

# FORTE Update



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**NRG**  
ONCOLOGY

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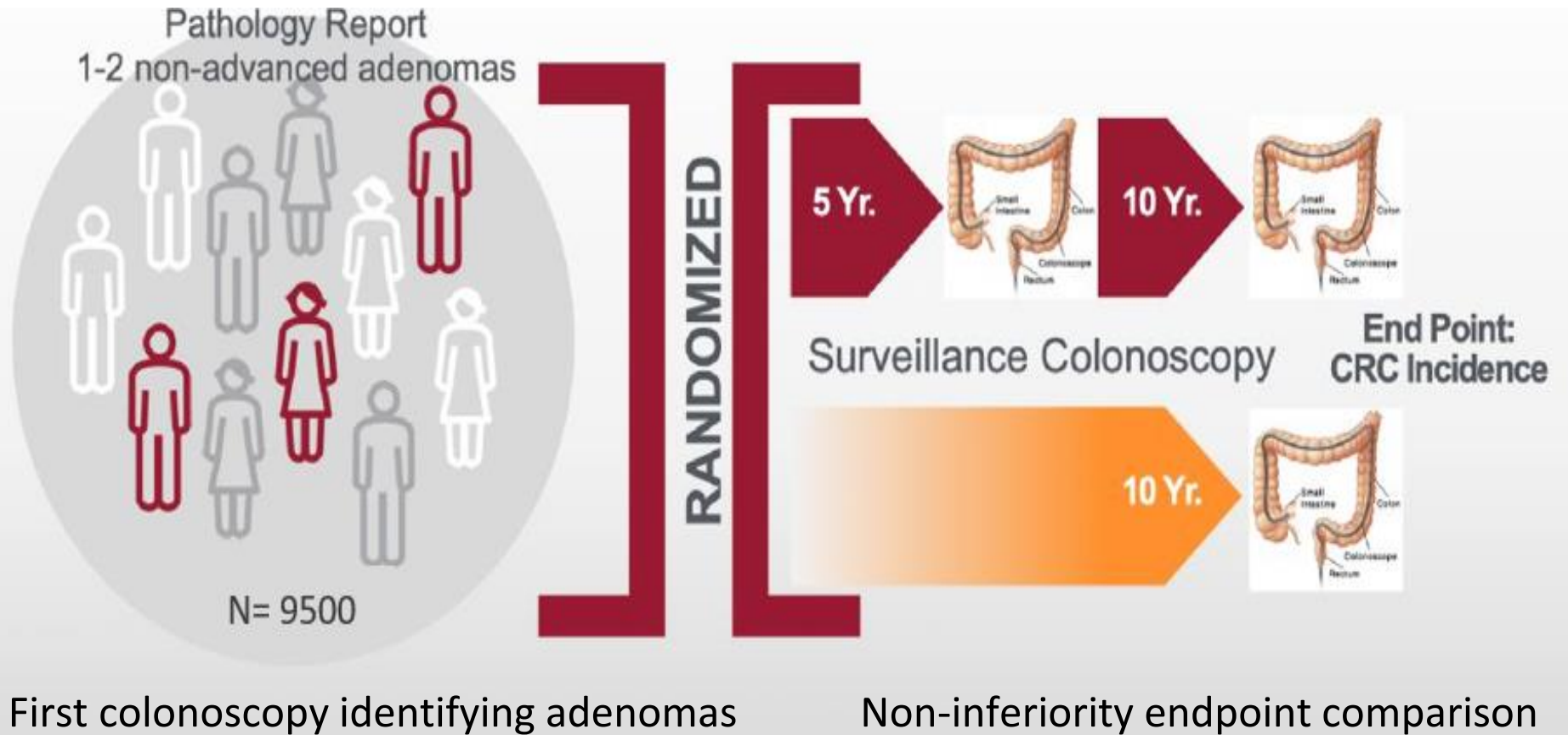
**NCORP**  
NCI Community Oncology  
Research Program

# What is FORTE?

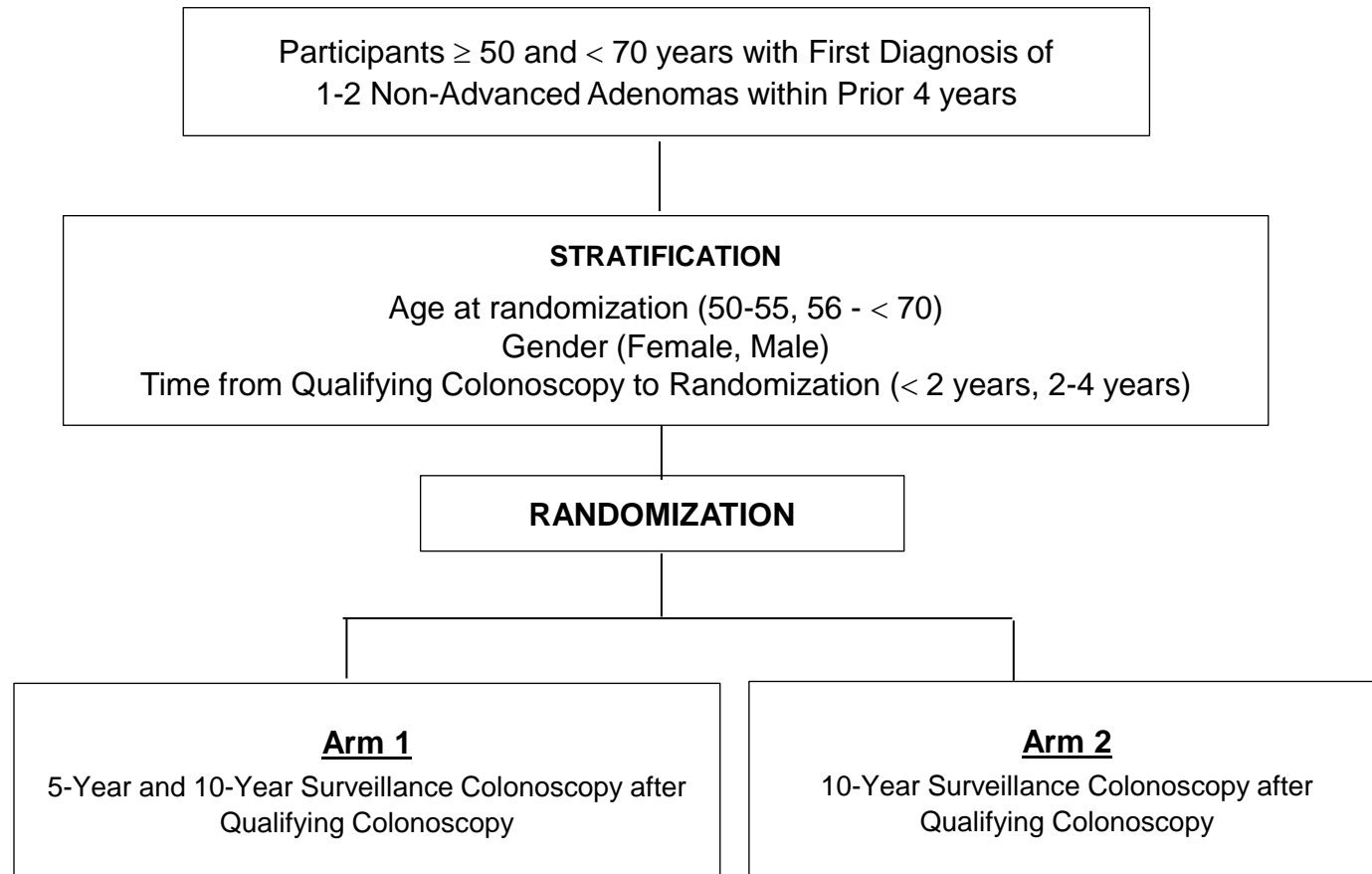
## FORTE:

Five **OR** Ten year colonoscopy for 1  
or 2 non-advanced adenomatous  
polyps.

# Schema



Qualifying Colonoscopy up to 4 yrs Prior to Randomization



Biorepository: One time blood draw, Stool q2y x 3

May 7, 2024



Thank you

1500

PARTICIPANTS

FORTE STUDY

# FORTE by the numbers...



**1500**

Total participants on  
May 7, 2024

**53**

Sites have randomized at  
least 1 participant

**115**

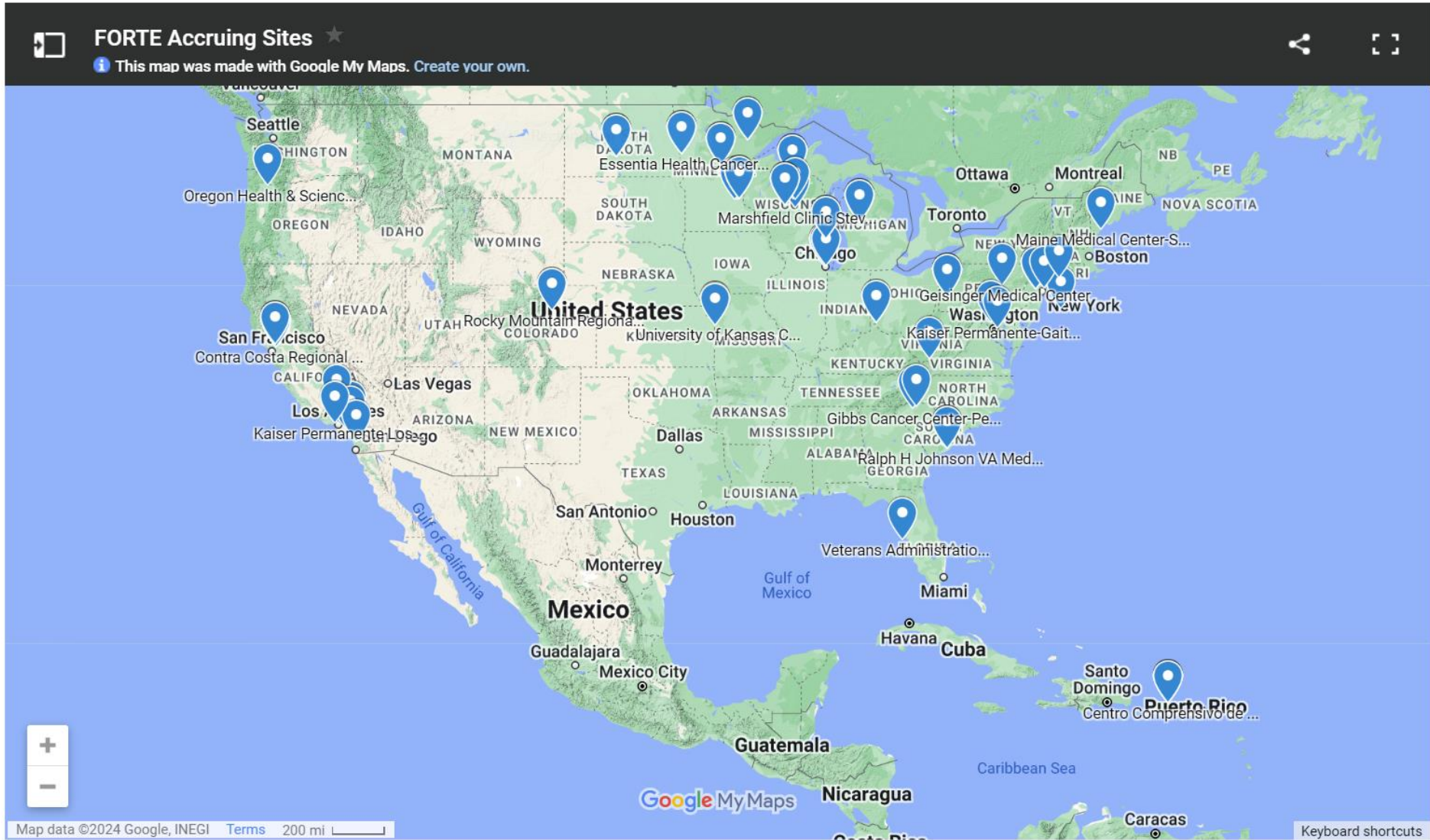
Participants accrued in  
March 2024

**5**

VA sites have randomized at  
least 1 participant

**Get involved with this colorectal cancer prevention clinical trial today!**

# March 29, 2024



- NCI set minimal recruitment goal of 950 by Sept 30, 2023
- FORTE recruited 941 by that date: 99.1% of goal
- Recruitment was supposed to increase from minimum of 63/month to 119/month beginning Oct 1, 2023

We need more centers and  
We need centers to perform at higher recruitment rates



## Recruitment: More enrollment per site:

- a. Patient Incentives
- b. Efficiency: Remote consent and Blood draw
- c. Advance IT to improve identification of eligible participants.

# Incentives

- “You will not be paid to take part in this study”
- \$0 - \$40 - \$100 for “travel allowance” or “offset the cost of your inconvenience and time”
- \$0 - \$25 - \$100 for submission of stool and/or blood specimen
  - Improve compliance with submission
  - Increases incentive to participate
- Incentives are a site by site decision
- We encourage sites to consider incentives

- Consent and Enroll Remotely
  - Phone call/zoom – participant sends photo or scan or snail mails their consent
  - Redcap – signature on phone or computer, copy automatically returns to patient
  - DocuSign
- Remote Blood Draw
  - U. Pittsburgh – >100 enrollees – who otherwise wouldn't do it!
  - No budgetary hit at site level
  - NRG Central Facilitation

# Electronic Identification of Eligible Participants

- Home grown tools: adenoma detection rate database
- EPIC – reminder systems (<4 years), Report generators – e.g. Provation, linking with pathology?
- NLP can analyze CS/pathology reports



# Pieces NLP Pipeline Criteria for FORTE Study

## Inclusion

- Procedure: Colonoscopy
- Patient age:  $\geq 50y$  AGE  $< 70y$
- Indication for colonoscopy: Screening or Diagnostic (not Surveillance)
- Complete colonoscopy with visualization of the cecum
- Adequate cleansing, per bowel prep score or evaluation
- Identification of 1-2,  $< 10mm$ , non-advanced, tubular or serrated adenomatous polyps

## Exclusion

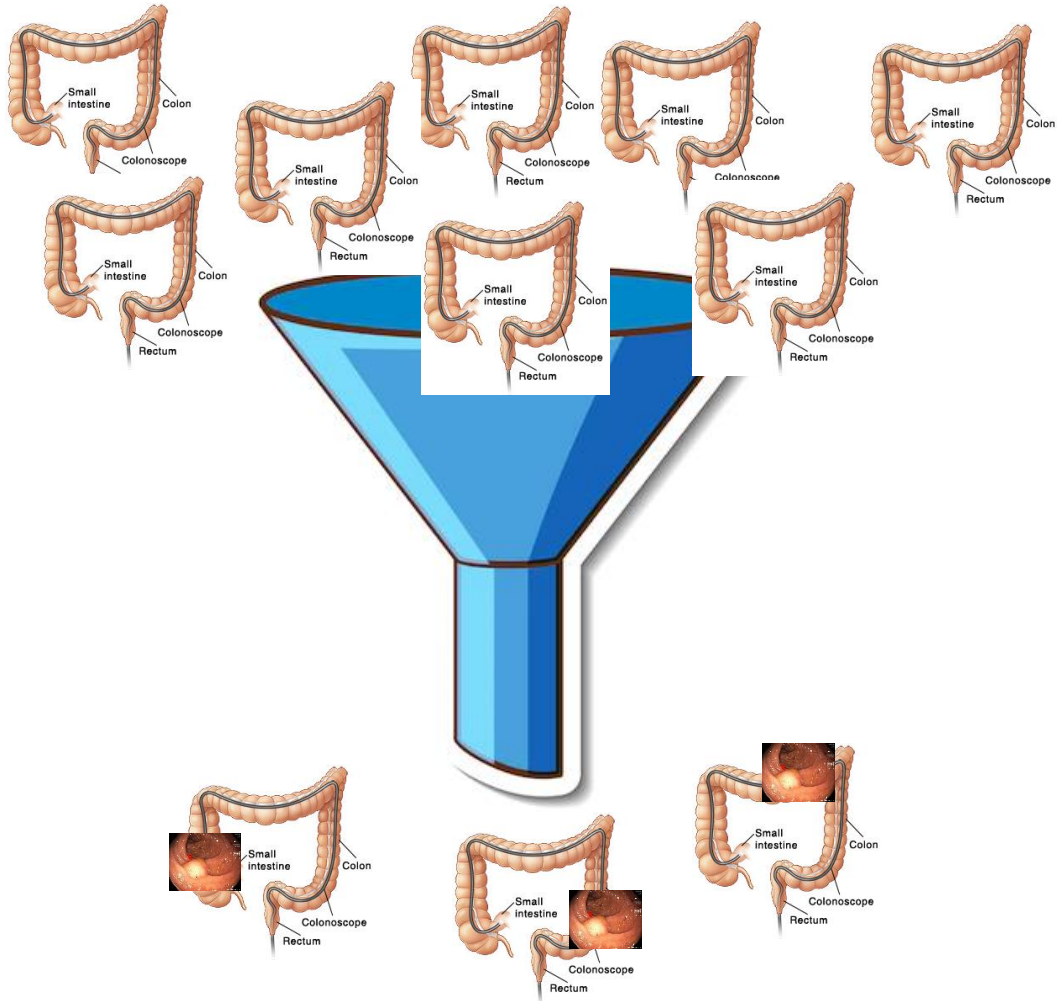
- Any advanced polyp identified, defined as:
  - villous or tubulovillous
  - traditional serrated
  - high-grade, cytologic, or severe dysplasia
  - hyperplastic polyp  $\geq 10mm$
- Adenocarcinoma of any part of the colon identified
- Tubular adenoma  $\geq 10mm$



## Pieces NLP Pipeline Validation - Comparative Analysis

Findings	UPitt	Pieces
Non-advanced adenoma	1,141 (27%)	1,128 (27%)
Advanced adenoma	411 (10%)	346 (8%)
No adenoma	2,671 (63%)	2,749 (65%)
Total	4,223	4,223

- Both UPitt and Pieces analyzed the same data set
- Neither is a gold standard or had 100% of cases reviewed
- Findings demonstrate a very high degree of overlap, thus validating both pipelines





- Exploring possibility of cloud based NLP application, that site could use to analyze it's own data within it's own system
- Application for up to 12K in funds to Pay for IT participation at individual sites

# Recruitment: More Sites

## “SuperSite” Initiative

- Continuous quest to enroll new centers:
  - VA
  - NCTN: Alliance/SWOG
  - More LAPS (lead academic participating sites)
  - Private Practice Groups

# SuperSite Initiative

<b>Funding Amount</b>	<b>\$10,000-\$50,000</b>	<b>\$50,000-150,000</b>	<b>\$150,000 - \$300,000</b>
<b>Enrollment Expectation per month</b>	<b>&gt;10</b>	<b>&gt;15</b>	<b>&gt;25</b>
<b>Patient Contact Expectation per month*</b>	<b>&gt;100</b>	<b>&gt;150</b>	<b>&gt;250</b>

\* Trial data thus far show that about 10 unique patient contacts are needed to successfully enroll a single patient. This estimate is for pre-screened, likely eligible participants with 1-2 non-advanced adenomas and includes mail and phone contact. Contacting a less-curated list will require even more outreach.

# Real-World Compliance with MSTF 2020 Guidelines

B.I. Deaconess: 3/21 – 5/22 - Screening CS:  
How Many People are getting rec's for 7-10 yrs?

N (%)	Pre-Guideline	Post-Guideline	P
LRA's	1/121 (0.8)	19/230 (8.3)	0.003

Only 8% of people were getting 7-10 year f/u recommendation  
The Standard of Practice Remains 5 yr Surveillance



Letter dated 6/18/2021  
to FORTE investigators:



**“The ACG, AGA, ASGE support  
the conduct of the FORTE Trial”**



- FORTE is answering a common and practice defining clinical question
- FORTE will be impactful
- From a site perspective – the trial is relatively “easy” to implement and conduct – study team has developed a lot of resources and strategies to assist you

# The Future:

- a. Lower age to 45
- b. Join us!



Robert E. Schoen – PI/Protocol chair  
Jeffrey Dueker – Protocol co-chair  
Douglas Corley – Chief scientific officer  
Hannah Bandos – Lead Statistician  
Jinbing Bai - Microbiome

#### NCORP PI's

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Joan Walker  
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#### Cancer Prevention Committee

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#### NCI

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Julie Kardell  
Judy Langer  
Francy Fonzi

