



Biomarker development needs tissue repositories

- no honey without bees

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Institut universitaire de médecine sociale et préventive, CHUV, Lausanne



the bee



the bee



the consumer



the bee



the beekeeper



the consumer



the bee
the patient



the beekeeper
the treating
physician



the consumer
the researcher



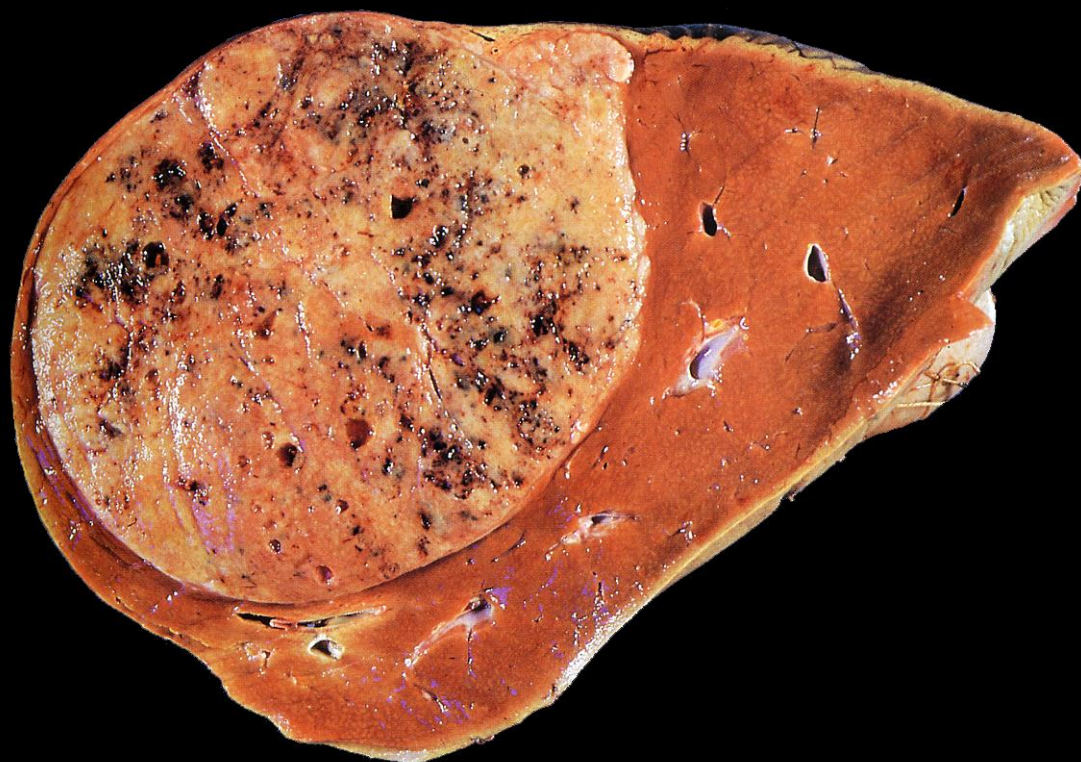
the bee
the patient



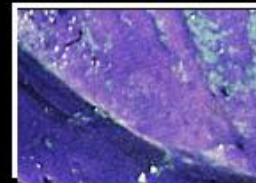
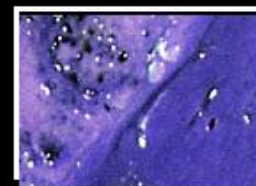
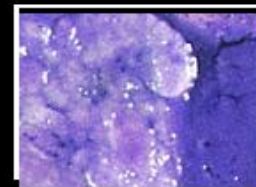
the beekeeper
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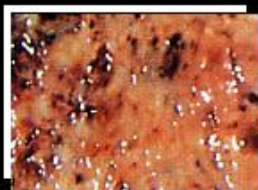
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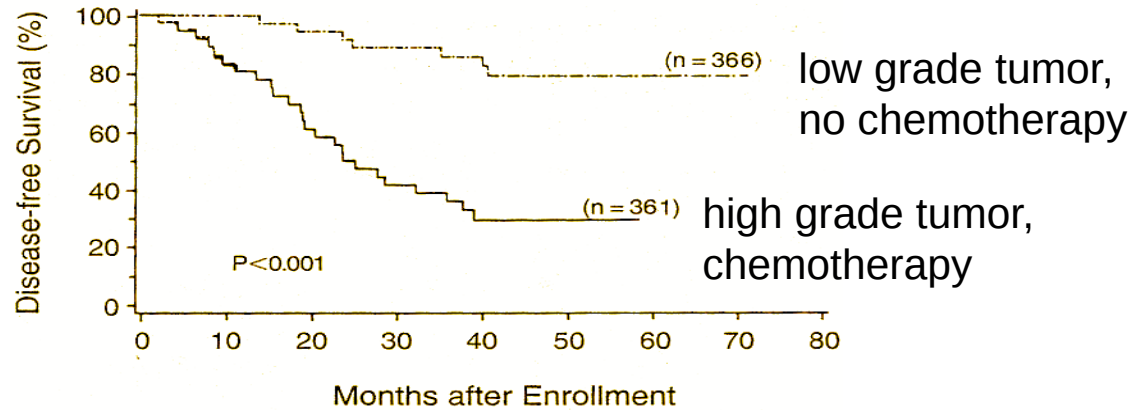
diagnosis



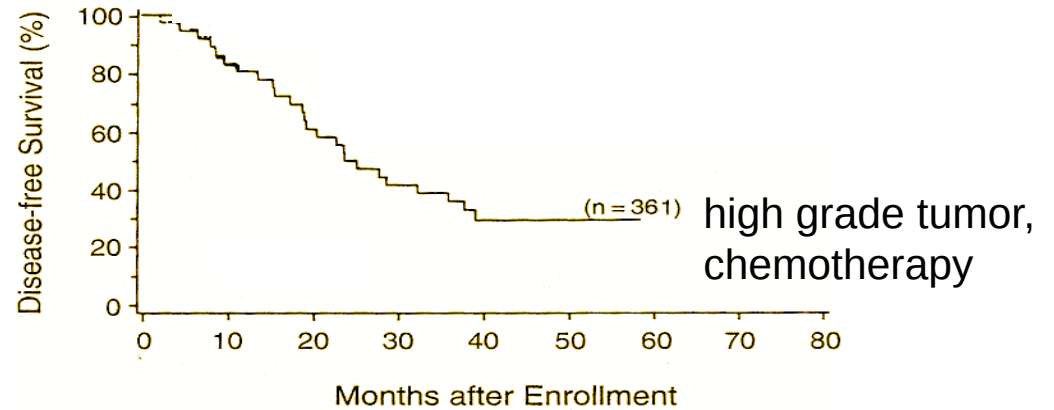
tumor tissue bank



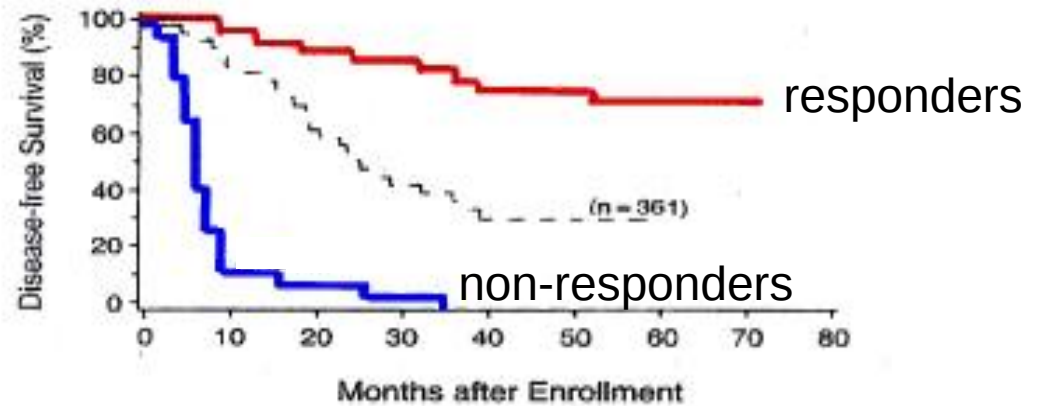
Question: Does a certain biomarker allow to predict the response to treatment?



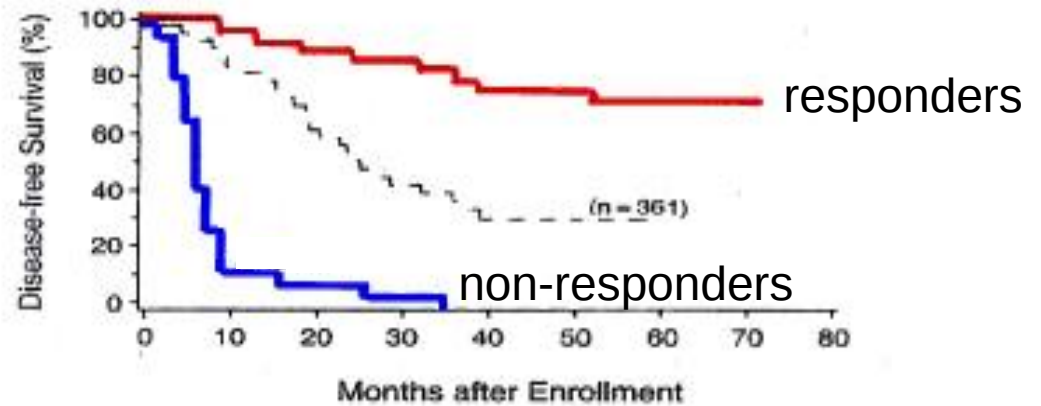
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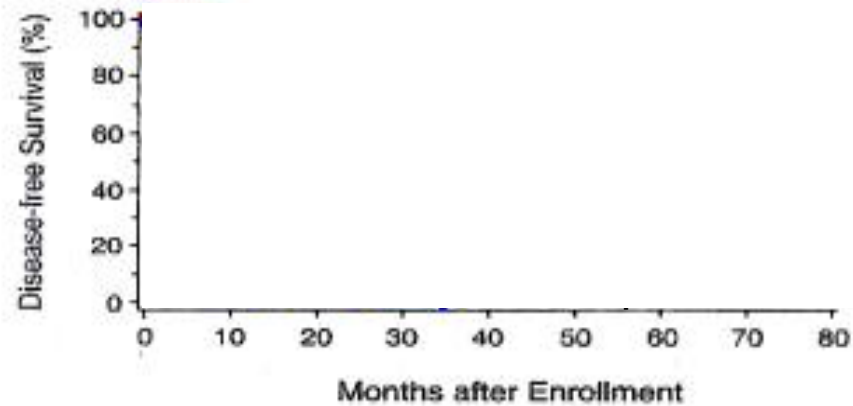
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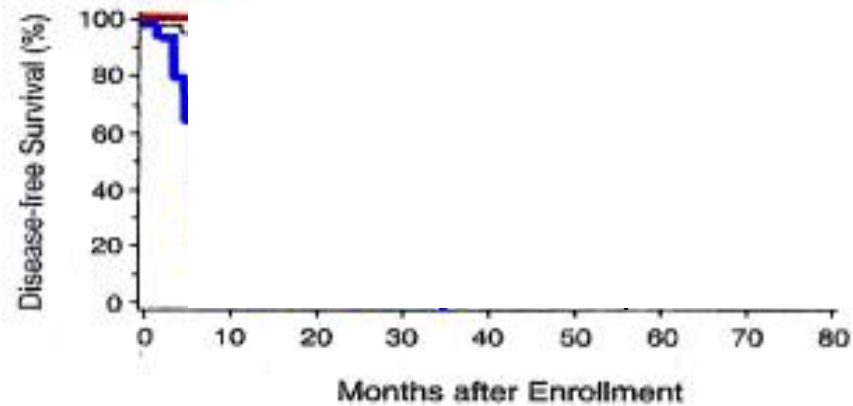
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2012 2013 2014 2015 2016 2017 2018 2019 2020

↑
biomarker study
(i.e. gene signature)

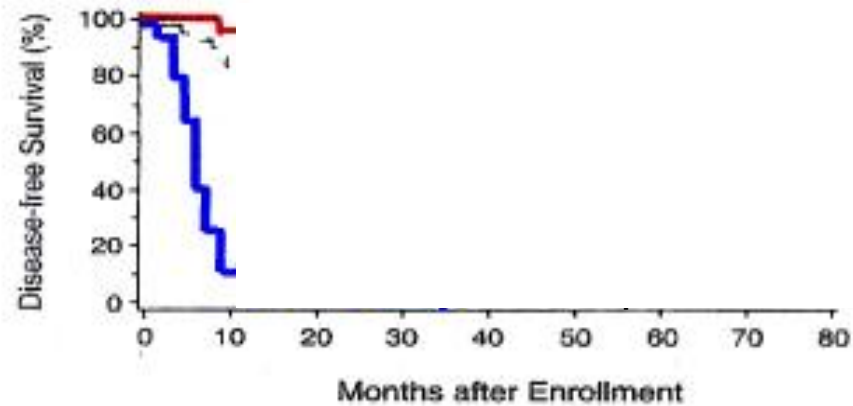
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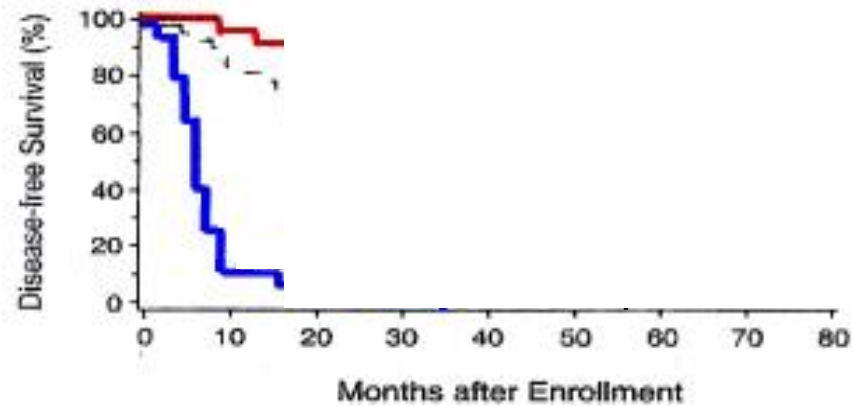
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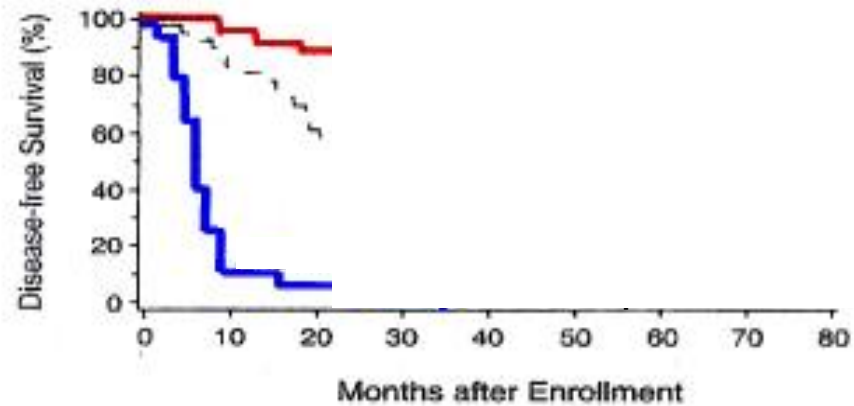
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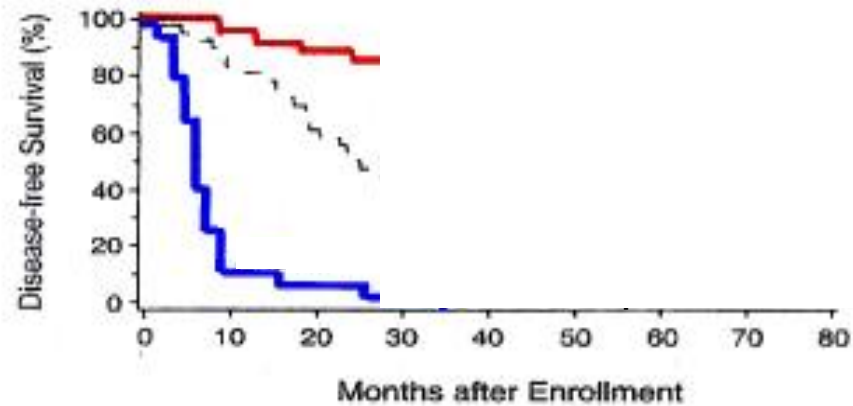
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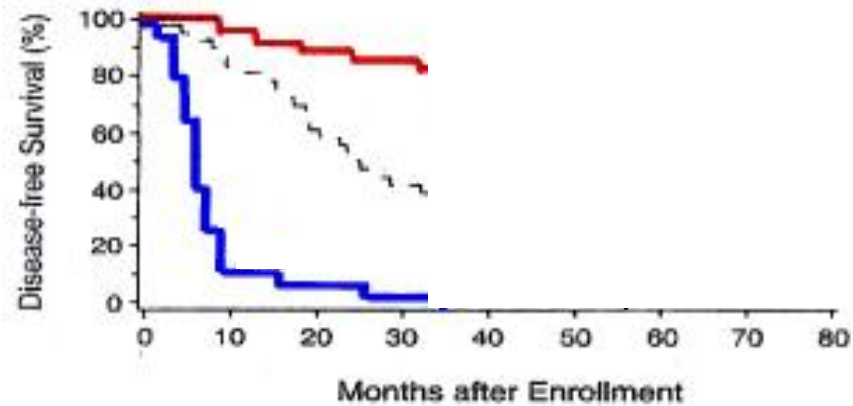
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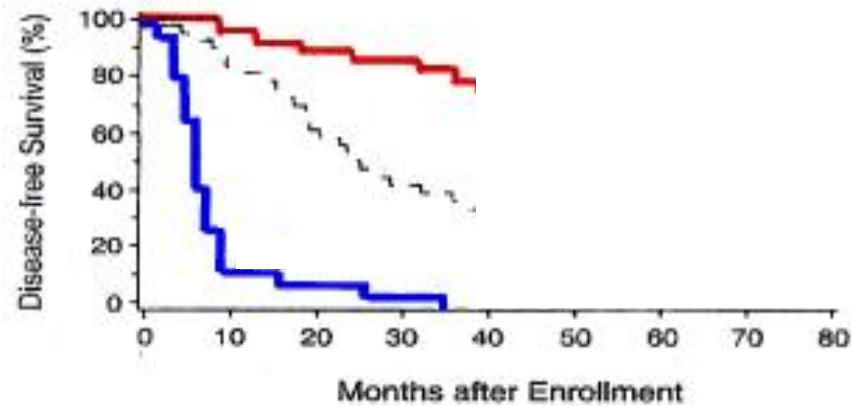
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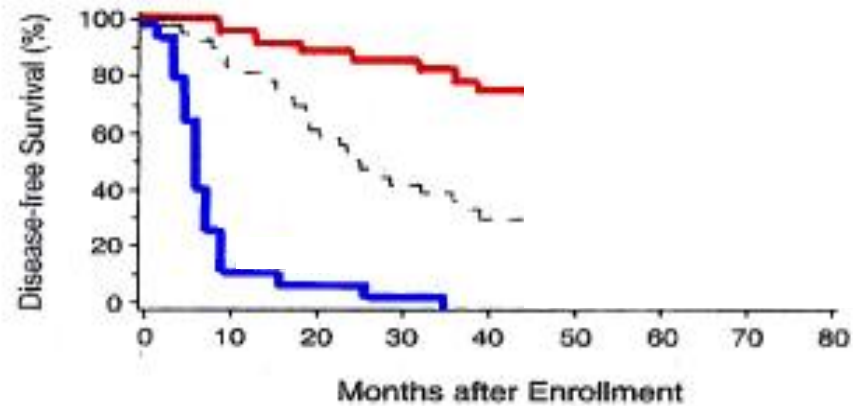
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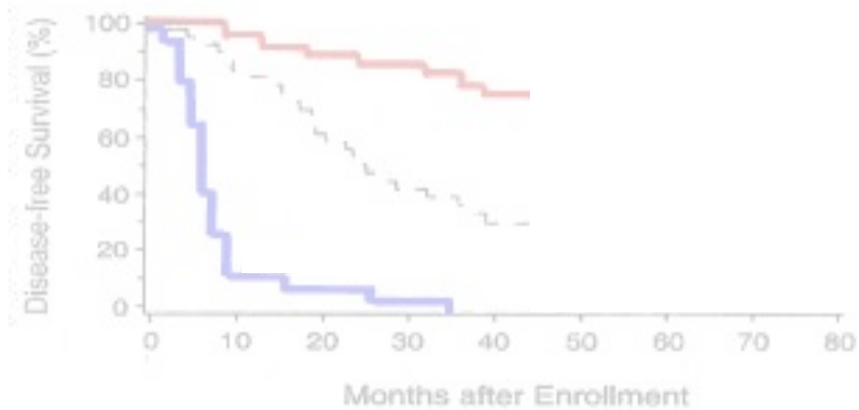
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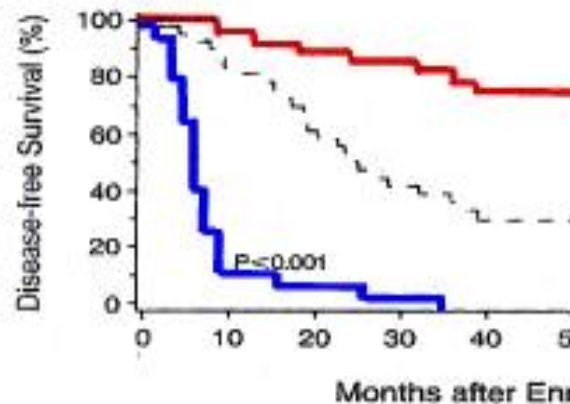
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use any „old“ clinical trial

- identify 50 responders
and 50 non-responders

in 2012

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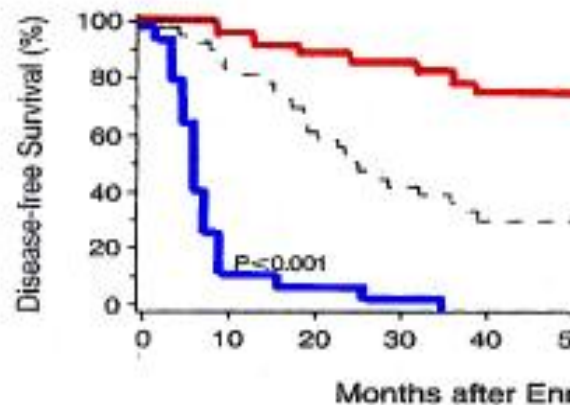
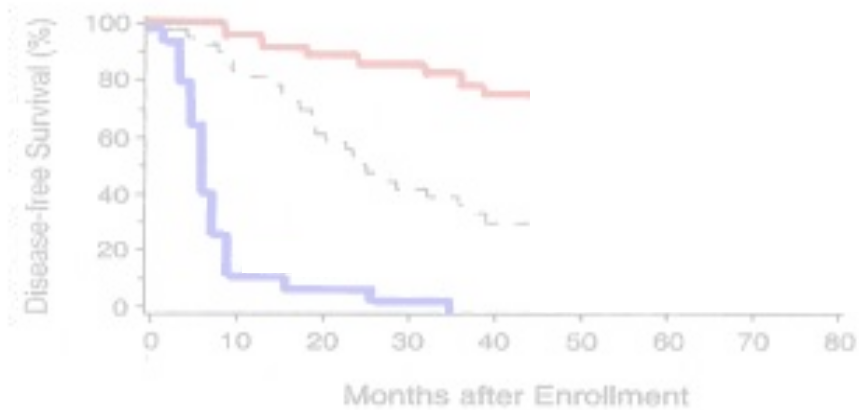


archived
tumor
tissue

biomarker study
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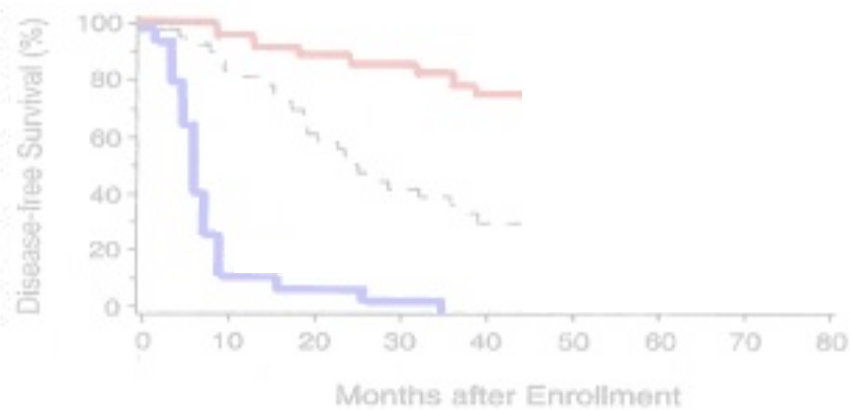


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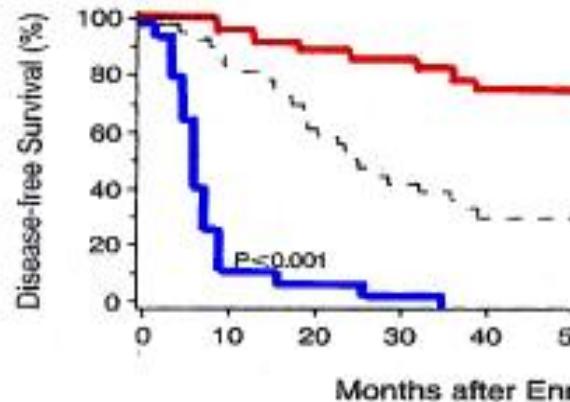
archived
tumor
tissue

2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020



potential patient benefit

vs.



potential patient benefit

Prerequisites for the use of archival tumor tissue



1. tissue repository (paraffin blocks, frozen tissue, DNA, etc.)
2. SOPs for fast (cave: degradation of genetic material), standardized tissue acquisition
3. well-controlled clinical information (i.e.digital patient file)
4. adequate data management (codification, link to clinical information, etc.)

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5. consent of ethical review board

6. consent of patient



One page letter-sized form requesting human tissue for research projects



Institut universitaire
de pathologie
Pathologie clinique
Rue du Bugnon 25
CH-1011 Lausanne

IUP.biobanque@chuv.ch
Tél: 021 314 59 64
079 556 60 49

Formulaire de demande d'échantillons tissulaires à la biobanque

RESPONSABLE DU PROJET		Espace réservé à la biobanque	
Nom		No du projet	Année
Adresse		Pathologue répondant	
Département			
Tél	E-Mail		

Autres personnes engagées dans le projet – nom, adresse, dpt, téléphone

- 1.
- 2.

Description succincte du projet, yc les méthodes utilisées

Tissu /organe

Type de tissu – congelé ou fixé

Nombre d'échantillons demandés

Personne à contacter en charge de la collection et du transport des échantillons

Nom

Tél /e-mail :

Je déclare qu'après utilisation pour le but du projet décrit ici, je détruirai les échantillons ou les restituerai à l'IUP. Je ne vais pas les commercialiser, les garder dans mon laboratoire, ni les donner à d'autres chercheurs ou personnes. Si par ailleurs une utilisation secondaire des échantillons est anticipée et dépasse le projet décrit ci-dessus, je recontacterai le responsable de la biobanque et documenterai cette intention sur un autre « formulaire de demande d'échantillons ». Je déclare que j'informerai le responsable de la biobanque de toute irrégularité dans la prise en charge des échantillons par mon laboratoire (pex : perte ou disparition).

Le responsable du projet - date

Le responsable de la banque de tissus - date

Espace réservé à la commission d'éthique du CHUV

La commission d'éthique a pris connaissance de ce projet et autorise la biobanque de l'IUP à fournir les échantillons demandés

Date :

Signature:

Commentaires éventuels :



Formulaire de demande d'échantillons tissulaires à la biobanque

One page letter-sized form requesting human tissue for research projects:

1. Who (PI, other persons handling tissue)

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Adresse			
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- 2.

Formulaire de demande d'échantillons tissulaires à la biobanque

RESPONSABLE DU PROJET

Nom

Adresse

Département

Tél

E-Mail

Espace réservé à la biobanque
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2. **Project** (brief project description)
3. **What** (organ, type of tissue, number)

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Nom

Je déclare que j'informerais le responsable de la biobanque de toute irrégularité dans la prise en charge des échantillons par mon laboratoire (pex : perte ou disparition).

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5. **Declaration of disposal /limitations**

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Nom	No du projet	Année	
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1.			
2.			
Description succincte du projet, yc les méthodes utilisées			

I declare that when the project described herein is finished, I will either destroy or return the left-over tissue to the biobanque. I will not sell the tissues, store them in my laboratory, or hand them to other researchers or persons. If I want to use the tissue in a secondard purpose that is not covered by the project described herein, I will recontact the responsible of the biobanque and document this purpose on a new form.
I declare that I will inform the responsible of the biobqne of any irregularity involving the tissues in my laboratory (i.e loss).

The responsible of the project – date

The responsible of the biobanque - date

Signature:

Commentaires éventuels :



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6. **Statement of the review board**

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this simplified procedure is used **only for codified tissues** (without patient identifiers)

the ethical review board has accepted this simplified procedure only after having **reviewed in detail our procedures of tissue handling and tissue codification**

the ethical review board has **five working days to respond**

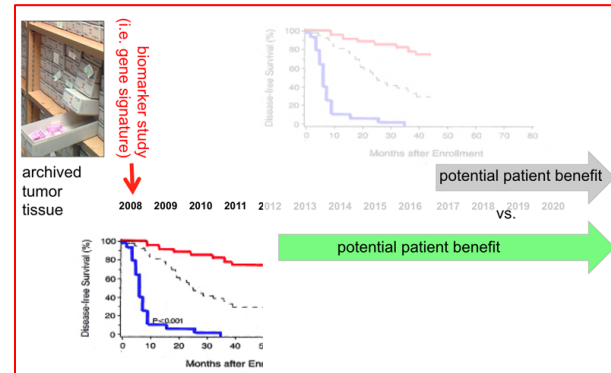
the review board has the **right to refuse it's consent** and request that a full-project request is submitted for standard review *(never happened in 15 years)*

Prerequisites for the use of archival tumor tissue

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5. **consent of ethical review board**
6. **consent of patient** 

researchers, physicians, member of the ethical review boards, and likely everyone in this audience has a good idea what the use of human tissue implies in terms of

benefit (for other patients)



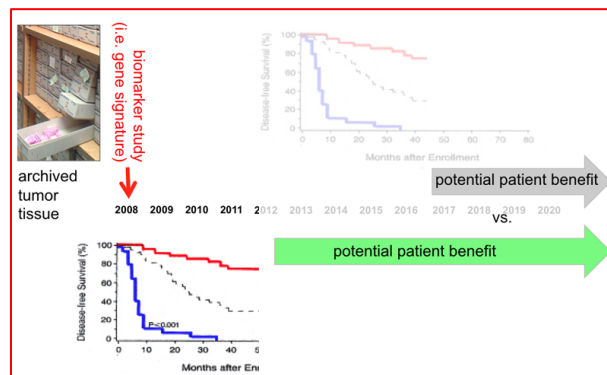
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and

risks (for the tissue donor)

- genetic dispositions to diseases
- abuse of information (insurance, employer, etc.)
- psychological trauma of confrontation with health risk



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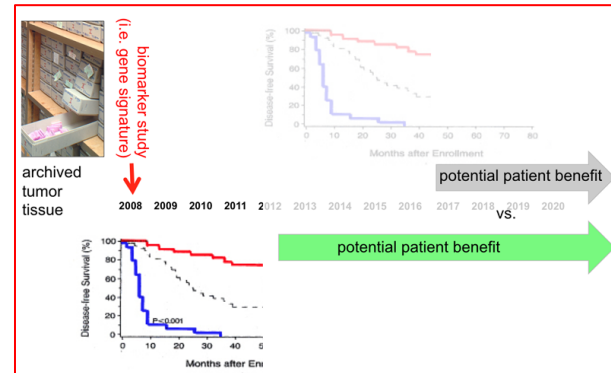
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Unanswered questions concern the balance of

autonomy (the right to consent, the right to know about research results) versus **protection** (the right to not be confronted, the right to not know research results)





think that we

We all know what's best for our patients, for the tissue donors.

How can we be sure?
Why not ask them.



krebsliga schweiz
ligue suisse contre le cancer
lega svizzera contro il cancro



We have obtained funding from the
Swiss Cancer Society
(*Ligue suisse contre le cancer*)

to perform focus group discussions
with 90 health professionals, patients,
and the general population,

to develop a questionnaire and

to perform computer-assisted tele-
phone interviews (CATI) of 1600 repre-
sentative members of the French- and
German-speaking Swiss population
(october 2010, mean duration: 13min)

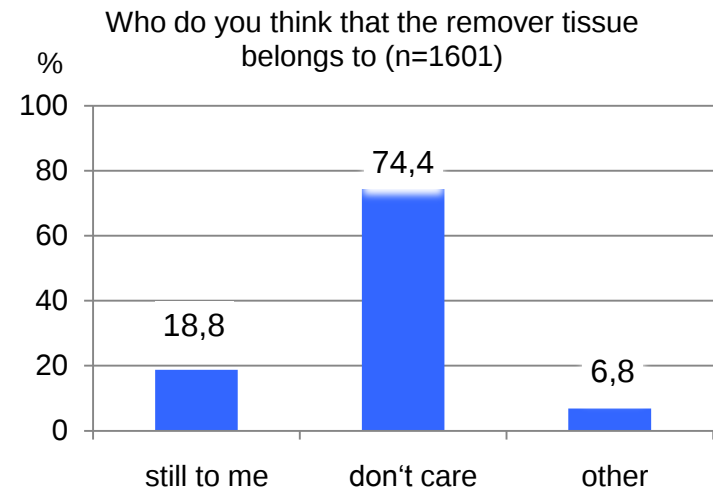
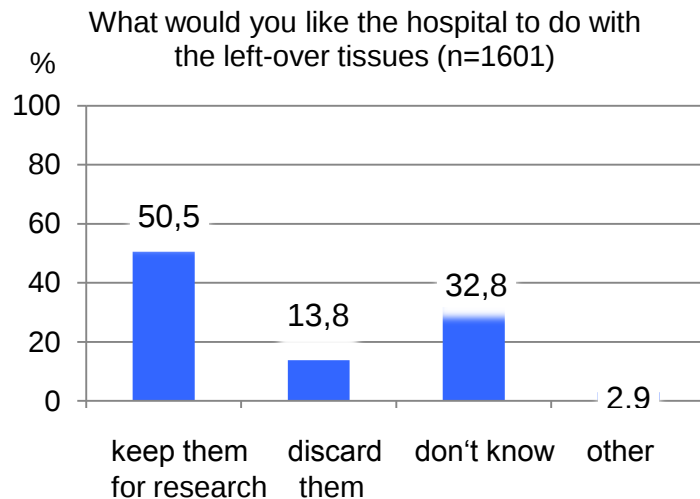
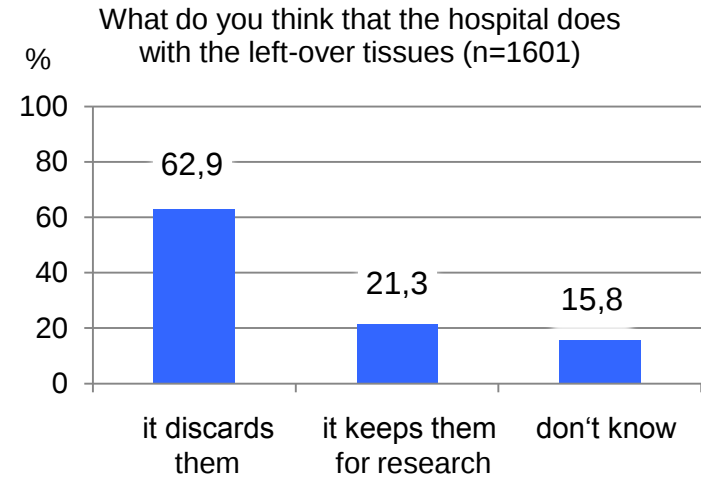
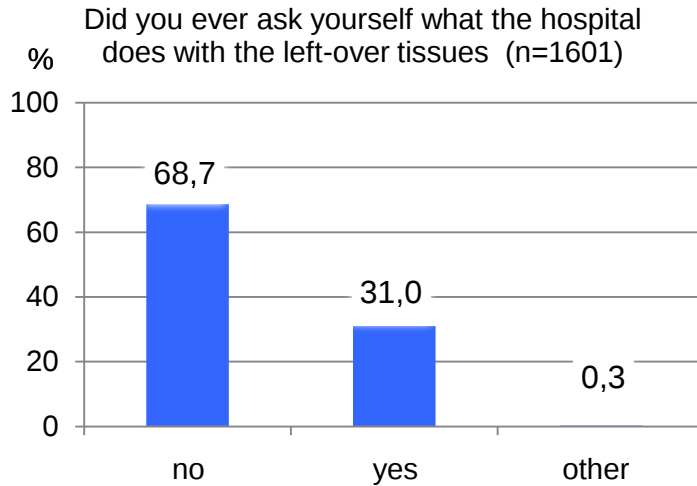
what did we learn from the focus group discussions ?

- the subject matter is new and very complex
- by far most members of the general population have never or rarely given any thought to the subject
- there is generally little knowledge about academic medicine, biomedical research, and about legal and ethical aspects involving the use of human tissue

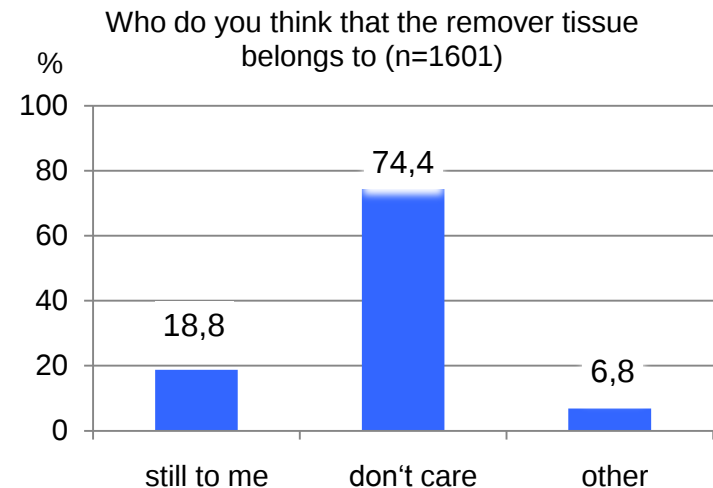
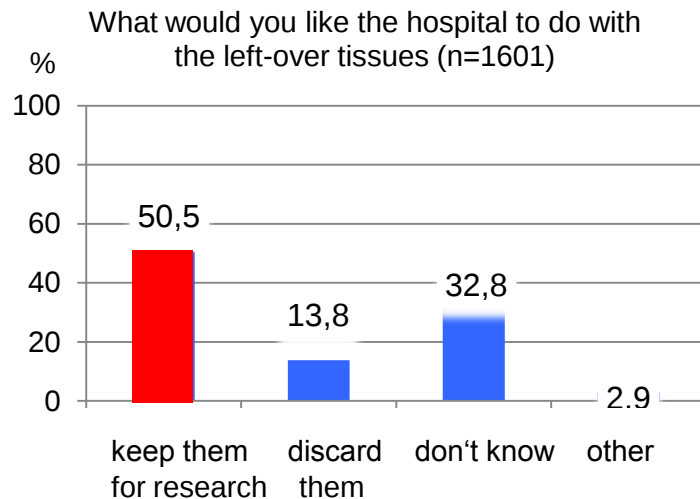
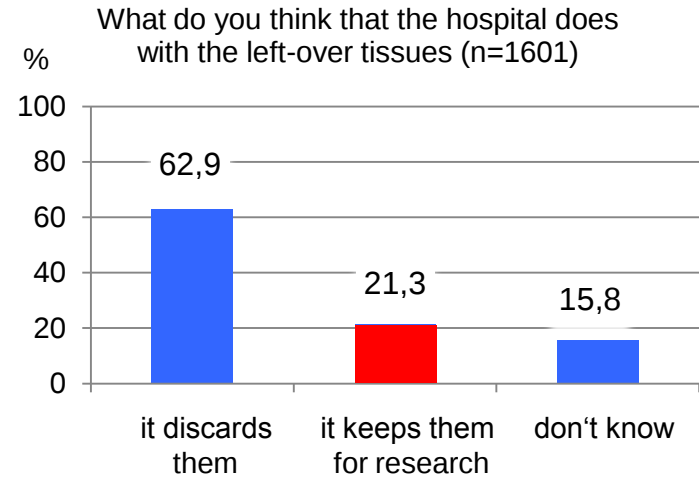
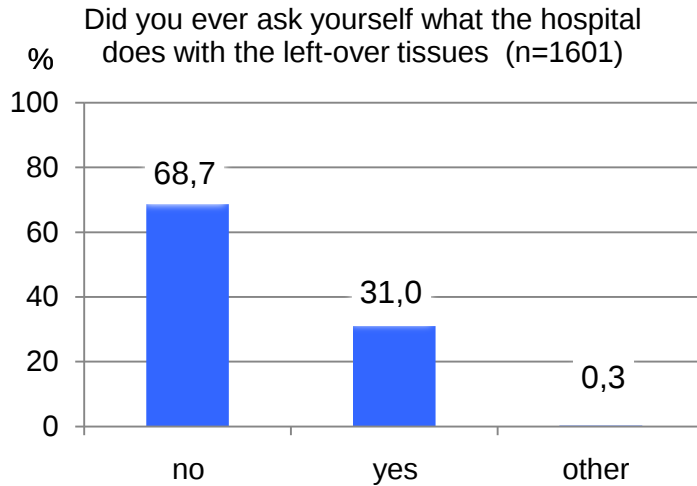
➤ need to first inform subjects, then to ask their opinion

- Some basic information was provided in a letter that was written to the households, in which the consent to the CATI was asked
- questions were formulated in a way that some basic information is given to the subjects, followed by a « yes/no, maybe, don't know » answer
i.e. « After the surgical resection of a tumor, the tumor is investigated by the pathologist. If after his examinations, a piece of the tumor is left over, do you think that »

results I: sensibility towards the subject mater



results I: sensibility towards the subject mater



Correspondence

Biobank donors should have a say

Our findings from a qualitative survey of patients, health-care providers, researchers and other members of the public in Switzerland support suggestions that the views of prospective tissue donors should be taken into account in securing biobank samples (*Nature* **478**, 312–313; 2011).

In 2009–10, we interviewed 90 people in focus groups, using fictitious case studies to explore perceptions about the use of human tissue.

Those professionals who preferred blanket consent from donors commonly expressed fears that providing information on tissue use to patients could make them reluctant to donate samples. The general population and patient groups, by contrast, usually wanted to be informed and have the opportunity to give consent.

Among patients, the need to be informed was linked to a wish to be appraised of their medical condition and to be a partner in the therapeutic process. Cancer patients were particularly enthusiastic about the use of their

tissues because it helped them to make sense of their illness and could potentially benefit others.

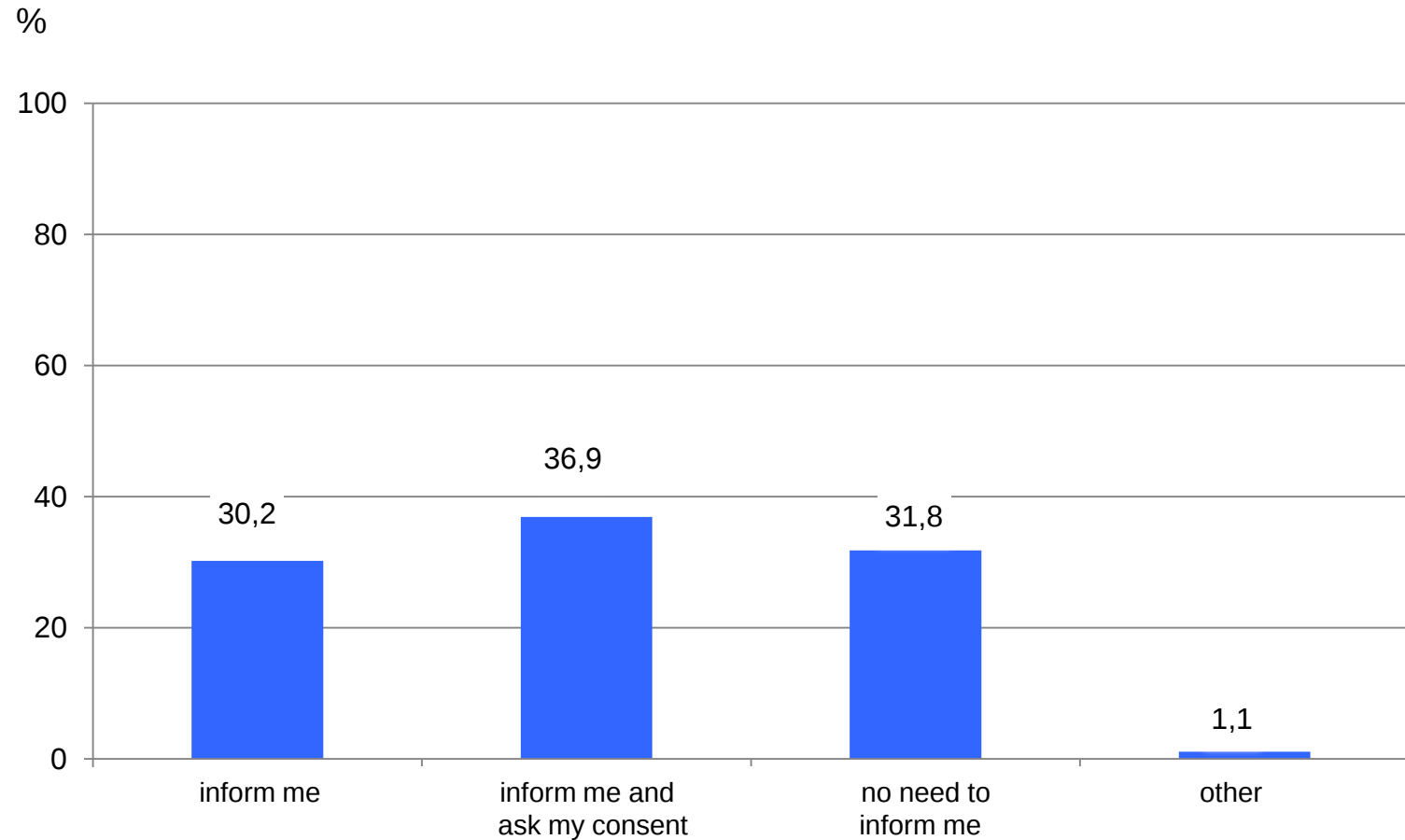
Brenda Spencer, Daria Koutaissoff, Hans-Anton Lehr
Lausanne University Hospital, Switzerland.
brenda.spencer@chuv.ch

CONTRIBUTIONS

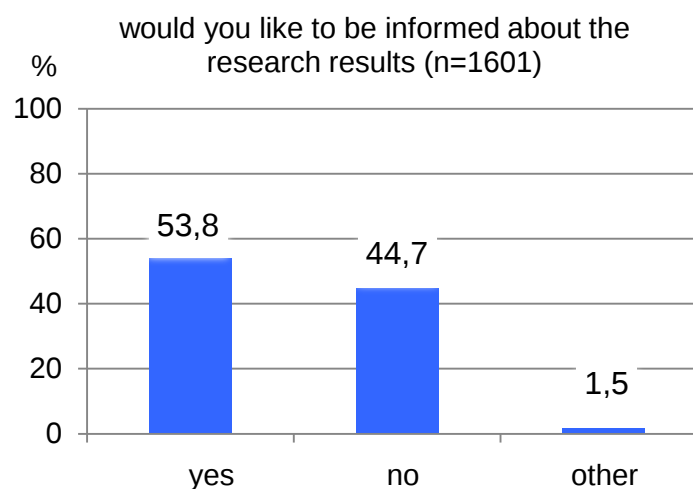
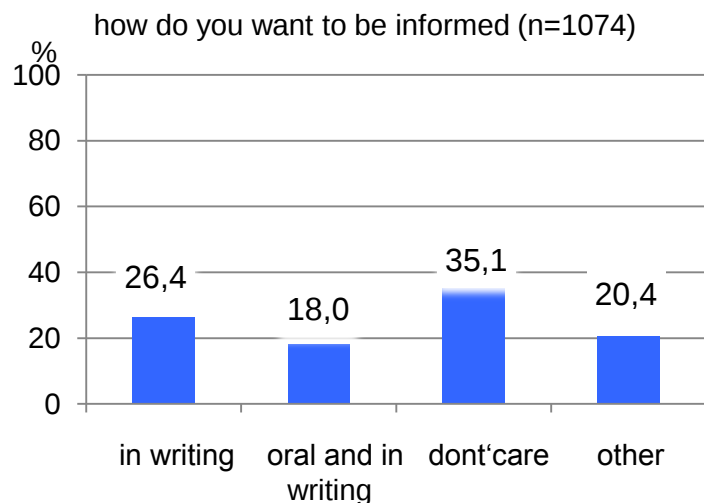
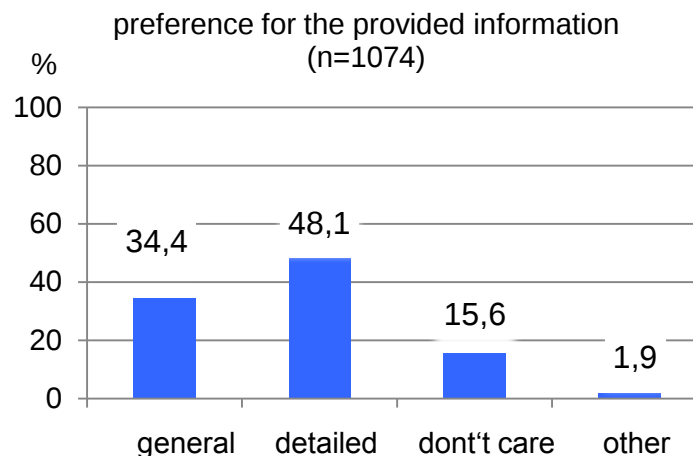
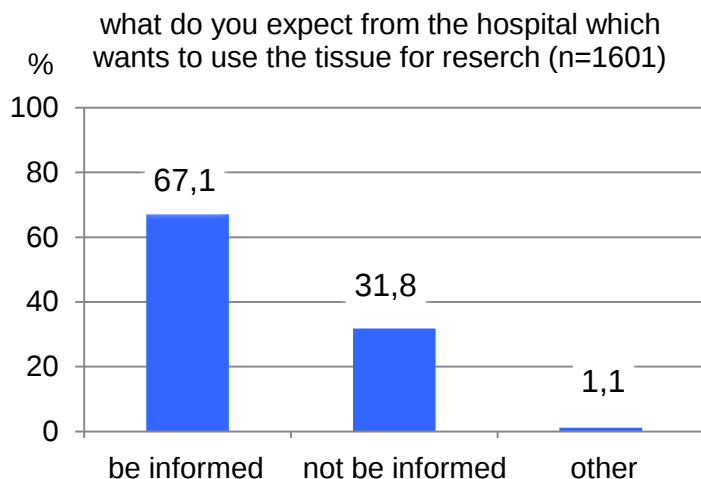
Correspondence may be sent to **correspondence@nature.com** after consulting the guidelines at **go.nature.com/cmchno**. Readers can also comment online: **www.nature.com/nature**.

results II: information and consent

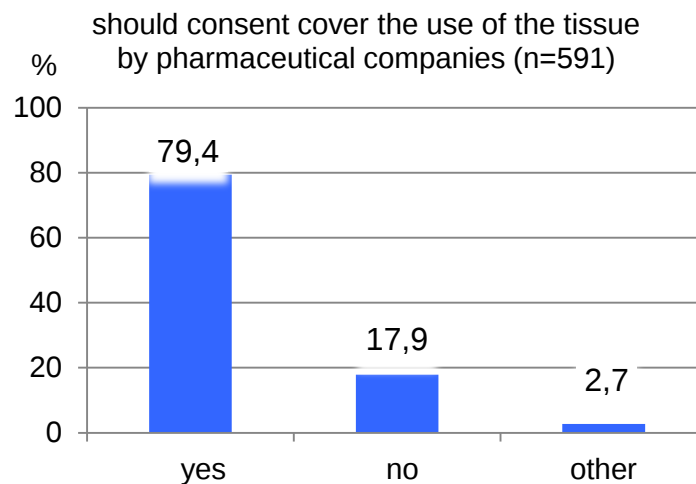
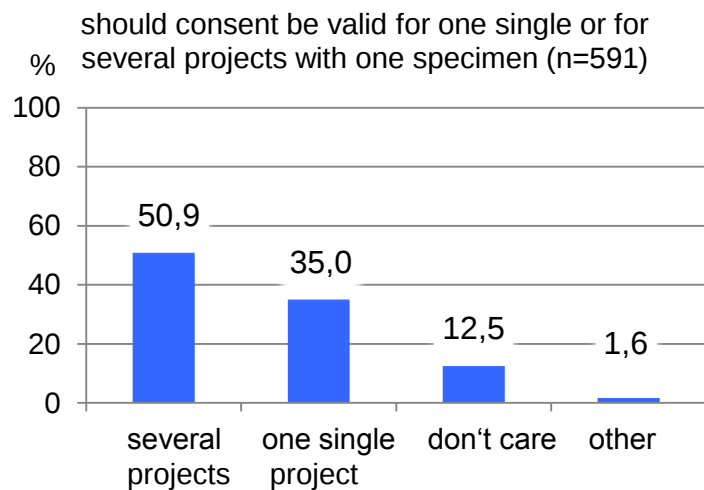
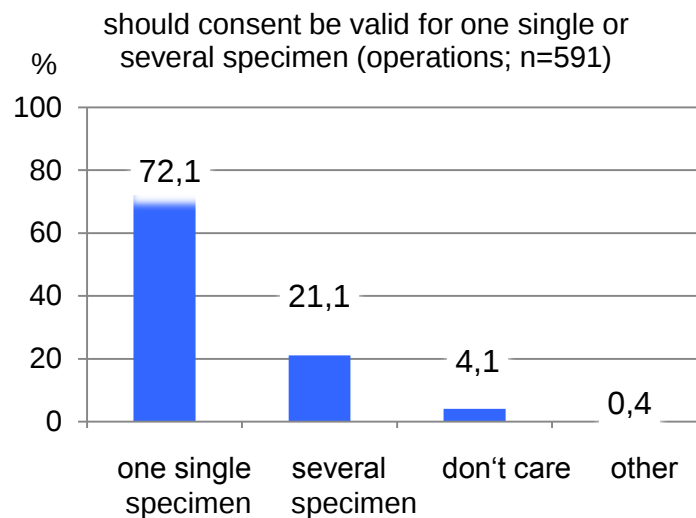
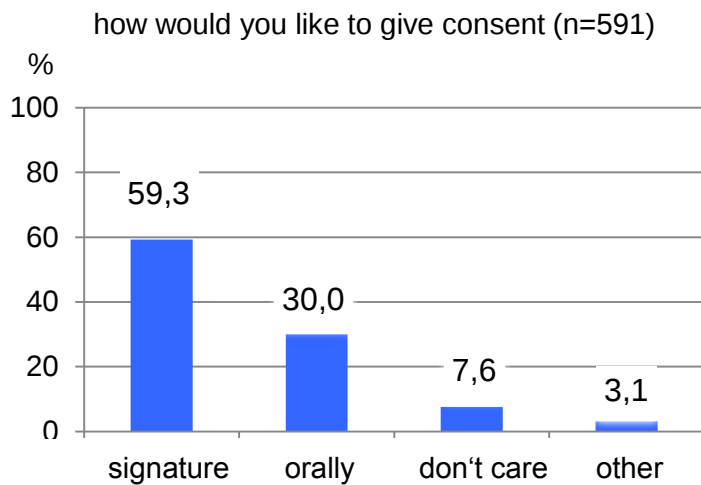
what do you expect from the hospital which wants to use your left-over tissue for research (n=1601)



results III: information to the patient



results IV: informed consent



sociodemographic bias I

- age

- the younger the subjects, the more they wanted to be informed
- the very young (< 30 ans) and the elderly (> 75 ans) tended to show the strongest confidence into biomedical research

- education

- the more educated subjects tended to have given prior thoughts at the matter and to think that the hospital might retain left-over tissues for research purposes
- the more the subjects were educated the more they tended to distrust the system and to request that strict rules be established and enforced under which their tissues could be used for biomedical research (written consent, etc.)

sociodemographic bias II

- sex

- sex did not have any influence on any of the opinions asked

- language

- the French-speaking Swiss (Romandie) tended to show greater confidence in research and the use of human tissues
- the same percentage of German-and French-speaking Swiss would like to be informed about the use of their tissues
- the French-speaking Swiss tended to be slightly more reluctant to consent to the use of their tissue be used for research
- the French-speaking Swiss tend to be less favorable to the use of their tissue by pharmaceutical companies

one unexpected outcome of focus group discussions

- Most guidelines by ethical institutions and review boards state that in case of unexpected findings during the research on human material, the patient be contacted and informed by the patient's **general practitioner**.



However, the general practitioners that we confronted with this statement responded that

(i) this has never been discussed with them and that

(ii) they are not willing to pull the hot potatoes from the fire for the « research establishment »

general conclusions

- the general public has not given much thought to the potential use of human tissues for biomedical research
- the population would like to be informed
- giving consent seems not to play such an important role
- the wish to be informed does not mirror a distrust in research but reflect their vision of transparency and partnership with the health professionals

Opinion: Occupy Science?

Biomedical research can learn from citizen science, which is grounded in strong relationships with study participants.

By Krishanu Saha and J. Benjamin Hurlbut | January 24, 2012



ISTOCK, SJLOCKE

Genomics research increasingly depends on access to large pools of individuals' genetic and health data, but there is mounting dissatisfaction with governance approaches that erect barriers between donors and the biomedical research in which they are participating. Typically, participants have little or no opportunity to track how their data are being used, what discoveries result, and what the new knowledge might mean for them, even when findings are of life and death significance for the participant.

Some frustrated communities have built their own scientific enterprises outside of traditional research settings. Disease advocacy organizations have established biobanks, for example, and firms like 23andMe and PatientsLikeMe have used crowdsourcing methods to build up repositories of genomic and health data, each attracting over 100,000 participants in just a few years. Often labeled "citizen science," these projects offer a two-way connection between participants and research—participants contribute their data, while seeing how it is used in research, what findings it generates, and how that new knowledge might impact their own lives.

general conclusions

- the general public has not given much thought to the potential use of human tissues for biomedical research
- the population would like to be informed
- giving consent seems not to play such an important role
- the wish to be informed does not mirror a distrust in research but reflect their vision of transparency and partnership with the health professionals
- based on our survey, there is no reason to assume that biomedical research could be endangered by the lack of confidence of the population towards the use of their tissues
- there is a need for wider information of the public

MEDIZIN

Lernen von den Killern



Krebskranke erkennen, wie wertvoll ihre Tumoren für künftige Heilmittel sind, und wollen jetzt eine eigene Gewebekbank gründen

Um das zurückzubekommen, was ihr wenige Wochen zuvor aus dem Leib geschnitten worden war, musste Anna Trapp* kämpfen. Den Knoten in ihrer Brust hatte ein niedergelassener Pathologe als Brustkrebs diagnostiziert, den Tumorblock aber dann in seinem Archiv verstaubt und sich geweigert, ihn herauszurücken. Die 42-jährige Juristin ließ nicht locker. „Mein Gynäkologe und ich bemühten uns einen Monat lang mit Anrufen und E-Mails um das Material.“ Die Krebspatientin wollte, dass ein Experte ihres Vertrauens die Tumorprobe erneut untersuchte und moderne, therapieentscheidende Tests damit anstellte. Erst als die Rechtsgelehrte eine einstweilige Verfügung auf Herausgabe ankündigte, lenkte der Pathologe ein. Zuvor hatte er angedroht, das unwiederbringliche Gewebe zu vernichten – unter dem Schutz des Gesetzes. Denn bis heute besteht in Deutschland keine rechtliche Verpflichtung, Tumorblöcke aufzubewahren.

Unhaltbar finden Krebsärzte und Patienten diese Gesetzeslücke und dass

BIBLIOTHEK DES SCHICKSALS

Für molekulargenetische Studien, die Kurt Zatloukal (Mitte) organisiert, stehen am Institut für Pathologie in Graz Hunderttausende von Tumorblöcken und 18.000 Kryopräparate bereit



TUMORGEWEBE im Visier. Ursula Goldmann-Posch kennt die Tücken und Chancen des entarteten Gewebes



BÖSARTIGER ZELLVERBAND Frisch entfernter Brustkrebs vor Präparation und Konservierung

KÄLTESCHOCK Wichtige Teile der Erbsubstanz halten sich nur bei minus 196 Grad Celsius

„Wir haben ein existenzielles Interesse daran, dass unsere Tumoren optimal aufbewahrt und genutzt werden“

URSULA GOLDMANN-POSCH, Initiative Mamazone

viele Pathologen die herausoperierten Krebsgeschwüre und Lymphknoten nicht systematisch aufbewahren und erfassen. „Dabei ist sein Gewebe von ungeahntem Wert für den Kranken selber, aber auch für den Fortschritt der Krebsforschung“, betont Hans Leirach, Direktor am Max-Planck-Institut für Molekulare Genetik in Berlin. „Der Technologiesprung in der Genomforschung macht Tumorgewebe zu einem unentbehrlichen Rohstoff“, so der Experte. An den bösartigen Zellen könnten Wissenschaftler entschlüsseln, wie Krebs entsteht und maßgeschneiderte Medikamente entwickeln.

„Deutschland holt erst jetzt seinen Rückstand in der klinischen Genomforschung auf“, weiß Heinz Höfler, der selber jahrelang in den USA gearbeitet hat. Die Mehrzahl der Pathologen sei nicht einmal speziell in Molekulargenetik ausgebildet, klagt der Direktor der Pathologie am Klinikum der TU München. Zudem würden sich die Krankenkassen scheuen, gerade besonders fortschrittliche Tests am Tumorgewebe zu bezahlen. Außerhalb großer Zentren fänden Fachkollegen deshalb wenig Anreiz, die Tumoren zu konservieren und zu archivieren.

Ignoranz, Finanznot und Machtkämpfe um das kostbare Biomaterial dürfen neue Strategien gegen ihren Todefeind Krebs nicht mehr blockieren, protestieren jetzt Brustkrebspatientinnen. Betroffene, die sich in der Selbsthilfe-

gruppe Mamazone zusammengeschlossen haben, wollen die erste patienteneigene Gewebekbank der Welt gründen. Täglich schließen sich neue Interessentinnen der Initiative an. „Wir möchten sicherstellen, dass unsere Tumoren uns für alle lebenswichtigen Untersuchungen zur Verfügung stehen“, erklärt die Initiatorin Ursula Goldmann-Posch aus Augsburg.

Um das Projekt so rasch wie möglich zu realisieren, planen die Frauen eine Kooperation mit dem Hannoveraner Biotech-Unternehmen LipoNova, das sich unter anderem auf die Kryokonservierung von OP-Präparaten spezialisiert hat. LipoNova friert für jeweils 500 Euro Gewebeproben ein und lagert sie für weitere 100 Euro jährlich. Aufwändiges Tieffrieren ist nötig, um lebendige Zellen dauerhaft zu erhalten.

Ein Gremium renommierter Experten will die Initiatorinnen bei der Auswahl der Forschungsanträge an ihren kostbaren Präparaten unterstützen. „Ich kann verstehen, dass Krebspatienten ungewöhnliche Wege beschreiten, um sich ihren Anteil am Fortschritt der Krebsmedizin zu sichern“, sagt etwa der Frauenarzt Michael Untch, Leiter des Brustkrebs-Forschungszentrums am Münchner Uniklinikum Großhadern.

„Bislang waren wir bei der Tumorklassifikation vor allem auf Tumorgroße sowie Struktur und Muster seiner Zellen angewiesen“, erläutert der Patho-

CHROMOSOMEN-TEST

Moderne Gen- und Proteinanalysen verraten mehr über die dynamischen Eigenarten eines Tumors als die herkömmliche morphologische Untersuchung



loge Hans-Anton Lehr, der an der Uni Mainz die Bereitstellung von Tumorgewebe für Forscher organisiert. Doch Geschwülste, die im Mikroskop identisch erscheinen, zeigen häufig völlig unterschiedliche Verläufe und sprechen verschieden auf Medikamente an.

Was ist besonders am Tumor jener Patienten, die ungewöhnlich lang überleben? Welche biologischen Prozesse sind schuld daran, dass bei anderen eine sonst bewährte Therapie völlig versagt? Welche molekularen Marker verheißen einen günstigen Verlauf, welche dagegen schlechte Heilungschancen? Fragen wie diese lassen sich an Hand des genetischen Programms von Tumoren und dem Vergleich mit den Krankengeschichten beantworten, berichtet



thank you for your kind attention

