IMPROVING SIGNAL-TO-NOISE RATIO IN SAFETY REPORTING

Clinical Innovators Summit

Organized by

Clin clinical works

May 1, 2019

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LEUKEMIA & LYMPHOMA SOCIETY®

THANK YOU

- **Len Rosenberg, PhD, RPh**
  Head, Clinical Operations Beat AML, LLC,
  A Division of The Leukemia & Lymphoma Society
  @LLSusa

- **Spencer Kalk**
  Associate Project Director
  Syneos Health

WHO IS LLS?

- The Leukemia & Lymphoma Society (LLS) is the world's largest nonprofit dedicated to fighting blood cancers.

- The LLS mission: Cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families.

- LLS funds research to advance lifesaving treatments, is the leading source of free education and support services, and advocates for state and federal policies on behalf of all blood cancer patients.

LEUKEMIA & LYMPHOMA SOCIETY®

LLS TAKES ON MOST DAUNTING CHALLENGE IN AML

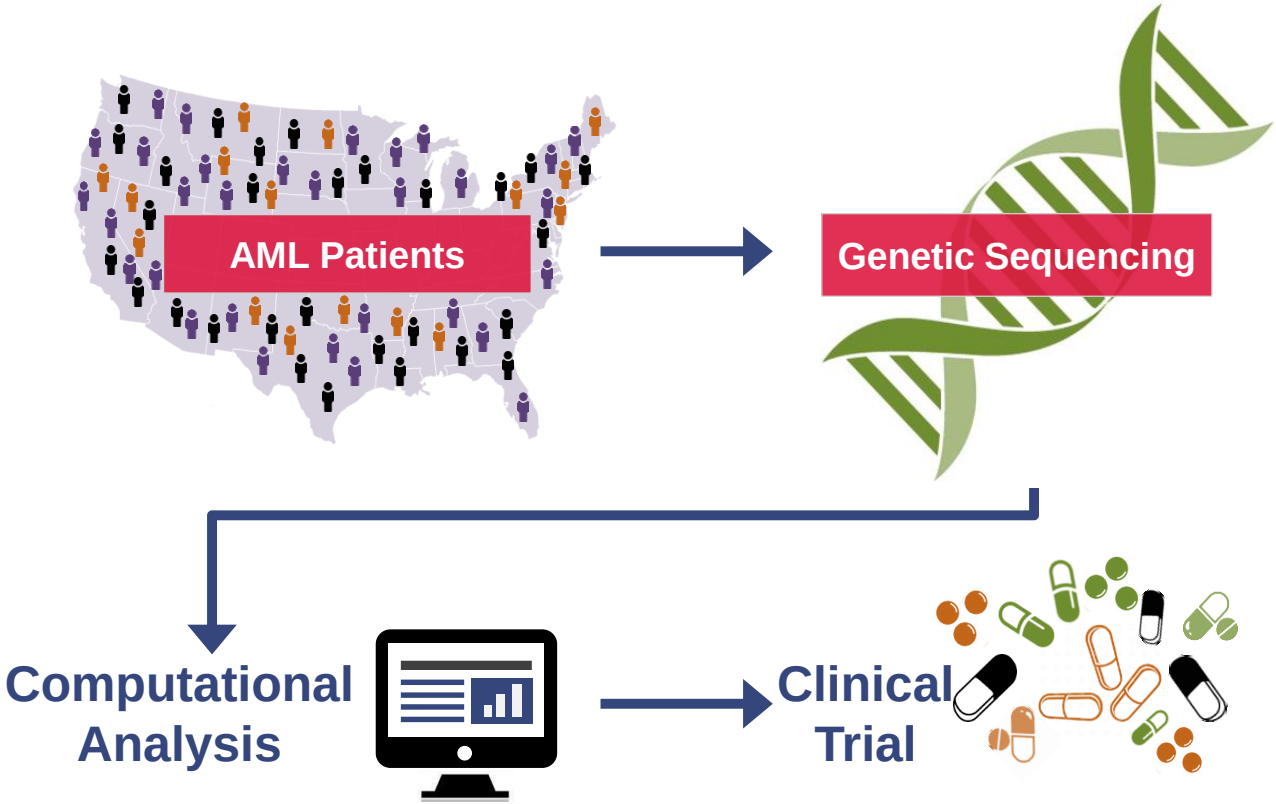
- **Most commonly diagnosed form of leukemia in adults**
- **Historically portends a dismal prognosis**
- **Standard of care has not changed much since the 1970s**
- **Even with intensive chemotherapy or bone marrow transplantation most older patients die of their disease**

With today's therapies,

only 1 in 4 AML patients survives

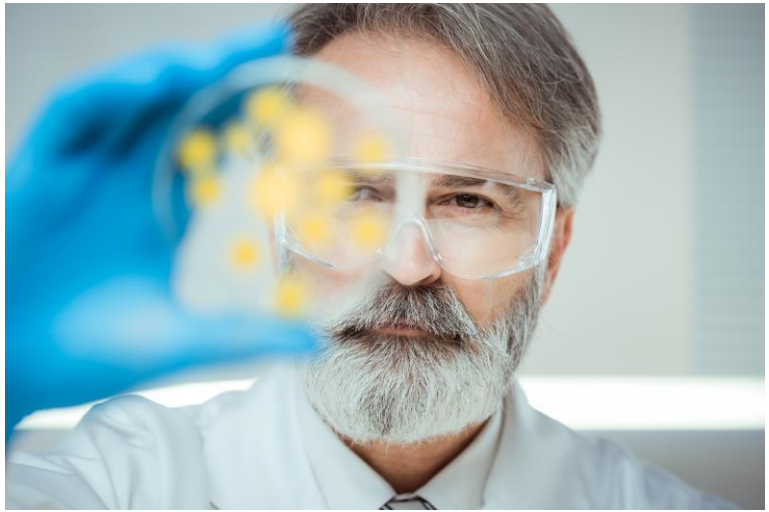
5 years beyond diagnosis

Beat AML®: Precision Medicine Approach to Treatment



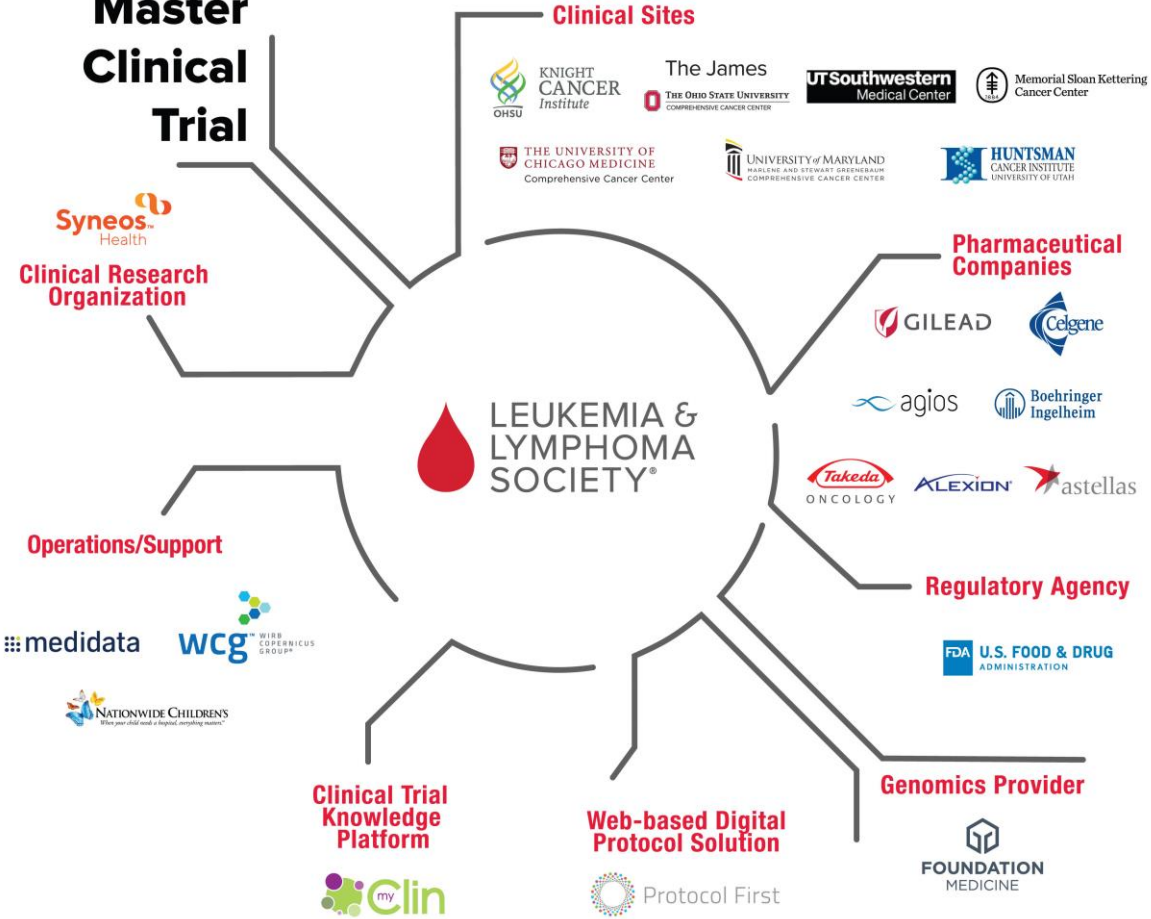
TRADITIONAL CLINICAL OPS WON'T WORK

- Master trial demands we challenge the norms
- Changing science requires changes in execution and operation
- Need alignment between IRB, contract/budgeting process, pharma partners, 3rd party vendors
- Important collaboration and compliance challenges (ICH E6 R2)



Beat AML® Master Clinical Trial Organizational Structure

Beat AML® Master Clinical Trial



Conventional vs. Master Trial

Conventional Trial	Functions	Master Trial
3	Labs (PK, PD, Banks, etc)	15+
1	Clinical Suppliers	2+
1	Pharma Sponsors	8+
1	Protocol(s)	10+
1+	Compounds	10+
1	PVG	10+
2	Vendors	5+
1	CRO	1
=	Sites	=

MASTER PROTOCOL CHALLENGES

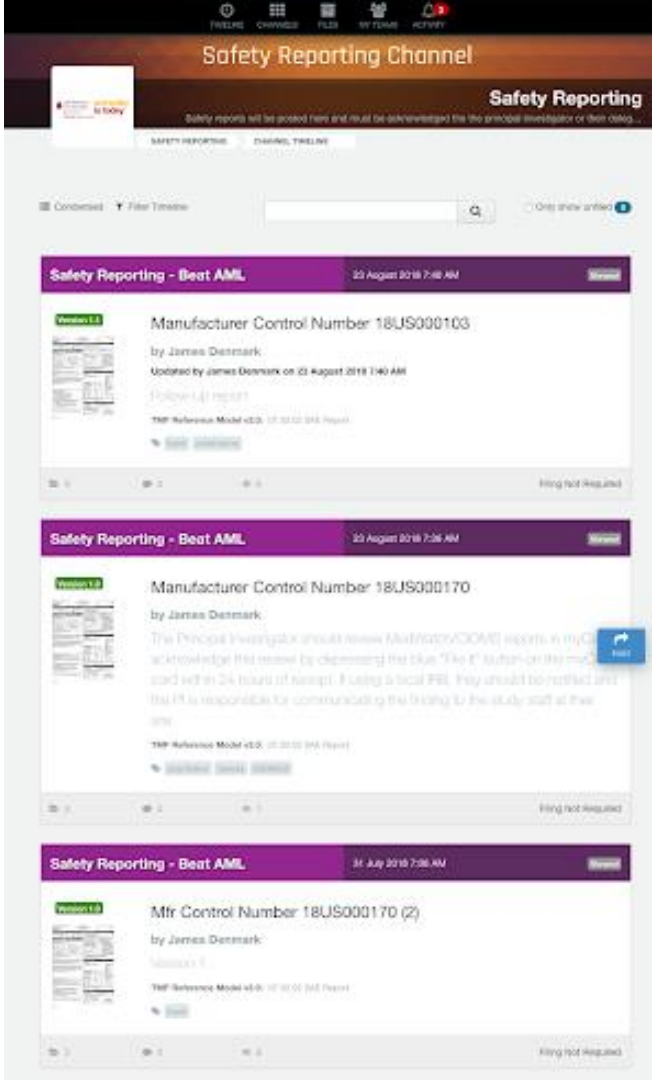
- Complexity, including combination arms
- Arduous information flow
- Early (and often) safety and efficacy evaluations
- Legacy data management systems
- Ongoing safety reporting (overload)
- ICH E6-R2 regulations overhang

ILLUSTRATION OF COMPLEXITY – PVG REPORTING

- **Beat AML holds IND that cross-files to Pharma Partner INDs**
  - PVG Agreements with each Pharma Partner
  - Beat AML Master Trial defines events for expedited FDA Reporting – different than Pharma Partners
  - FDA Regulations – do not specify obligations in this situation
  - Central IRB reporting requirements?
- **Novel/Novel Treatment Arms**
  - Two or more Pharma Partners involved
  - Curation of events vs reporting obligations
- **Clinical Research Sites and Local Reporting**
  - When and how often to report?
  - Formal acknowledgments

PVG - SAFETY

- Disease-related SUSARs – no need for cross reporting
- Cross reporting –IND holder defines if and how periodic reports are submitted
- PVG agreements, with Pharma at outset
- Weekly safety calls with PIs and coordinators
- Planning for combination trials and AEs of special interest

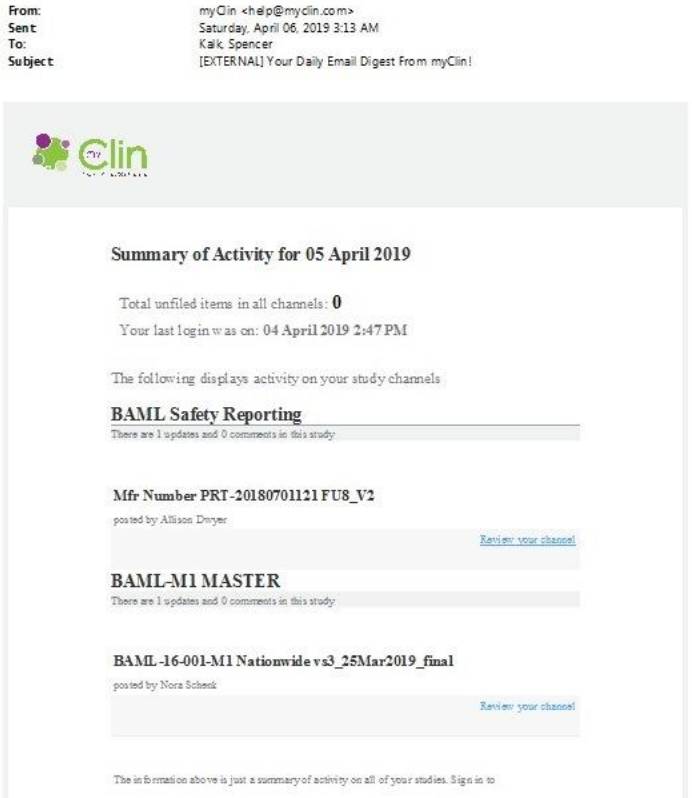


PVG – MYCLIN – FOR SIMPLIFIED SAFETY REPORTING

Benefits:

- 75-80% reduction in emails
- PVG reporting integrated with main study communication
- Robust, auditable acknowledgment mechanism for compliance
- Central, searchable archive of PVG reports

Overall outcome: ***Less noise, more signal***



From: myClin <help@myclin.com>
Sent: Saturday, April 06, 2019 3:13 AM
To: Kalk, Spencer
Subject: [EXTERNAL] Your Daily Email Digest From myClin!

myClin

Summary of Activity for 05 April 2019

Total unfiled items in all channels: **0**

Your last login was on: **04 April 2019 2:47 PM**

The following displays activity on your study channels

BAML Safety Reporting

There are 1 updates and 0 comments in this study

Mfr Number PRT-20180701121 FU8_V2

posted by Allison Dwyer

Review your channel

BAML-M1 MASTER

There are 1 updates and 0 comments in this study

BAML-16-001-M1 Nationwide vs3_25Mar2019_final

posted by Nora Schenk

Review your channel

The information above is just a summary of activity on all of your studies. Sign in to

MYCLIN

An IT Platform for Compliance, Communication and Collaboration

Features

- Create central communications Hub for correspondence and stakeholder communication
- Reference documents – single source of the truth
- Training
- Compliance / audit trails
- Consolidated e-mail updates – daily and weekly
- Provides an electronic investigator study file
- Very low adoption burden for site users
- Fast, flexible and adaptable setup
- Administration managed by project staff
- Channels gate information to specific pharmas

THE LEUKEMIA & LYMPHOMA SOCIETY IS AT THE FOREFRONT OF THE FIGHT TO CURE CANCER.

- This is not just another clinical trial…this is a paradigm-shifting trial not only for blood cancers but for any devastating disease
- Demonstrates the “nimbleness” of LLS to manage a complex, highly visible and dynamically changing program
- Decision-making is quick and oversight maintained with a small group

THANK YOU

Clinical Innovators Summit

Organized by

myClin clinical works

We have one goal: A world without blood cancers

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