Clinical Trials In A New Age:

How You Can Connect

Wednesday, February 25, 2015

To listen to the presentation by phone,

Dial: 866-952-1906

Code: TRIALS

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WELCOME

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Director of Navigation and Support Services

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THANK YOU

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OUR MISSION

Sharsheret is a national not-for-profit organization supporting young Jewish women and their families facing breast cancer. Our mission is to offer a community of support to women, of all Jewish backgrounds, diagnosed with breast cancer or at increased genetic risk, by fostering culturally-relevant individualized connections with networks of peers, health professionals, and related resources.

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BACKGROUND

- 1 in 40 Ashkenazi Jews carries a BRCA gene mutation
- ~ 80% risk of breast cancer
- ~ 40% risk ovarian cancer

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BENEFITS TO THE JEWISH COMMUNITY

- Attitudes of the Jewish community toward clinical trials
- Preservation of life
- Impact on the next generation

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CLINICAL TRIALS AND JEWISH LAW

- Travel and transportation
- Dietary concerns
- Family

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RESEARCH, ACCESS, AND PARTICIPATE

Susan Domchek, MD,

Executive Director

Basser Research Center for BRCA

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Susan Domchek, MD
Executive Director, Basser Research Center for BRCA
Basser Professor in Oncology
Abramson Cancer Center
University of Pennsylvania

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Clinical Trials Part I Recap

- Cancer clinical trials are research studies designed to learn how to better screen, treat, and prevent cancer
- Some studies are registries or biobanking studies
- Drug treatment trials for cancer
  - Goal is to find new medications which work BETTER than what we currently have

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Clinical Trials Part I Recap

- Less than 3% of people participate in cancer clinical trials. About 20% of patients are eligible.

- Some groups are less likely to participate or be asked to participate in trials, including some minorities and medically underserved groups.

- Your doctor will not always mention trials to you
  - No good trial for your situation
  - No trial at the site you are at
  - Never hesitate to ask:
    "Is there a trial for me?"

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Clinical Trials Part I Recap

- Drug treatment trials for cancer
  - Phase I: Examine toxicity (side effects)
    - Sometimes these are “first in humans”
    - Sometimes there are new combinations
    - Often multiple tumor types
  - Phase II: Examine efficacy (is there a signal?)
  - Phase III: Compare to standard of care

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What We Will Cover

- Finding a clinical trial
- Understanding your clinical trial
- Challenges of clinical trials
- Questions to ask
- Special considerations for *BRCA1/2* carriers
- From Bench to Bedside

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Finding a Clinical Trial

- Talk to your local medical oncologist
- Connect with your local, academic medical center
- Visit clinicaltrials.gov
- Visit basser.org/openstudies or Facing Our Risk of Cancer Empowered (FORCE)

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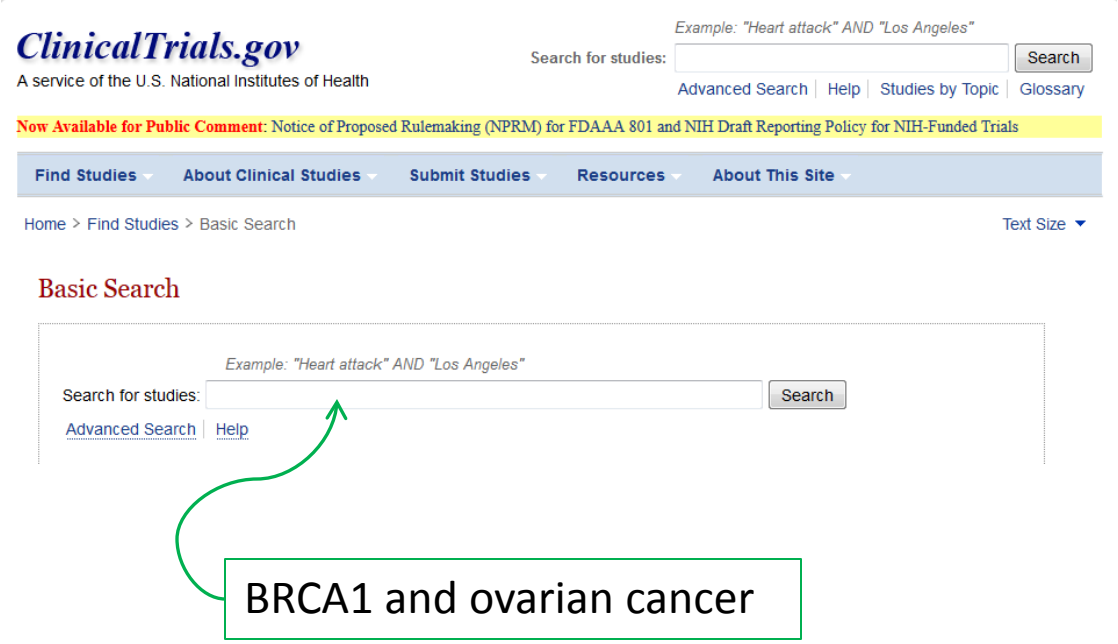
Finding a Clinical Trial

Example: A 40 year old woman with a *BRCA1* mutation is looking for trials related to ovarian cancer.



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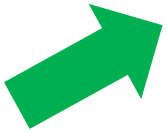

Recruiting	BMN 673 (Talazoparib), an Oral PARP Inhibitor, in People With Deleterious BRCA1/2 Mutation-Associated Ovarian Cancer Who Have Had Prior PARP Inhibitor Treatment	
	Condition:	Ovarian Cancer
	Intervention:	Drug: BMN 673 (talazoparib)
Active, not recruiting	AZD2281 Plus Carboplatin to Treat Breast and Ovarian Cancer	
	Conditions:	Breast Cancer; Ovarian Cancer
	Intervention:	Drug: AZ2281 + Carboplatin
Not yet recruiting	BRCA1 and BRCA2 Mutation in Romanian Population: a Study of Genotype - Phenotype Correlation at Diagnosis With Prospective Disease Outcome and Survival	
	Condition:	To Determine the Prevalence, Penetrance of BRCA1 and BRCA2 Mutations in Romanian Womens With Breast or Ovarian Cancer
	Intervention:	Genetic: NGS BRCA 1 and BRCA 2 full sequencing
Active, not recruiting Has Results	Study to Assess the Efficacy and Safety of a PARP Inhibitor for the Treatment of BRCA-positive Advanced Ovarian Cancer	
	Condition:	Ovarian Neoplasm
	Intervention:	Drug: KU-0059436 (AZD2281)(PARP inhibitor)

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Finding a Clinical Trial

Example: A 40 year old woman with a *BRCA1* mutation is looking for trials related to ovarian cancer.

104 studies found for: BRCA1 and ovarian cancer

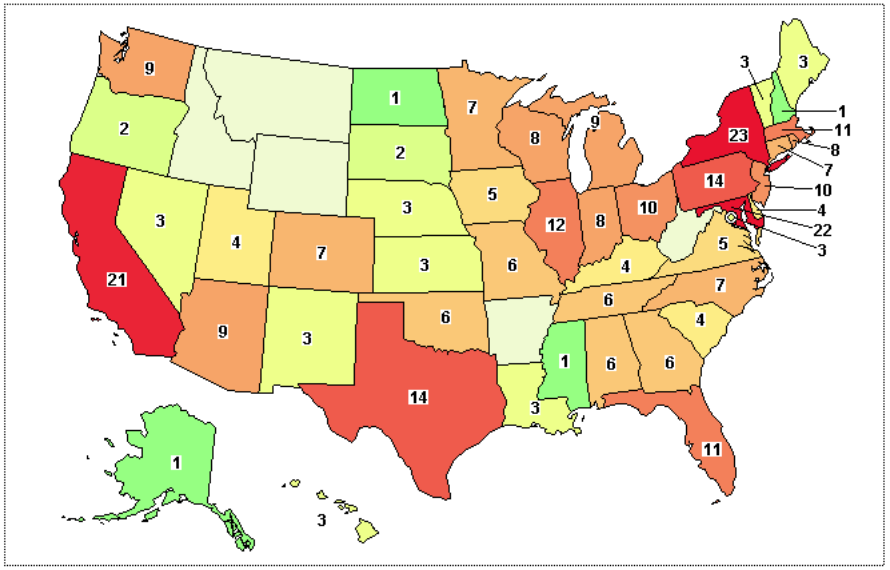
Modify this search | How to Use Search Results

List | By Topic | On a Map | Search Details

104 studies found, shown on map.

A similar map is available for all studies in ClinicalTrials.gov

Click on the map below to show a more detailed map (when available) or search for studies (when map not available).



Can search a list, by location or by topic

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Finding a Clinical Trial

Example: A 40 year old woman with a *BRCA1* mutation is looking for trials related to ovarian cancer.

BMN 673 (Talazoparib), an Oral PARP Inhibitor, in People With Deleterious **BRCA1**/2 Mutation-Associated **Ovarian Cancer** Who Have Had Prior PARP Inhibitor Treatment

A Phase 2 Pilot Study of BMN 673 (Talazoparib), an Oral PARP Inhibitor, in Patients With Deleterious **BRCA1**/2 Mutation-Associated **Ovarian Cancer** Who Have Had Prior PARP Inhibitor Treatment

Background:

- The new drug BMN 673 (talazoparib) has been shown to fight **tumor** cells in animals and some people. It is a PARP inhibitor. It works on **tumor** cell DNA damage repair process. Researchers want to see if BMN 673 shrinks **cancer** again in women with **ovarian cancer** and whose **cancer** initially got shrunk but grew back on the first PARP inhibitor.

Objective:

- To study BMN 673 (talazoparib) in people with **ovarian cancer** born with a **BRCA** mutation and whose **cancer** got shrunk but became worse after they took a similar drug.

Eligibility:

- Women at least 18 years old:
- with recurrent and/or metastatic gBRCAm-associated **ovarian cancer** AND
- whose disease is growing after already being treated with PARP inhibitors AND
- with no other treatment(s) in between the first PARP inhibitors and a screening visit.

Do you meet these criteria?

Design:

- Participants will be screened with medical history, physical exam, and heart and blood tests.
- Participants will take the study drug by mouth once daily. They will take the drug in 28-day cycles.
- They will keep a diary of doses and any side effects.
- Participants will have 4 study visits in cycle **1**, then **1** visit every cycle. Visits may include:
- Blood tests
- Physical exam
- Computed tomography (CT) or magnetic resonance imaging (MRI) scans. Participants will lie in a machine that takes pictures of their body.
- Ultrasound
- Participants will have a biopsy before starting the study drug. A small piece of **tumor** tissue will be removed by needle, guided by a scan. They may have two more biopsies later.
- Participants will be followed for 30 days after taking the last dose of study drug. A physical exam, blood tests, and CT or other scans will be done.
- Participants will have follow-up calls to ask about any side effects.

Are you willing and able to participate in these interventions?

Location and contact information also listed for each open study.

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Finding a Clinical Trial

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What We Will Cover

- Finding a clinical trial
- Understanding your clinical trial
- Challenges of clinical trials
- Questions to ask
- Special considerations for *BRCA1/2* carriers
- From Bench to Bedside

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Understanding Your Clinical Trial

- Eligibility Requirements
- Clinical Trial Phases
- Informed Consent
- Institutional Review Board & Data Safety Monitoring Boards

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Eligibility Requirements

- Inclusion and exclusion criteria regarding age, gender, disease stage, prior treatments, and other medical factors

A Randomized, Phase 2 Study of the Efficacy and Tolerability of Veliparib in Combination with Temozolomide or in Combination with Carboplatin and Paclitaxel Versus Placebo Plus Carboplatin Paclitaxel in Subjects with BRCA1 or BRCA2 Mutation and Metastatic Breast Cancer

Eligibility:

- *BRCA1* or *BRCA2* mutation
- Advanced stage breast cancer

Characterization of High Risk Breast Cancer Families and Individuals Without BRCA1/2 Mutations (Whole Exome Sequencing Study)

Eligibility:

- No detectable *BRCA1* or *BRCA2* mutation through clinical genetic testing
- At least 18 years old
- Previous diagnosis of breast cancer, whether male or female
- Family history of greater than 2 breast cancer cases in family members
- Pre-test chance of testing positive for a *BRCA1/2* mutation is greater than 30% (to be determined by genetics specialist)
- Woman with more than 2 primary cancers, 1 of those cases being breast cancer
- Woman with diagnosis of both breast and ovarian cancer.

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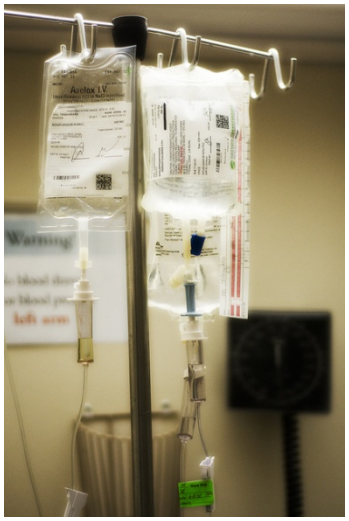
Phases of Clinical Trials

- Phase I: Examine toxicity (side effects)
  - Sometimes these are “first in humans”
  - Sometimes there are new combinations
  - Often multiple tumor types



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Phases of Clinical Trials

- Phase II - The drug or treatment is given to a larger group of people to see if it is effective ("signal" that it works) and check safely in larger group of patients
  - Usually the same tumor type
  - Sometimes randomized

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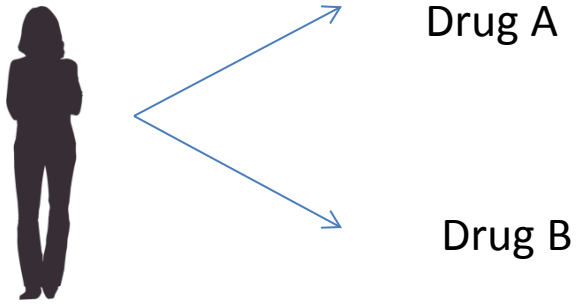
Phases of Clinical Trials

- Phase III - The drug or treatment is given to large groups of people to confirm its effectiveness and compare it to commonly used treatments

- RANDOMIZED:
  - Experimental arm
  - Standard of care arm
  - Neither you (nor your doctors!) get to pick

- Sometimes BLINDED
  - You don't know (during the study) which treatment you are getting



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Phases of Clinical Trials

equipoise

- *noun* equi·poise \ˈe-kwə-ˌpȯiz, ˈē-\

Definition of *EQUIPOISE*

1: a state of equilibrium

2: counterbalance

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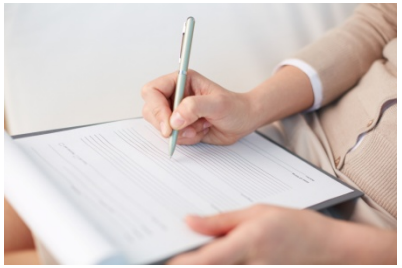
Informed Consent

- Information is provided to eligible individuals about a clinical trial
- Explains the **objective** of the study
- Explains the **risks** and **benefits** of the study
- Explains process for **withdrawing** from the study
- Individual has the option to sign, therefore providing informed consent, or decline



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Institutional Review Board

- The mission of the IRB is:
  - To promote the rights and welfare of human research participants
  - To facilitate excellence in human research by providing timely and high quality review of human research
  - To provide professional guidance and support to the research community

Source: University of Pennsylvania

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Data Safety Monitoring Boards

- Data Safety Monitoring Boards are:
  - Independent committees set up specifically to monitor data throughout the duration of a study to determine if continuation of the study is appropriate scientifically and ethically

Source: University of Pennsylvania

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- From Bench to Bedside

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Challenges of Clinical Trials

- Costs:
  - Medications usually covered by study
  - Physician visits, labs and scans are usually billed to your insurance
  - Consent form should detail anticipated costs

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Challenges of Clinical Trials

- Finding a study that is close to you
- If you can't find a study in your location:
  - Where do you stay?
  - How many visit are required?
  - Costs if you go to a different or out-of-network hospital?

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Questions to Ask About Trials

- What is being studied?
- Why do researchers believe the intervention being tested might be effective? Why might it not be effective? Has it been tested before?
- What are the possible interventions that I might receive during the trial?
- How will it be determined which interventions I receive (for example, by chance)?
- Who will know which intervention I receive during the trial? Will I know? Will members of the research team know?
- How do the possible risks, side effects, and benefits trial compare with those of my current treatment?

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Questions to Ask About Trials

- What will I have to do?
- What tests and procedures are involved?
- How often will I have to visit the hospital or clinic?
- Will hospitalization be required?
- How long will the study last?
- Who will pay for my participation?
- Will I be reimbursed for other expenses?
- What type of long-term follow-up care is part of this trial?
- If I benefit from the intervention, will I be allowed to continue receiving it after the trial ends?
- Will results of the study be provided to me?
- Who will oversee my medical care while I am participating [illegible] trial?
- What are my options if I am injured during the study?

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Considerations for *BRCA1/2* Carriers

- Everyone has *BRCA1* and *BRCA2* genes.
- Some individuals are born with a mutation in their *BRCA1* or *BRCA2* genes.
- Individuals of Ashkenazi Jewish descent have a **1 in 40** chance of carrying a BRCA mutation. This is **10 times** greater than the general population.

1 in 40

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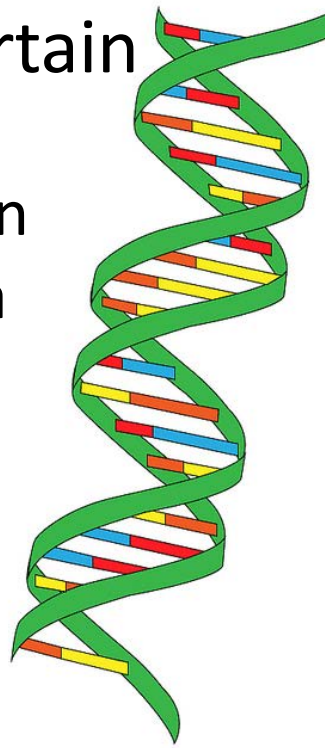
Considerations for *BRCA1/2* Carriers

- These individuals are at increased risk for certain cancers, most notably breast and ovarian
  - Women who carry BRCA mutations have up to an 80% risk of developing breast cancer and up to a 45% risk of developing ovarian cancer.
  - Men who carry BRCA mutations also have increased cancer risks.
- Men and women can carry BRCA mutations
- BRCA mutations can be passed on to children



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Considerations for *BRCA1/2* Carriers

- Types of studies for *BRCA1/2* carriers
  - Cancer treatment studies
    - Smaller population – may look for specific drug rather carrier specific trial
  - Cancer risk, risk reduction, prevention studies
  - Communication studies (family, children)
  - Reproduction and fertility implication studies

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From Bench to Bedside: An example

- Olaparib, a twice-daily oral cancer drug, has been studies in a number of trials
- In one, an international research team studied nearly 300 patients with inherited *BRCA1* and *BRCA2* mutations who had advanced cancers that were still growing despite standard treatments. Patients were enrolled and treated at 13 centers around the world

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From Bench to Bedside

- The majority of patients in the study, olaparib was at least their third different cancer therapy
- In addition to the overall shrinkage or disappearance rate in tumors following treatment with olaparib, researchers also found no further growth in cancer for at least eight weeks in 42% of patients

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From Bench to Bedside

- In December, the FDA approved olaparib for the advanced stage BRCA-related ovarian cancer (after three or more lines of therapy)

FDA News Release

FDA approves Lynparza to treat advanced ovarian cancer

First LDT companion diagnostic test also approved to identify appropriate patients

For Immediate Release December 19, 2014

Release

Español

The U.S. Food and Drug Administration today granted accelerated approval to Lynparza (olaparib), a new drug treatment for women with advanced ovarian cancer associated with defective BRCA genes, as detected by an FDA-approved test.

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Ask about clinical trials!

- The only way we make progress is via clinical trials
- Critical importance of patients and advocates that we get this right!

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PERSONAL STORY

A Sharsheret peer supporter shares her personal story about participating in BRCA clinical trials.

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QUESTION & ANSWER SESSION

To ask a question, please dial *1 or enter your question into the chat box.

Questions will be addressed in the order received.

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EVALUATION

Your feedback is important to us.

Please complete the online evaluation that will be sent to you.

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TRANSCRIPT AND AUDIO AVAILABLE

You can access the transcript and audio of the webinar series at:

http://www.sharsheret.org/resources/transcripts

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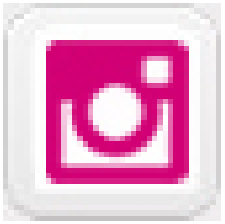

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