Efficacy Review

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Need to Treat Sinusitis with Effective Medications

- To reduce patient suffering
- To reduce orbital complications, brain abscess, meningitis, chronic sinus disease
- To reduce emergence of resistant bacteria

Effective Antibiotic Treatments for ABS

	Dose	Frequency	Duration
Amoxicillin-clavulanate*	2 g – 125 mg	2X	10d
Cefdinir*	600 mg	1X	10d
Cefpodoxime proxetil	200 mg	2X	10d
Cefuroxime axetil*	250 mg	2X	10d
Levofloxacin*	750 mg	1X	5d
Moxifloxacin	400 mg	1X	10d
Telithromycin	800 mg	1X	5d

* Found effective in pre- and post-treatment sinus aspirate and culture studies

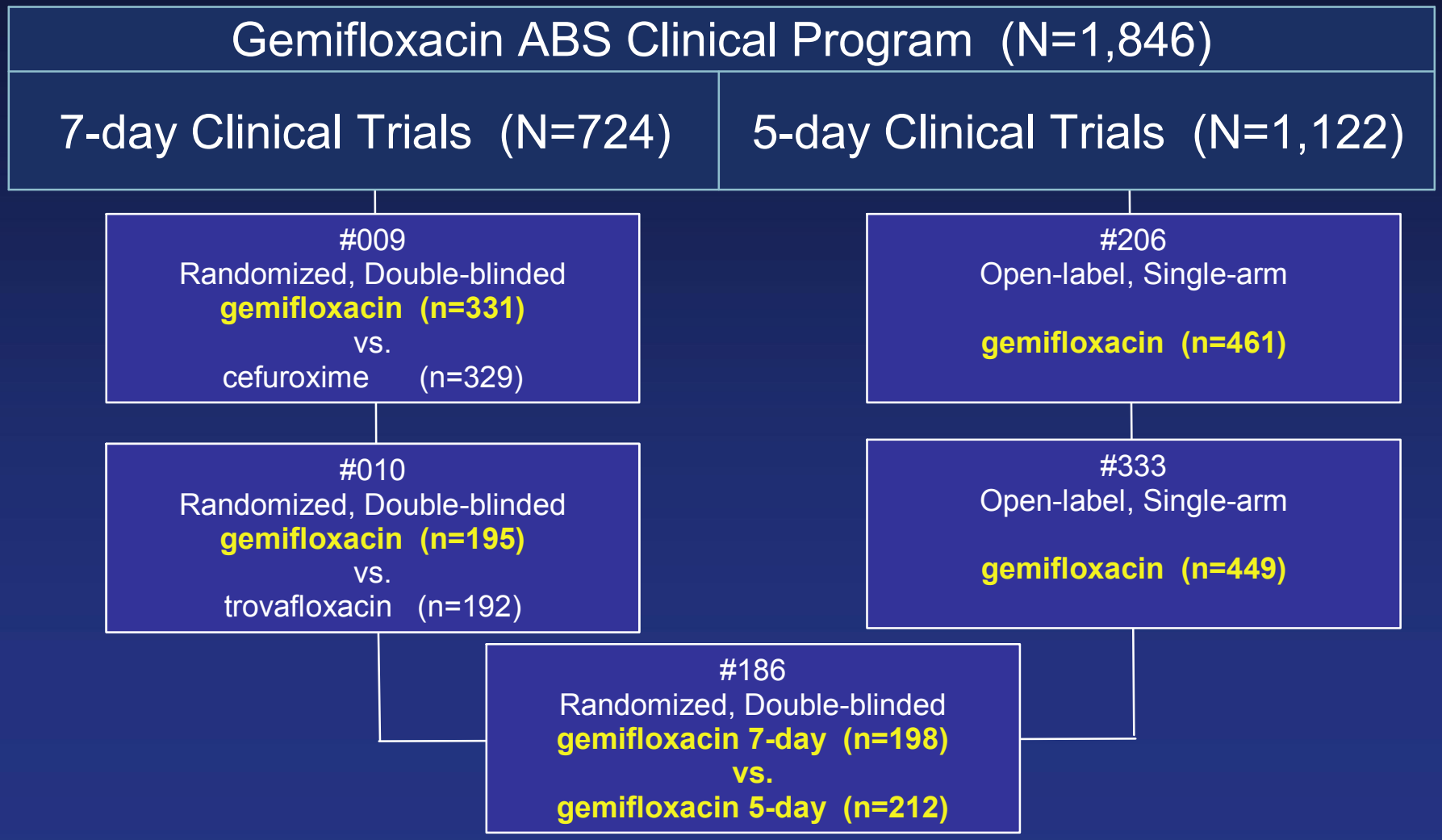
Adapted from Gwaltney, Jack M., Jr., MD, Sinus. In: Mandell, G.L., MD, Bennett, J.E., MD, Dolin, R., MD, *Principles and Practice of Infectious Diseases, 6th Edition;* 2005: chap. 55.

Benefits of 5-Day vs. 7-Day

- Increased compliance
- Increased patient satisfaction
- Decreased pressure for resistance

ABS Clinical Trial Program

5-day ABS Data in >1,100 Patients



Inclusion Criteria for All Studies

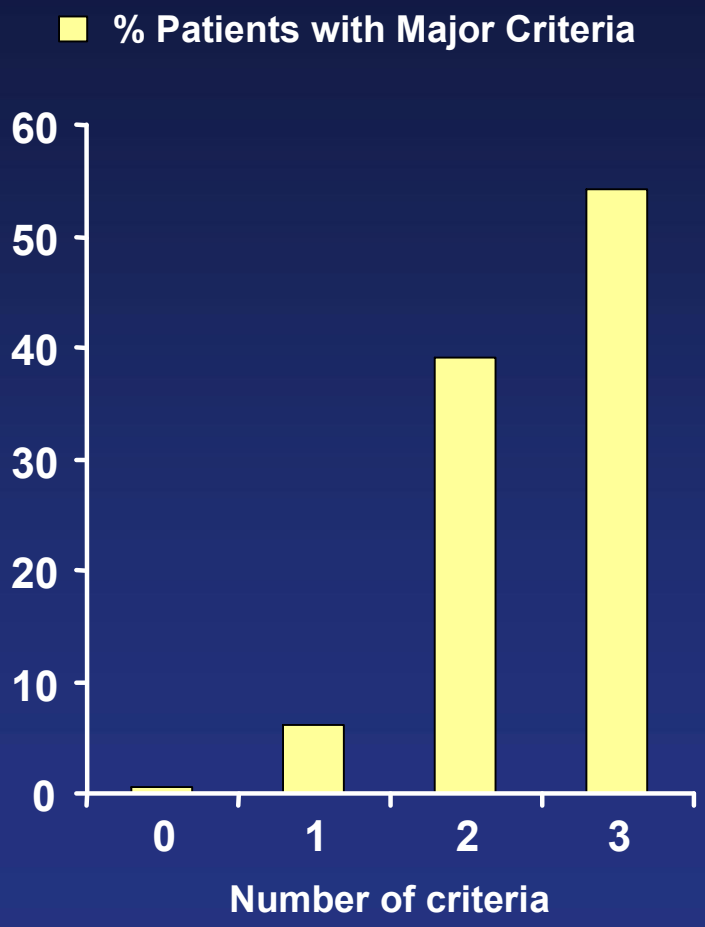
- ≥7* days <28 days
- Nasal purulence/post-nasal discharge at screening visit
- Radiographic evidence of opacification or air fluid level
- One major criteria or two minor criteria
  - Major: facial pain/pressure, nasal obstruction
  - Minor: tooth pain, earache, headache, sore throat, cough, halitosis, fever, change in smell

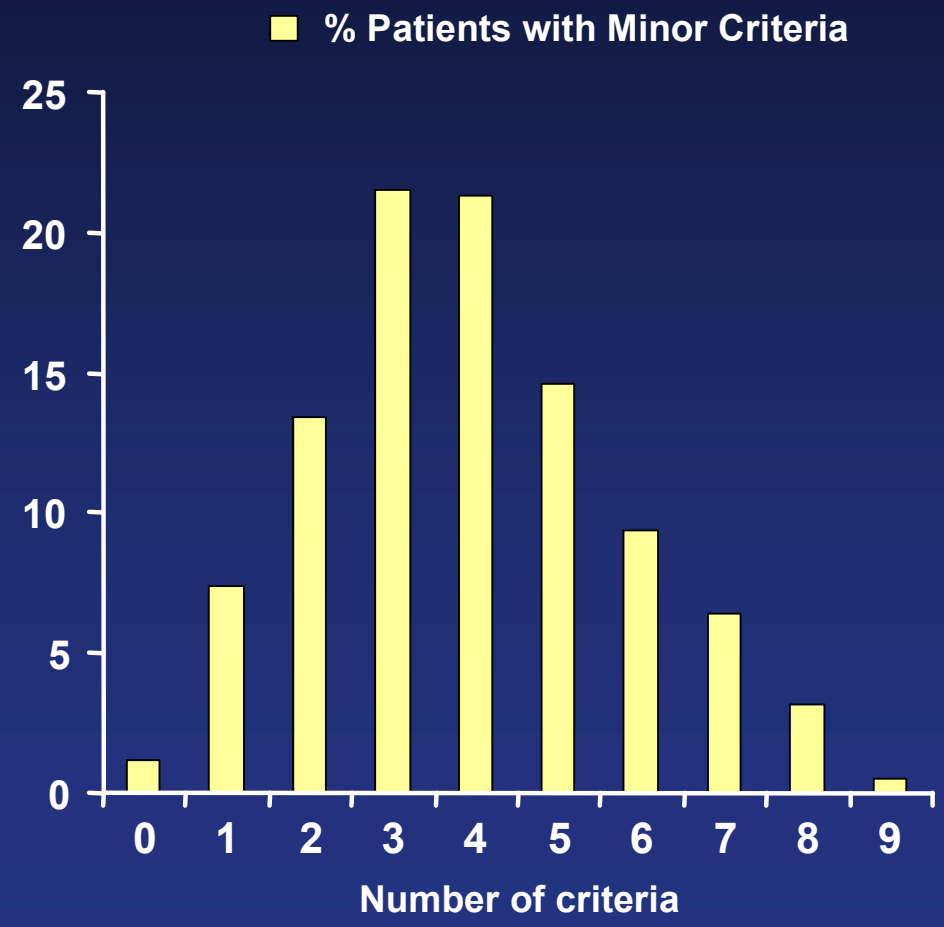
***Tap studies three days with severe symptoms**

Exclusion Criteria

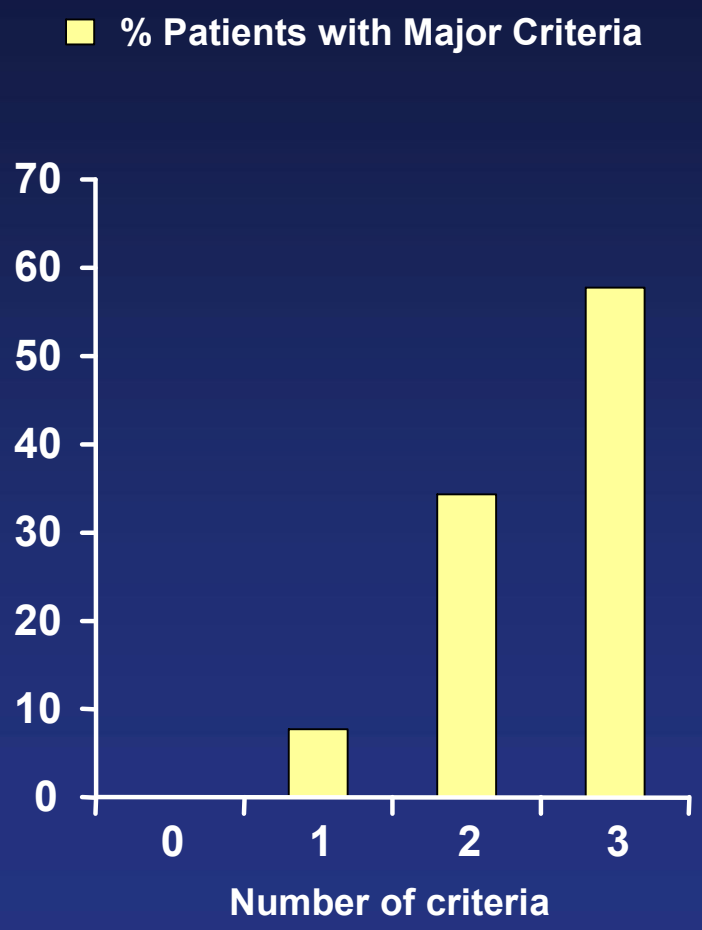
- Antibiotics in last 7 to 14 days
- Nasal polyps distal to middle turbinate
- Sinus surgery within last 6 months

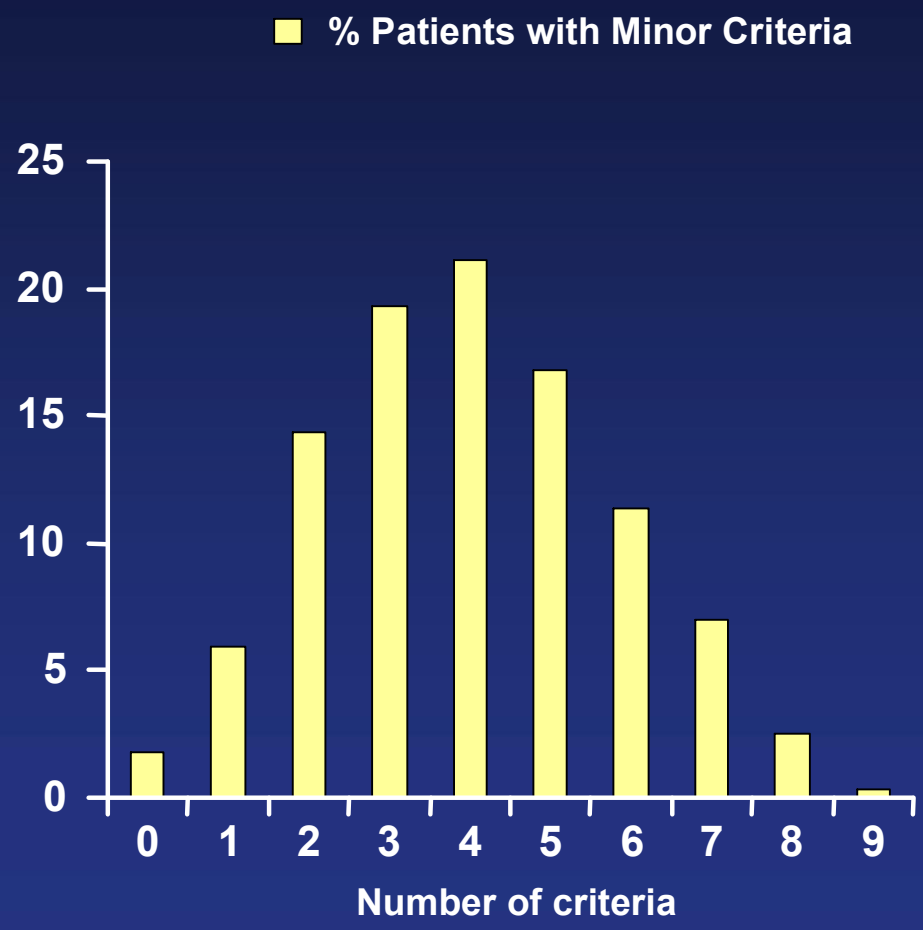
Major and Minor ABS-Related Criteria (CITT ≥3 Day Patients n=404)





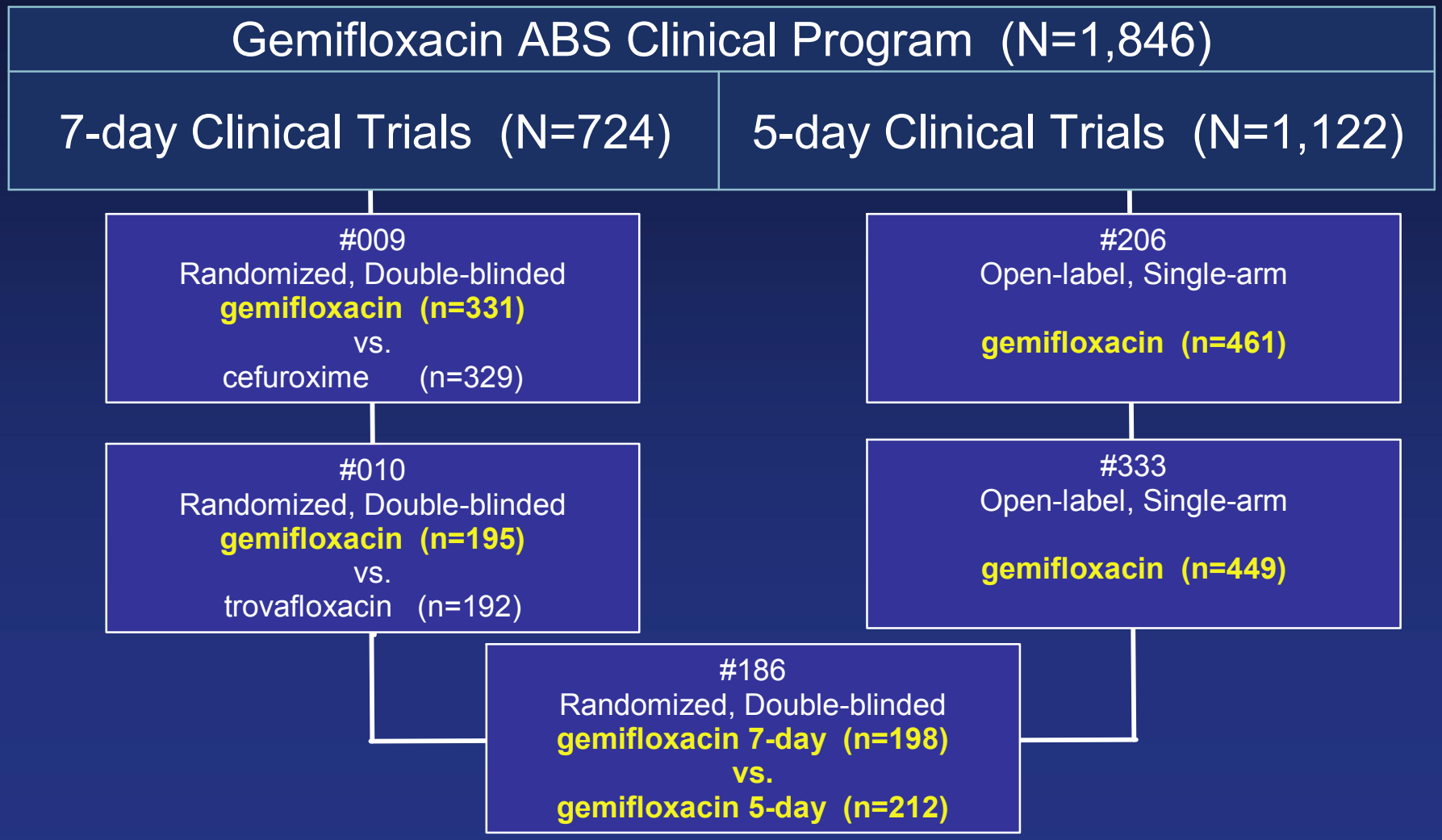
Major and Minor ABS-Related Criteria (CITT ≥7 Day Patients n=1,444)



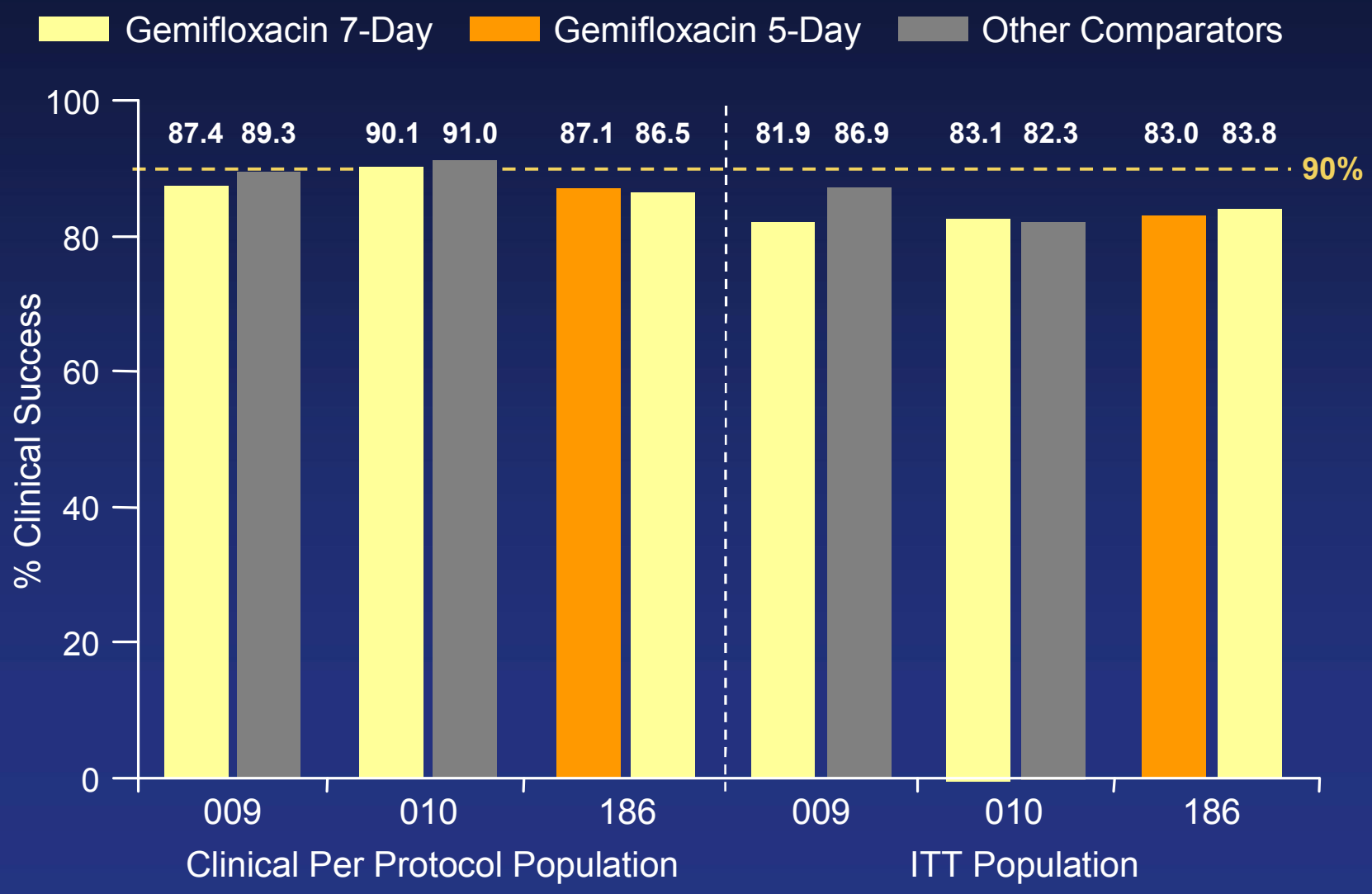


ABS Clinical Trial Program

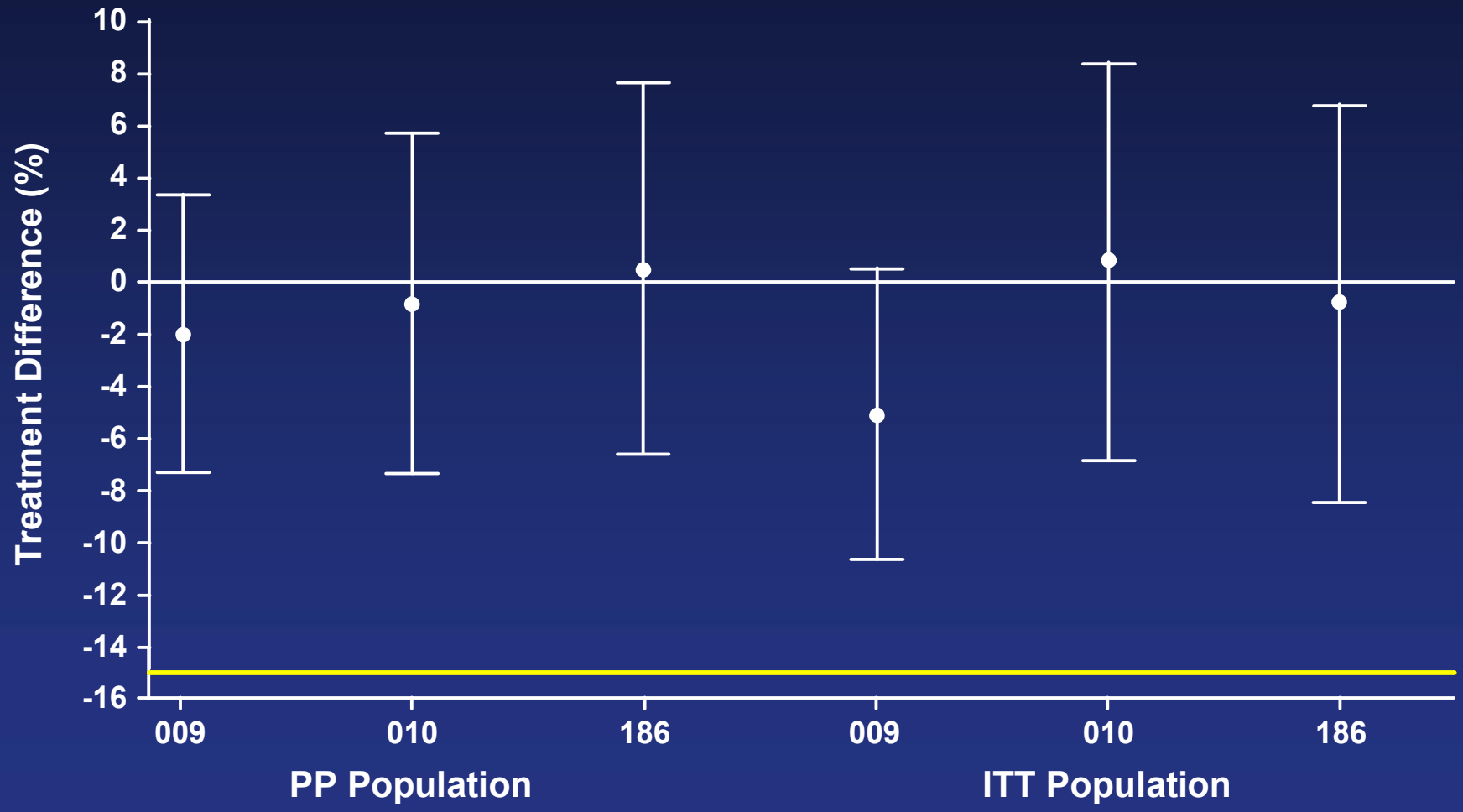
5-day ABS Data in >1,100 Patients



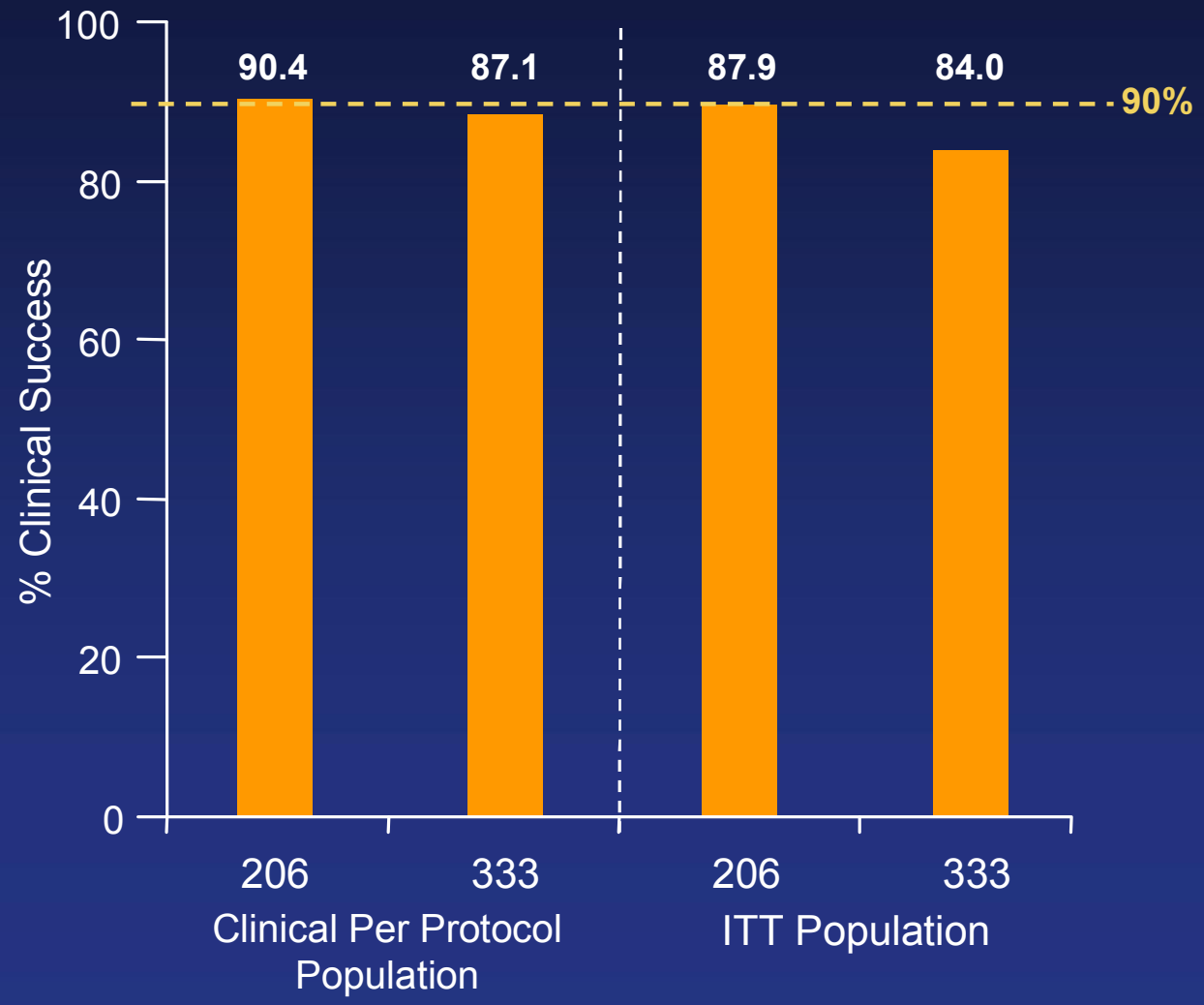
Follow-Up: ABS Controlled Studies
High Clinical Success Among All Groups



ABS Clinical Response at Follow-Up: Treatment Differences / 95% Confidence Intervals



Follow-Up: ABS Open-Label Studies
High Clinical Success Among All Groups



Clinical Success Rates for Key Pathogens in the Bacteriologically Evaluable Population: Study 009

	Gemifloxacin 320 mg OD 7 days	Cefuroxime 250 mg BID 10 days
	N=133 n/N (%)	N=138 n/N (%)
S. pneumoniae	54/55 (98.2)	54/58 (93.1)
MDRSP	14/14 (100.0)	12/15 (80.0)
H. influenzae	26/28 (92.9)	30/31 (96.8)
S. aureus	12/14 (85.7)	8/9 (88.9)
M. catarrhalis	7/7 (100.0)	5/5 (100.0)

Bacteriology PP Population

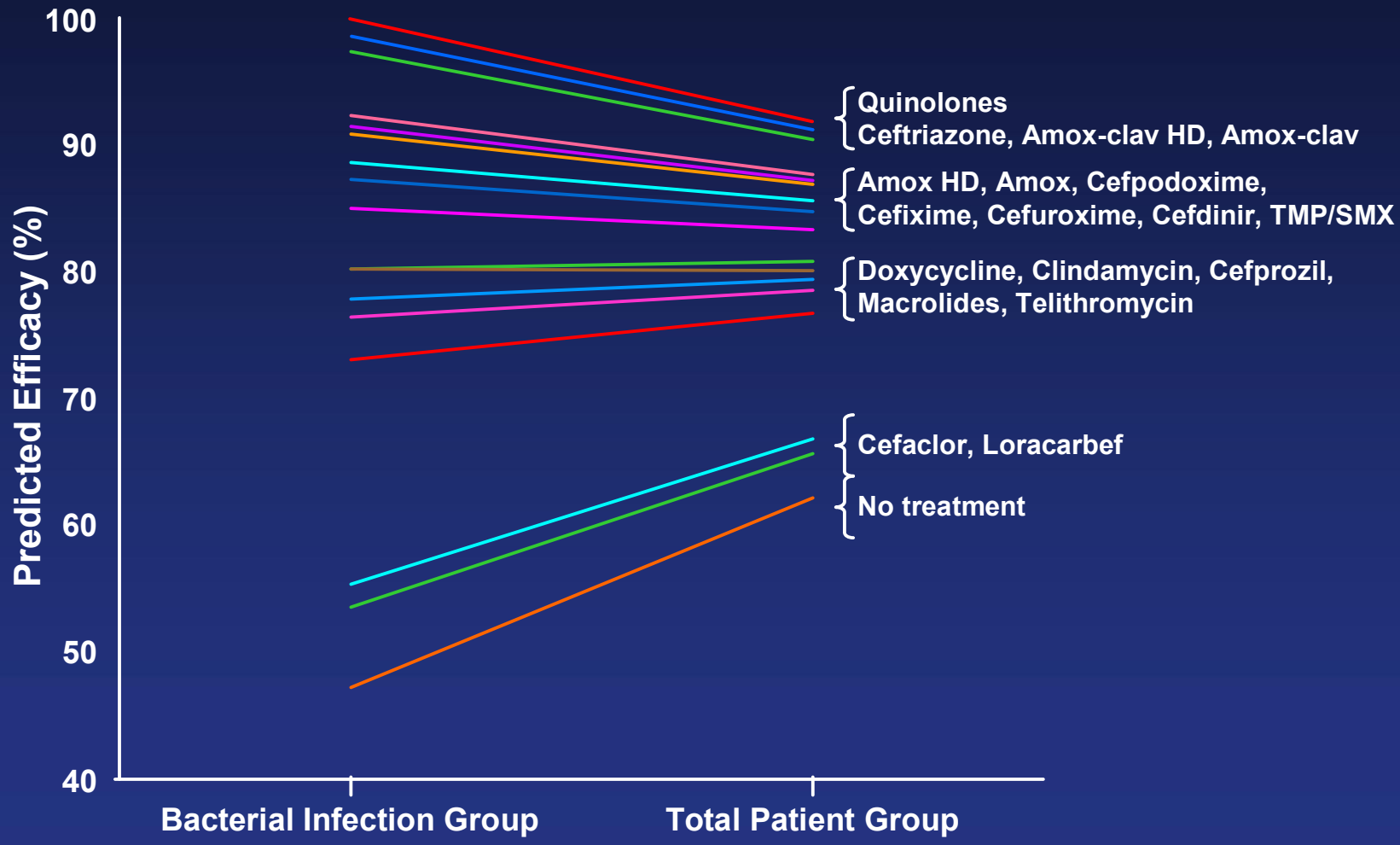
Clinical and Bacteriological Efficacy Follow-Up: Studies 009, 206/333 Combined

	Study 009 Gemifloxacin 320 mg OD 7 days	Studies 206 and 333 Gemifloxacin 320 mg OD5 days
	N=133 n/N (%)	N=267 n/N (%)
S. pneumoniae	54/55 (98.2)	96/103 (93.2)
MDRSP	14/14 (100.0)	24/24 (100.0)
H. influenzae	26/28 (92.9)	51/53 (96.2)
S. aureus	12/14 (85.7)	13/16 (81.3)
M. catarrhalis	7/7 (100.0)	17/17 (100.0)

Bacteriology PP Population

Acute Bacterial Sinusitis – Adult

Modeling Predicts Quinolones Most Effective Treatment



Sinus and Allergy Health Partnership. *Otolarynol Head Neck Surg*. 2004.