

Reasons for CRADA Delays

In the Past

- Sponsors hesitant and not familiar with CRADA process
- ORO
- Little experience within the VA system working through CRADAs and CRADA challenges
- Growing pains as VMRF and VA work with CRADAs' R&D processes

Ongoing

- Sponsors waiting for Master to be completed
- Sponsors insist on Non Exclusive Royalty Free License (NERF) in Phase I or II trial
- Lacking responsiveness by Sponsors
- Sponsors use outside legal counsel

Going Forward

- More Master CRADAs and single use CRADA “repeat customers”
- Experience with who in the VA can help with which issue
- More defined R&D processes and significant process improvements

LIST OF CRADA MASTERS

FULLY APPROVED:

(for Phase III and IV)

- Amgen
- Genentech
- Novartis
- Pfizer
- Roche
- Sanofi-Aventis
- Sucampo
- Bristol-Myers Squibb
- Astellas

If a phase II with these companies is needed please contact Tami Penner (tami@vmrf.org).

IN CONCURRENCE PROCESS:

(for Phase III and IV)

- AstraZeneca
- Avigen
- Lilly & Lilly (when Quintiles is CRO)
- Merck
- Takeda
- OncoGenex
- GSK
- Regeneris Biomedical, Inc.

Under NEGOTIATION and/or Companies who have expressed an interest:

- Abbott
- Boston Scientific
- OSI
- Boehringer-Ingelheim
- Novo Nordisk
- Fibrogen Celgene
- Medtronic
- Lantheos