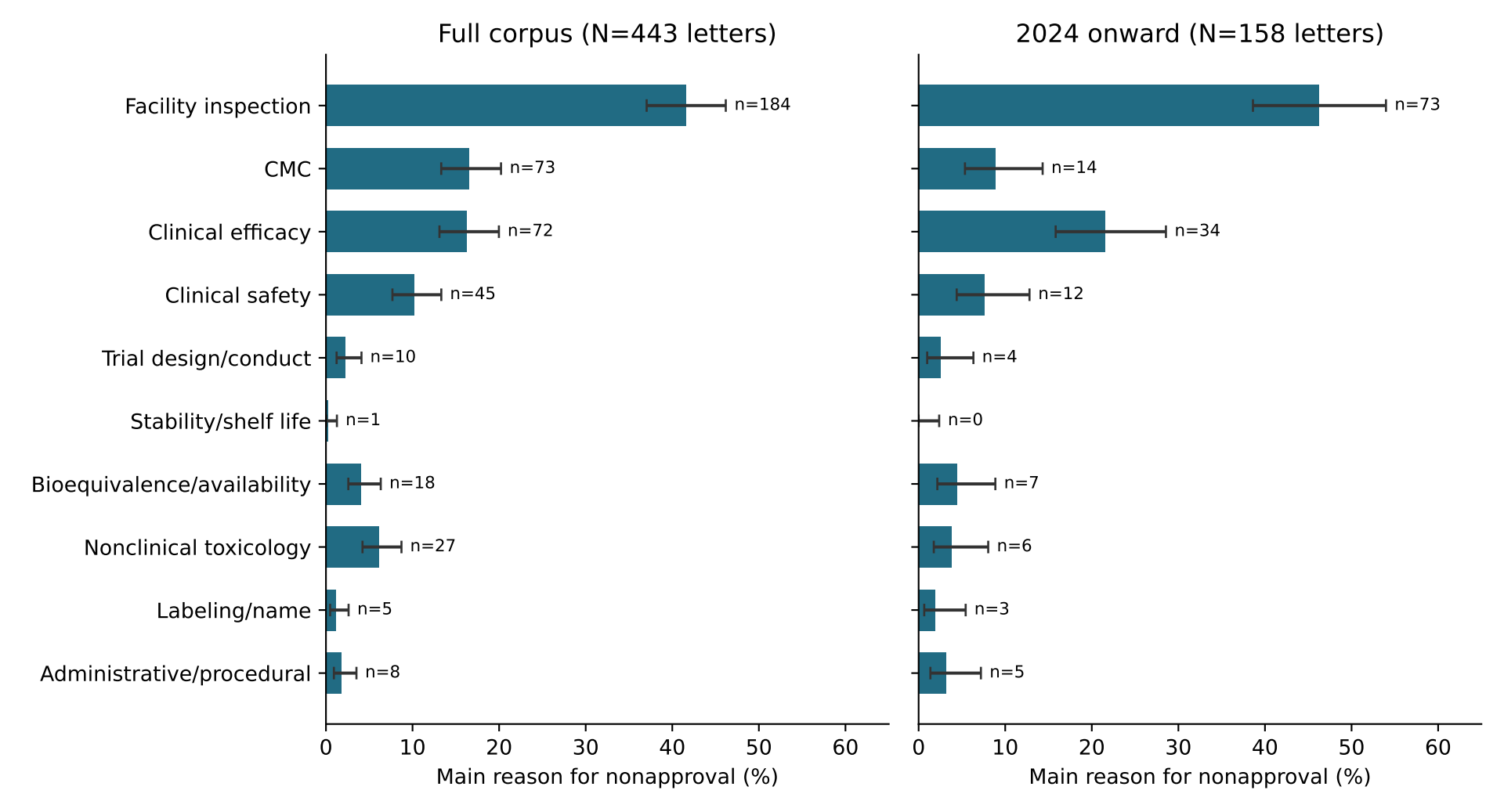

Full corpus (N=443 letters)
2024 onward (N=158 letters)
Facility inspection
CMC
Clinical efficacy
Clinical safety
Trial design/conduct
Stability/shelf life
Bioequivalence/availability
Nonclinical toxicology
Labeling/name
Administrative/procedural
n=184
n=73
n=72
n=45
n=10
n=1
n=18
n=27
n=5
n=8
n=73
n=14
n=34
n=12
n=4
n=0
n=7
n=6
n=3
n=5
0
10
20
30
40
50
60
Main reason for nonapproval (%)