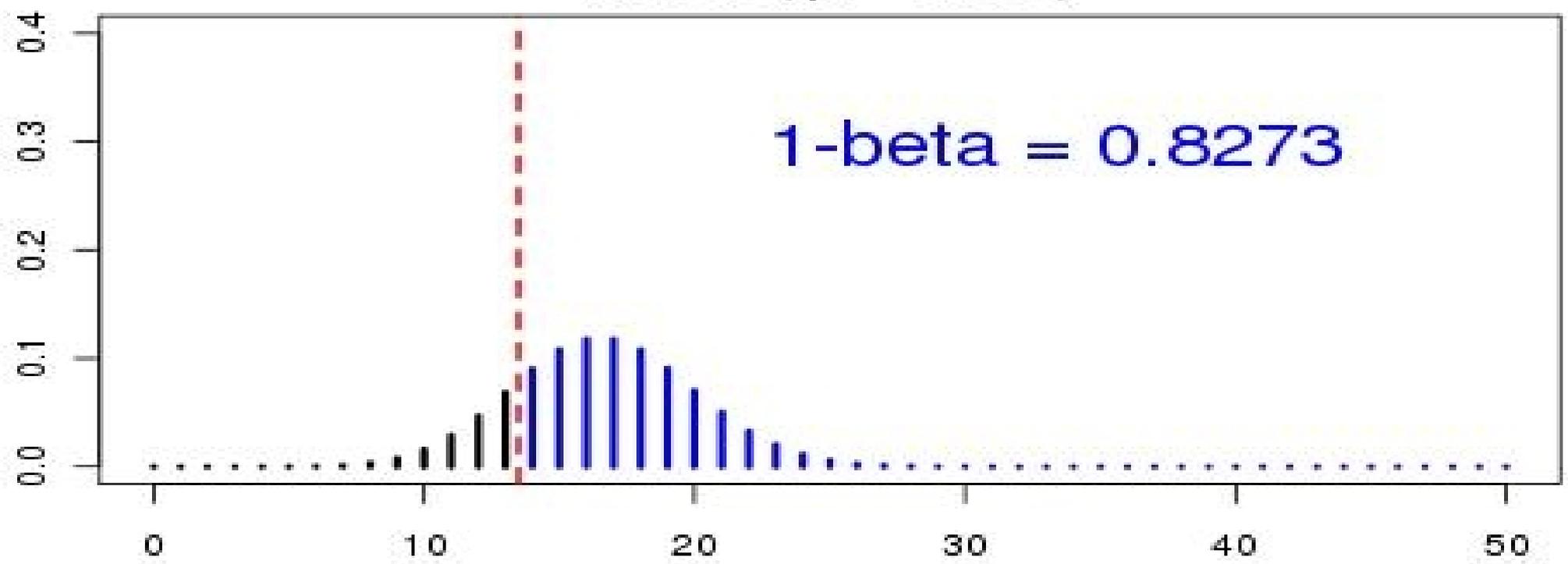


H0 true ($p_0 = 0.167$)

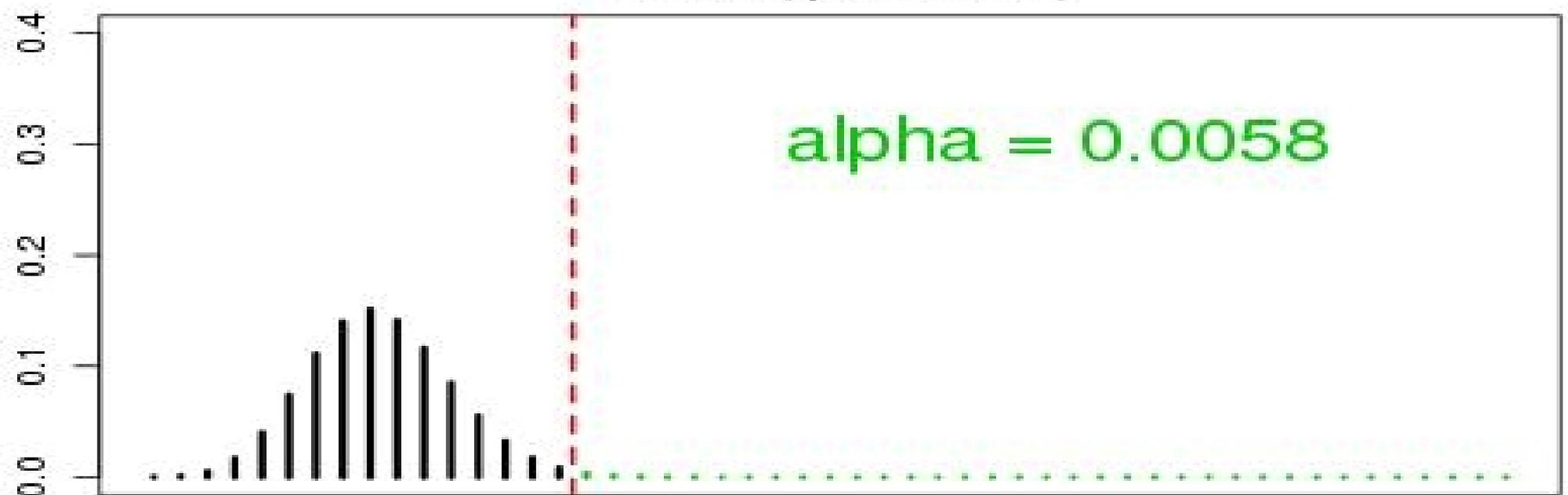


H1 true ($p_1 = 0.333$)

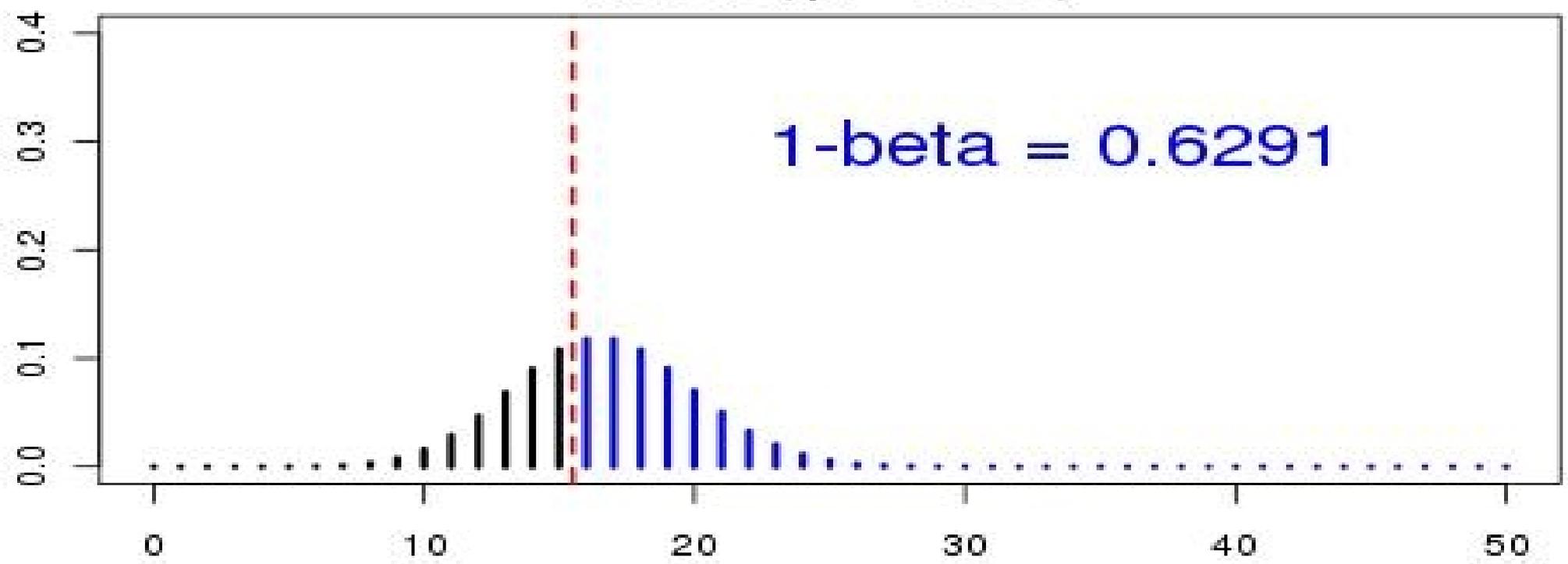


$n = 50 / c = 14$

H0 true ($p_0 = 0.167$)

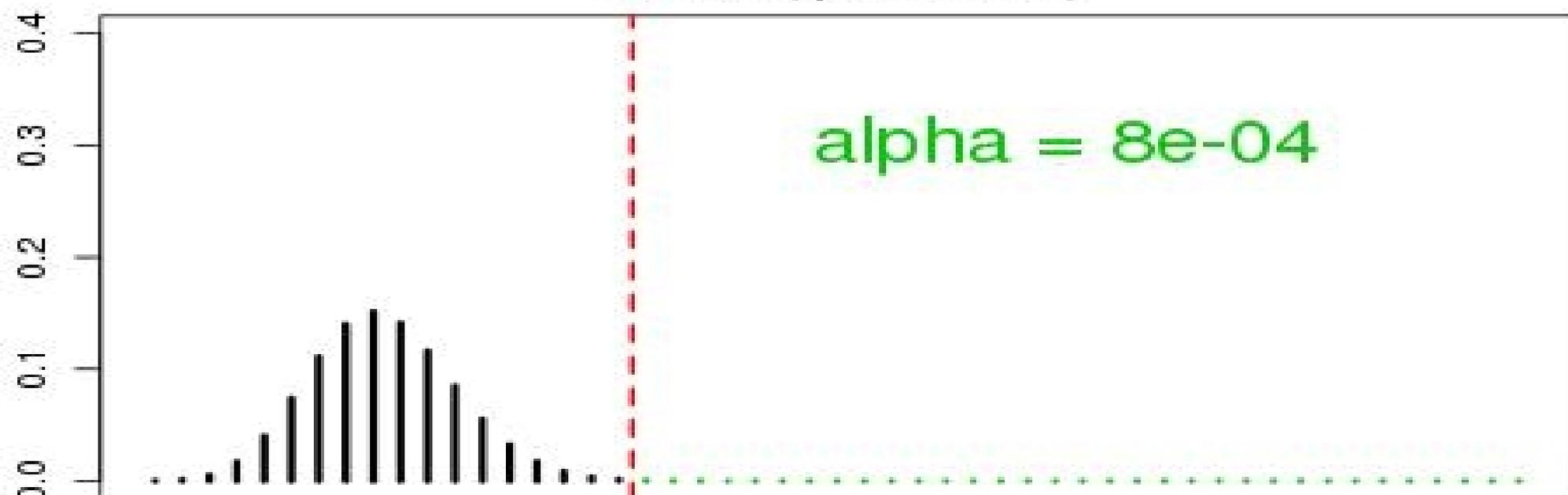


H1 true ($p_1 = 0.333$)

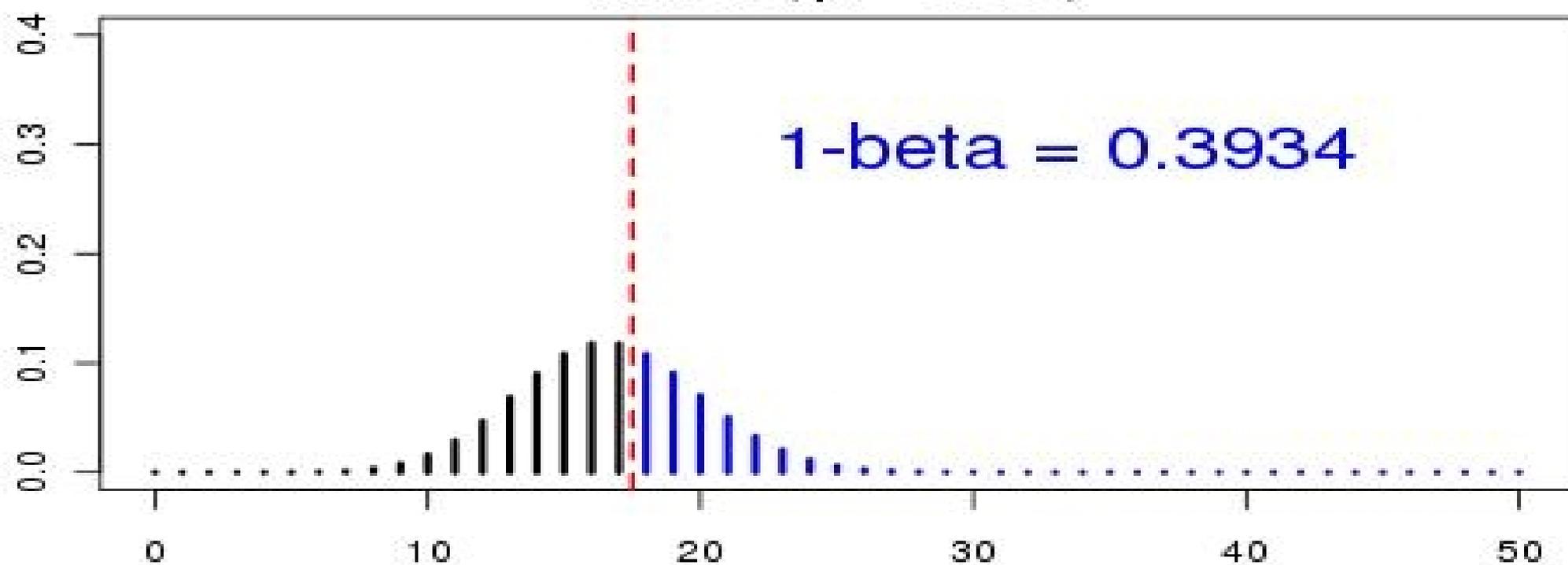


$n = 50 / c = 16$

H0 true ($p_0 = 0.167$)

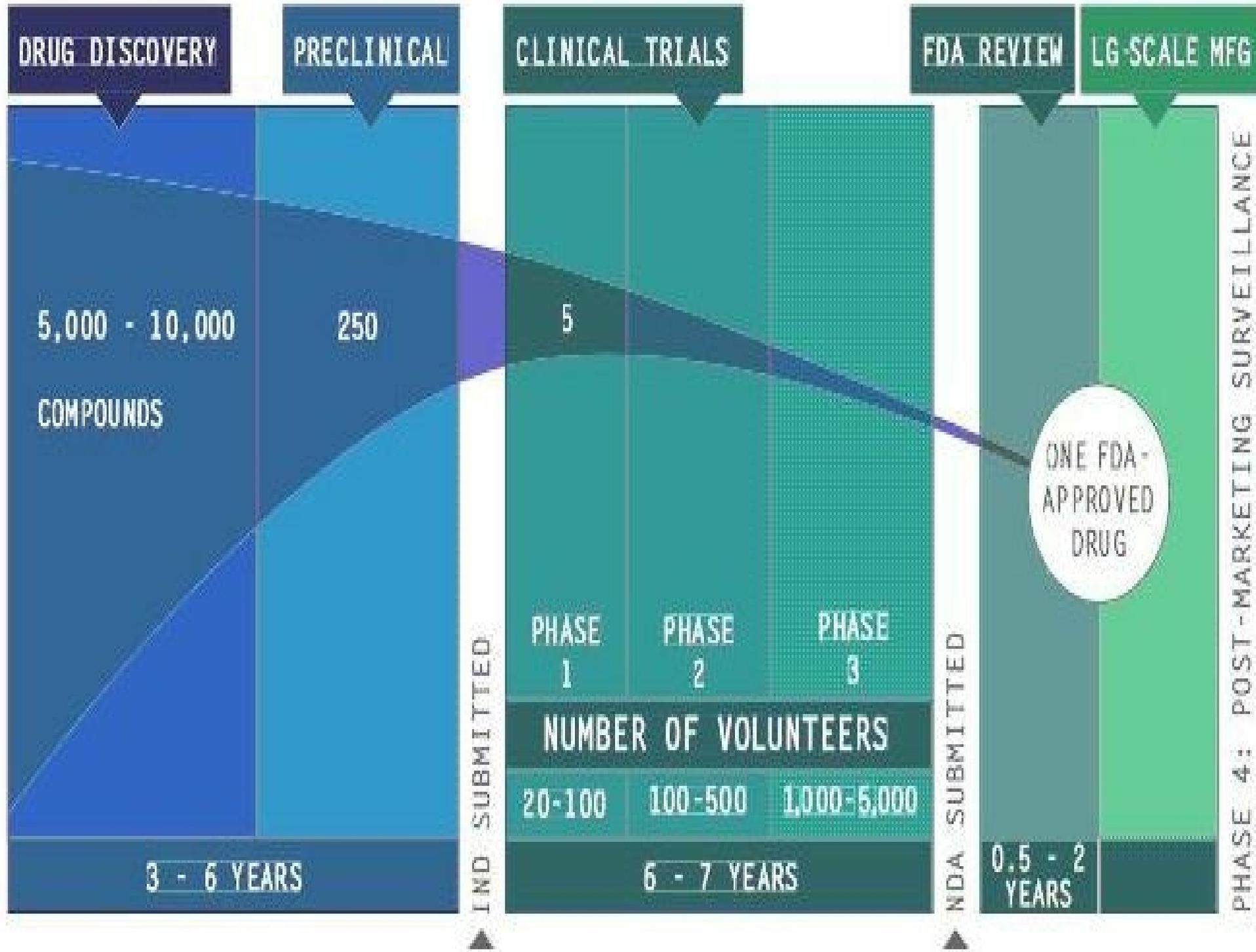


H1 true ($p_1 = 0.333$)



$n = 50 / c = 18$

PRE-DISCOVERY



Phase 1: Maximal Tolerierbare Dosis MTD

- Keine Statistik – fixe Regeln
- „**3 + 3 Design**“
 - 3 Patienten mit LD10/10
 - **Alle drei OK**: Drei neue Patienten mit höherer Dosis
 - **Sonst**: Abbruch (oder ähnliche Variante)

Phase 2: Effektivität

- Ist das Medikament bei Menschen erfolgsversprechend?
- Lohnt sich eine extrem teure Phase 3 Studie?
- Uninteressante / interessante Wirkwahrscheinlichkeit?
- **Einseitiger Binomialtest**



Pancreatic Cancer



Phase 2 Studie

- „Phase II trial of S-1 and concurrent radiotherapy in patients with locally advanced pancreatic cancer“

(Kim et.al., Cancer Chemotherapy and Pharmacology (2009); 63: 535 - 541)