

Community Cancer Centers The Crisis in Clinical Trials

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N.C. Trial Distribution

- n Total sites open: 334
- n Total trial opportunities: 2,160 protocol openings
- n Distribution by number of open protocols
 - 10 or more protocols open: 75 sites
 - 1-9 protocols open: 117 sites
 - No protocols currently open: 142 sites

Major Practice Issues

- n Overall reimbursement issues
- n Regulatory burdens
- n Funding level for NCI trials
- n Competition from industry trials
- n Insurance coverage issues
- n Problems with trial publicity

Reimbursement Issues

- n Declining chemotherapy reimbursement
 - Problem of “underwater” drugs
 - Referral of marginal payers to hospitals
- n Threatened Medicare payment cuts
 - Operation with essential staff only
- n Problem sustaining practice in borderline areas
 - Less time per patient as providers decrease

Regulatory Burden

- n Large document volume – special staff
- n Time away from active patient care
- n Need to develop support from hospital
 - Difficult for rural practices
- n Trained personnel to deal with audits
- n Need to access local IRB for NCI trials
 - NCI CIRB still requires local control
 - Industry trials use central IRB

Funding for NCI Trials

- n Inadequate to cover personnel costs
 - Requires partner to subsidize (hospital)
 - Can shift some industry trials revenue
- n New partnerships between NCI and industry
 - Treatment trial involving IND
 - Trials often more complex
 - Payment higher but work load much greater
 - Patient demands often greater

Competition from Industry

- n Budget system allows payment for work required
 - May be sustainable system in private practice
- n Often direct competition with NCI trials
- n More phase II designs – easier to accrue
- n Appearance of industry-only networks
 - Regulatory burden handled centrally
 - More efficient for industry partners
 - Excludes Cooperative Group trials

Insurance Coverage Issues

- n Private insurance and state law
 - Coverage of routine costs in 23 states
 - Still subject to retrospective review
 - Includes only patients in purchased plans
- n Coverage variable in other states
 - Some companies have clinical trial policies
 - Risk passed to patient (really to provider)
- n Many large companies now self-insured

Insurance Coverage (cont'd)

- n ERISA pre-emption of state law
 - Self insured plans offered as benefit
 - May involve 50% of patients in some areas
- n ERISA law states:
 - Employers not required to provide health insurance
 - If provided, falls under ERISA (no mention of clinical trials)
 - ERISA provisions override all state laws

ERISA Fixes

- n H.R. 2676 (Pryce) adds standard coverage language to ERISA
 - Republican sponsored
 - In committee and not on Democratic agenda
- n S. 2999 (Brown) has same language
 - Bipartisan bill (Specter)
 - Recently introduced
- n Change in state law language won't work

Medicare Trial Coverage

- n Clinton executive order mid-1990s
 - Established coverage for routine costs
- n CMS working on policy changes
 - Limiting coverage for IND exempt trials
 - Other restrictions being considered
- n CMS CED policy as substitute for trials
 - NOPR recent example
 - Faster and more realistic data acquisition

Clinical Trials Publicity

- n Harris Poll 2000 – only 16% of public aware of clinical trials
- n Trial searching often difficult
 - Multiple sites available
 - Inaccurate data (missing and closed studies)
 - Not regionalized
- n Regional search engines
 - Georgia CORE
 - NC Comprehensive Cancer Program

Conclusions

- n Community participation essential for timely trial completion
- n Increased need for outside support will dominate system
- n Increase in industry trials at expense of NCI trials
- n Insurance/payment issues not resolved
- n May require joint regional effort