

***“IBC Review in the
Context of New
Settings and Multi-Site
Trials: The Western
Model”***

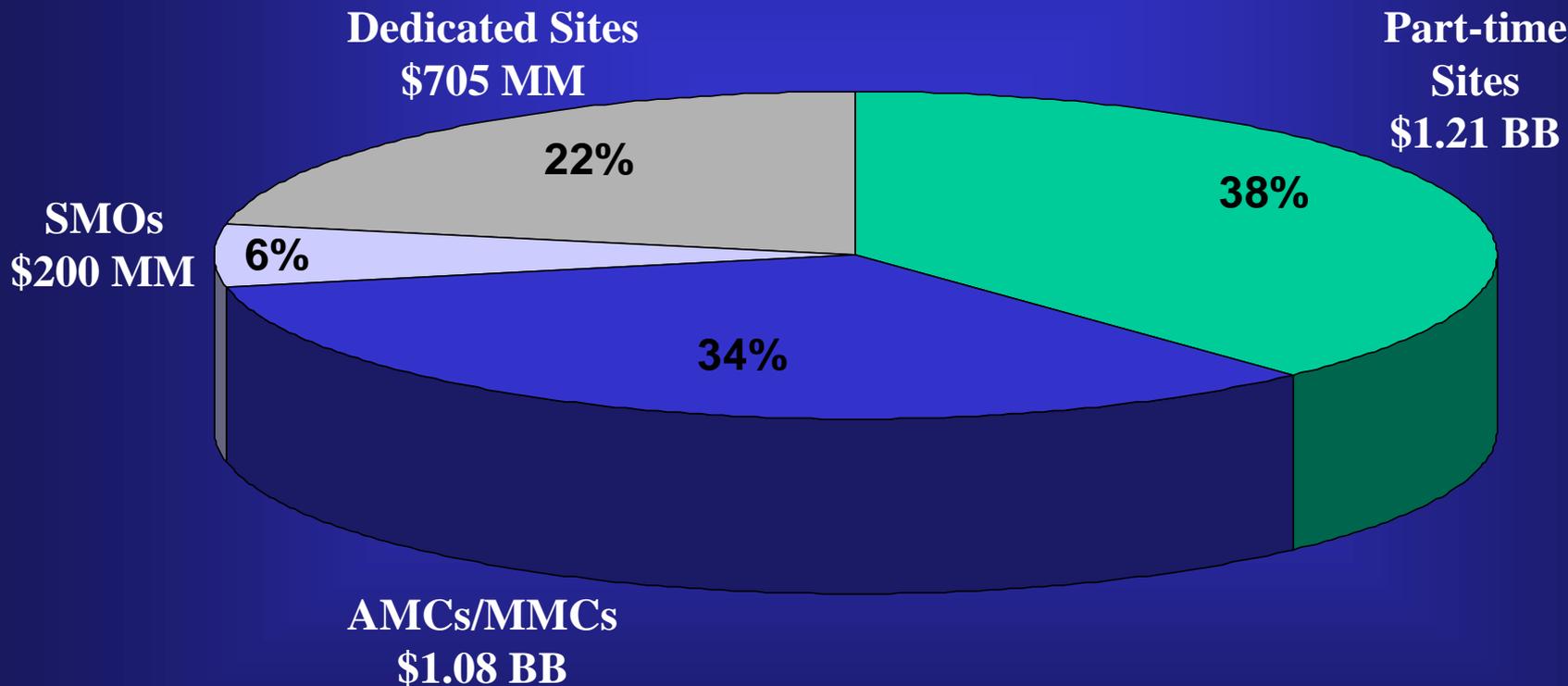
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REALITY

**Significant clinical research
is done outside the context
of federally funded
institutions.**

Market Share of Industry-Sponsored Clinical Trial by Site Type

1999E=\$3.20 Billion



Source: CenterWatch Analysis, November 2000

THE “WESTERN MODEL”

Why ?

What ?

How ?

WHY

IBC oversight at sites
conducting human gene
transfer research is
important and must be both
meaningful and practical.

WHAT

- **Human Gene Transfer
Clinical Trials**
- **Biosafety Risk Levels 1 & 2**
- **Central Administration of
Site-Specific Committees**

HOW

- **Structure**
- **Functions**
- **Meeting Forum**

STRUCTURE

- **Membership**
- **Accountability**

FUNCTIONS

- **Resource for Site**
- **Protocol Evaluation**
- **Site Assessment**
- **Consent Form**
- **Recommendations**

MEETING FORUM

- **Discussion Format**
- **Public Access**
- **Multi-Center Studies**

**This biosafety committee
model can provide the
benefits of both “on-site”
reviews and central
coordination.**

BENEFITS OF CENTRAL COORDINATION

- **Greater Access to Expertise**
- **Best Practices for Compliance**
- **Consistent Oversight**
- **Minimizes Conflicts of Interest**

The Guidelines should be interpreted to allow for flexibility, while maintaining stringent oversight.