# Life Cycle of an Expedited Project

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# Life Cycle of an Expedited Project

*“I’ve got my hands on the wheel, and my big foot on the gas”*

*- Sammy Hagar*

# Planning Stage

- Identify projects requiring expediting
  - National Research Planning Meeting (NRPM)
  - Determine timing of the project
    - 24 months
    - 18 months
    - <18 months
  - Some projects are adjusted on the fly based on registrant submissions.

# Planning Stage

- Keep everybody in the loop
  - Registration Manager, Study Director, RFCs, FRDs, LRD and QA.
  - Several steps are required to pull off an expedited project so good communication is critical.

## Laboratory Setup

- Early validation of analytical method using existing untreated control samples or store-bought controls.
- Preparation of storage stability samples.

# Sample Progress and Shipping

- Coordinate with RFCs and FRDs when field trials will be harvested.
- Determine shipping method
  - Fed-Ex
  - ACDS
  - Try to balance extra cost and risk with Fed-Ex shipping vs samples taking longer via ACDS.

## Sample Analysis

- Schedule sample analysis when the majority of samples have arrived.
- Prioritize sample processing to keep the samples coming to the analyst(s).
- Maximize sample set size to minimize overall analysis times (12-20+ samples/set).
  - Utilize multiple chemists if needed.

## Sample Analysis

- Coordinate closely with QAU for critical phase audits.
- Update Registration Manager and Study Director on progress.

# ASR Preparation

- Skeleton of ASR can be prepared once method validation is complete.
- Data from each analytical set is added to ASR on the fly.
- ASR is proofread and QAU is apprised when they should expect the ASR for QA auditing.
- Analyst(s) and report writer work quickly to address findings.

# Examples of Expedited Projects

- PR#10635 Spirotetramat/Pineapple
  - 5 trials, 3 crop fractions (RAC, juice, processed fraction)
  - Critical time points identified on P. 1 of protocol.
    - Exp. Start:  12/2010
    - Exp Termination:  2/2012
    - Study Completion:  11/2012
    - 23 months

# Examples of Expedited Projects

- PR#10635 Spirotetramat/Pineapple
  - Method was validated shortly before the arrival of the last field trial (7/11).
  - Analysis was completed in 2 weeks (8/11).
  - All samples shipped via Fed-Ex
  - Report to QA: 8/11
  - Report to HQ: 10/11

# Examples of Expedited Projects

- PR#B8873 Etoxazole/Hops
  - 4 trials
  - Critical time points identified on P. 1 of protocol.
    - Exp. Start:  3/11
    - Exp Termination:  12/11
    - Study Completion:  6/12
    - 15 months

# Examples of Expedited Projects

- PR#B8873 Etoxazole/Hops
  - Method was validated shortly before trials arrived (10/11)
  - Analysis was completed in 1 week (10/11)
  - All samples shipped via ACDS
  - Report to QA: 10/11
  - Report to HQ: 11/11

# Examples of Expedited Projects

- PR#09289 Quinoxyfen/Tomato
  - 13 trials, 3 crop fractions (RAC, puree and paste).
  - Critical time points identified on P. 1 of protocol.
    - Exp. Start:  3/11
    - Exp Termination:  11/12
    - Study Completion:  10/13
    - 30 months

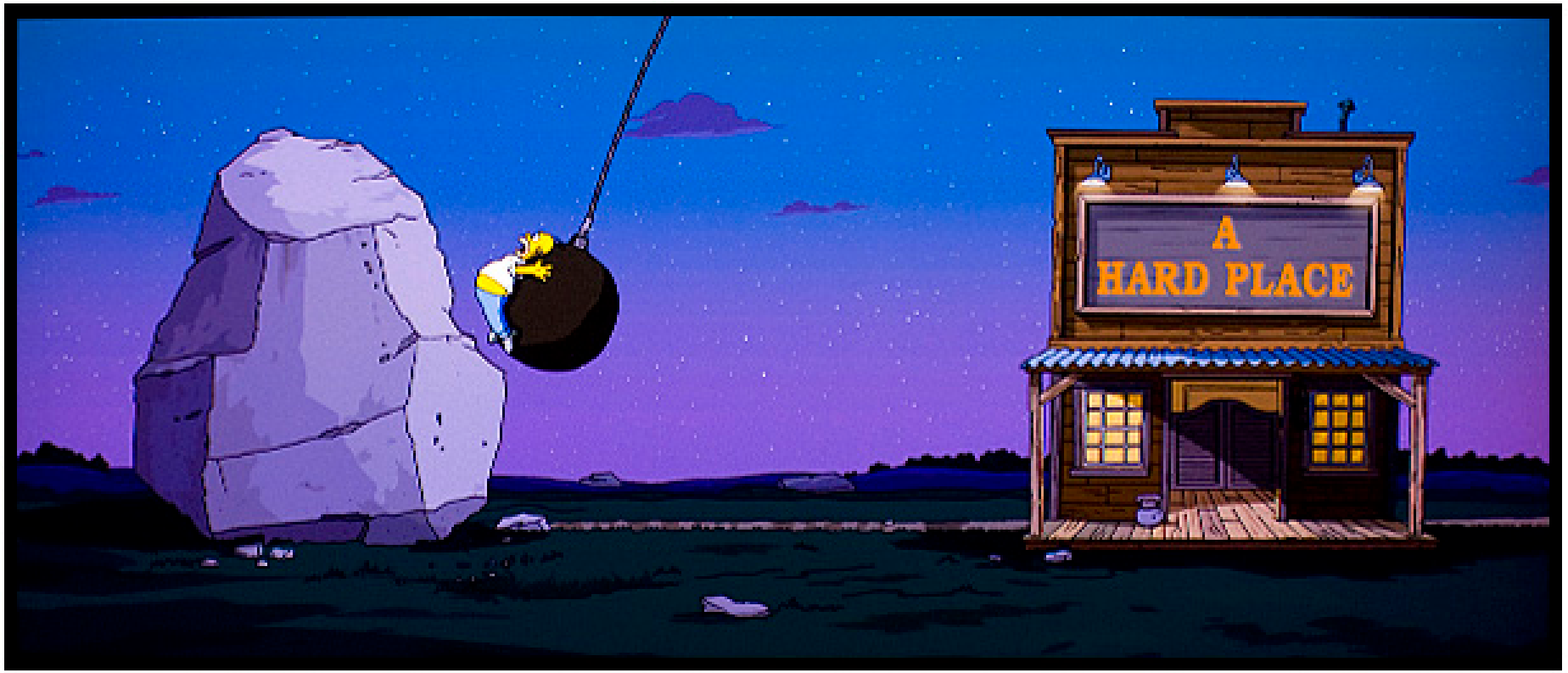
# Examples of Expedited Projects

- PR#09289 Quinoxyfen/Tomato
  - And then Dow called…….
  - New time points
    - Exp. Termination:  4/12
    - Study Completion:  9/12
    - 18 months

# Examples of Expedited Projects

- PR#09289 Quinoxyfen/Tomato
  - Method was validated after the arrival of the last sample (12/11)
  - Analysis was completed in 2 weeks (12/11)
  - All samples shipped via ACDS
  - Report to QA:  12/11
  - Report to HQ:  1/12

## And just remember…….




# COMMUNICATE!!!