

# Welcome to T2K! Time to Break Old Habits

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**A** NEW MILLENNIUM — *if ever there was a right time to break bad habits, to start afresh and to make predictions, this is it. The global clinical research community can use this momentous occasion as a springboard for implementing changes to improve operations. I propose we declare Y2K as the launch for T2K — Training 2000 — the beginning of a new era in training initiatives for those involved in bringing new medical products to market. Our common goal is to enhance regulatory, protocol and ethical compliance by everyone involved.*

In the US, both the Food and Drug Administration (FDA) and the Office for Protection from Research Risks (OPRR) have indicated a growing interest in seeing evidence of Good Clinical Practice (GCP) training, particularly for clinical investigators, monitors and institutional review board (IRB) members. Regulatory, protocol and ethical noncompliance can frequently be linked to inadequate training. Every clinical research organization at every level needs to make training a priority. It is far better to be proactive and ahead of the crowd rather than reactive and trailing behind.

We launch our T2K initiative by examining two common and ineffective organizational training habits — inadequate training records and insufficient training budgets — and offering strategies for changing them into proactive, benchmarking standards.

## TRAINING HABITS

### **Old Habit #1:**

#### **Inadequate training records.**

The proverbial, “If it wasn’t documented, it wasn’t done,” applies to training activities as it does to clinical research. If it is important enough to

warrant training, it is important enough to document.

### **New Habit #1:**

#### **Training activities will be documented and records will be organized, complete and available.**

Comprehensive training records typically include the following documents:

- standard operating procedure (SOP) for training
- training calendars
- detailed training plans
- participant training materials
- trainer’s manuals
- attendance sign-in sheets
- certificates of completion
- participant evaluations for each training activity
- internal report for each training activity
- individual training files.

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Depending on the size of the organization, administrative support for the trainer is critical for developing and maintaining these records.

**Old Habit #2:  
Insufficient training budgets.**

Because management is cost-conscious and responds to numbers, training should have a budget. Training expenses should be planned and followed monthly, quarterly and annually.

**New Habit #2:  
Training expenses will be projected and tracked; training budgets will be organized, complete and available.**

Comprehensive training budgets typically include the following categories:

- trainer(s) and administrative staff salaries
- prorated participants' salaries while they attend training
- registration for external meetings and conferences

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- "off-the-shelf" instructional programs
- reference materials
- training aids
- production and printing costs
- equipment
- "on-site" training programs
- consultants
- travel expenses
- meeting services.

The more detailed the expenses, the better the budget will be at capturing the true costs of training. Historical data is an important source for justifying training expenses.

Now that Y2K has become the newest addition to our global lexicon and Y2K momentum and expectations are high, we ought to take advantage of this unique opportunity and move Y2K up to the next level — T2K — Training 2000. We can jump start our T2K initiative by forever banishing two disagreeable habits — inadequate training records and insufficient training budgets. Let's make 2000 the beginning of many new training initiatives for the global clinical research community.

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