A regulatory interaction is the wrong time for an original thought.

Our team prepares you to win with regulators in face-to-face and virtual environments.

US Regulatory

Advisory Committee Meetings

Application Orientation Meetings

Type B & Type C Meetings

NDA / BLA / PMA Clinical Modules

Label Negotiations

IR Support

CRLs / FDRRs / MDLs

ACIP & Work Group Meetings

EU Regulatory

Oral Explanations

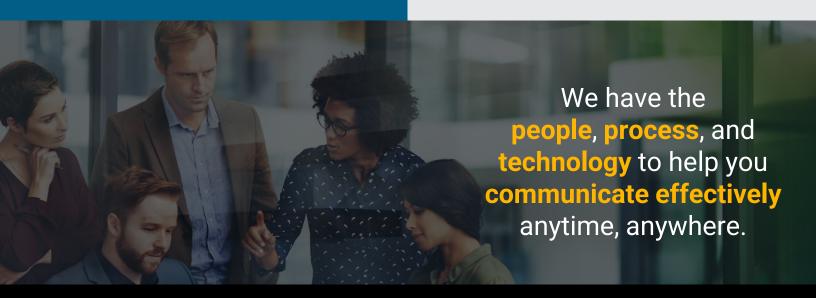
SAG, AHEG & PRAC Meetings

COMP Meetings

Day 120 / 180 /195 Responses

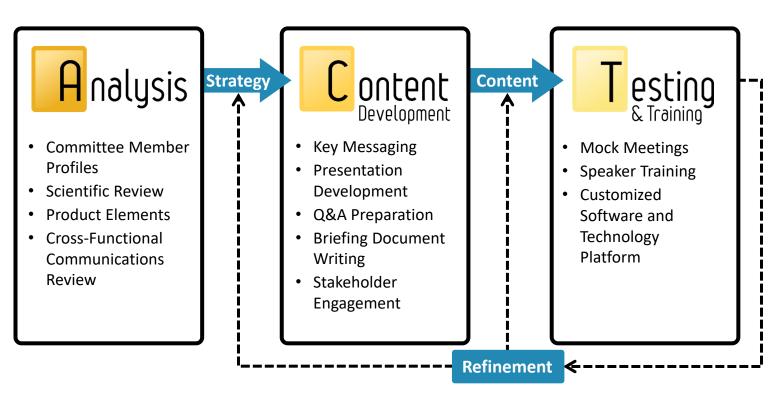
Clarification Meetings

Rapporteur Meetings

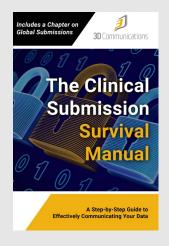


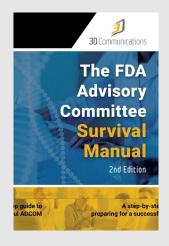
Prepare with a practical, proven process.

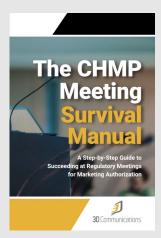




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