

NAV1.954449.006

NM6SD-137

INVESTIGATIONAL AGENT STATUS REPORT

REPORT 57180L MED 6710-10

1. FROM: Commanding Officer
 Naval Hospital
 San Diego, CA 92134-5000

TO: Recorder, NIDRB, Naval Health Sciences
 Education and Training Command (Code 31)
 Naval Medical Command, National Capital
 Region, Bethesda, Maryland 20814

VIA:

2. CIP/R&D PROJECT NO.
 #87-02

3. TITLE
 Emergency One-Time Use of 5-Azacyridine on a Single Patient

4. INVESTIGATIONAL AGENT
 5-Azacytidine

5. FIRST REPORT?
 YES NO

6. PROJECT STATUS

A. Emergency use in one patient only.

B. Drug/device used

C. Protocol active

On going approved protocol.

Drug/device not used

Protocol completed

Protocol abandoned

Drug has received FDA approval (Date of FDA approval)

7. PRIMARY EFFECT

Positive effect on the course of patient's condition

Undetermined effect

Adverse effect (Specify below)

No effect

8. SIDE EFFECTS

None

All side effects were explained within the consent form.

Side effects were unanticipated and not explained within the informed consent. (Specify below, attach a copy of the revised CPHS-approved consent form which indicates the new side effects, and complete section 9)