Cancer Currencies: Making and Marketing Resources in a First-in-Human Drug Trial in Denmark

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Vignette: Trial Qualities on Display

It is early morning. Only the day before, Line received her final clearance to participate in a ‘site initiation visit’ between a cancer clinic in a Danish public hospital and a sponsor from a multi-national pharmaceutical company. The meeting’s purpose is to settle and formalise agreements that will enable and kick off a new cancer drug trial. The trial to be started is a ‘first-in-human trial,’ which means that the drug has so far only been tested on animals. The new drug is hypothesized to affect a specific genetic mutation in colon cancer tissue. Still, at this early drug development stage, it is only the toxicity of the drug that will be assessed. If the sponsor finds the hospital unit to be a suitable place to locate the study, the drug will be included in the unit’s targeted therapies offered to incurably ill patients who have exhausted all standard treatment options.

Line arrives at the office building just across the hospital, and two of the trial nurses from the unit, Lena and Sarah, greet her and invite her to take a seat at the table in the small room. They will be responsible for coordinating the trial’s clinical procedures, supervising the nurses in the clinic and schedule treatment with the enrolled patients if the sponsor decides to locate the study at the unit. Present at the meeting are also a sharply-dressed medical doctor flown in from the US-based pharmaceutical company sponsoring the drug, the overseas lead, a research project nurse from their Danish subsidiary company, and ‘the monitor’ – an external consultant – whose job is to control and assess the quality of data collected during the trial. Lena,

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the trial nurse, shows Line the day’s program, which lists time slots for the next 5 h with new people dropping in and out of the meeting every half hour. Lena explains that the purpose of the meeting is to go over all procedures to reassure the sponsor: that all relevant staff have been trained according to the regulatory standards that the hospital can recruit the right patients for the trial, and all clinical procedures will follow protocol standards.

During the first 30 min, the unit’s principal investigator, Doctor Mathew, joins the meeting to go through the book-thick trial protocol, the details of the quality assessments, and the examinations to be performed in the trial. At one point, the industry collaborator voices his concern about recruitment. He doubts that the unit will be able to enrol enough patients within the timeframe of the trial. Doctor Mathew promptly responds, “We already have relevant patients waiting, we can start tomorrow!” During the next hours, staff from across the hospital arrive at their allocated time slots: ‘pharmacy’, ‘lab’, ‘economic officer’ – all to ensure the sponsor that their part of running the trial will be smooth and efficient as logistics of recruitment or data handling are brought forward again and again. Showing their support, the nurses noddingly confirm the staff’s short presentations and assure everyone in the room by saying: “you couldn’t get a more qualified person for this task”.

The above vignette describes an event from Line Hillersdal’s ethnographic fieldwork exploring the negotiations and practical work involved in setting up new cancer drug trials for personalised medicine in a public hospital in Denmark. As described, the meeting unfolded as a neatly orchestrated demonstration of the unit’s professionalism, reliability and procedural excellence. What struck us in the situation was how it unfolded as a business meeting in which the hospital staff presented themselves as a unit worth investing in, an ideal research site containing the state of the art infrastructure of patients, clinical staff and equipment needed to run a high quality trial. The way the unit ‘sold’ itself and its capacity to recruit relevant patients and to execute clinical trials according to the highest standards made us curious. What, in effect, were they selling, and how do collaborations with pharmaceutical companies intersect with the research and care practices at the unit?

**Introduction**

The Danish healthcare system builds on universalism and tax-financed health care principles and provides free and equal access to healthcare for all citizens. At the same time, recent developments within welfare state service delivery have shown an increasing reliance on public-private collaborations and a push towards turning core welfare provisions into a profitable business working on an international scale (Larsen and Stone 2015). Particularly within cancer treatment development, the cost of medical research is increasing, and many policymakers see partnerships between private and public partners as mandatory to sustain public welfare services (Ministry of Finance 2015). In Denmark, personalized medicine has become an important focus. The Danish Regions governing Danish healthcare and the Danish
governments announced a national strategy on personalized medicine emphasizing both economic gain and an improved treatment based on genome sequencing and tumour profiling in oncology (Ministry of Health 2016; Danish Regions 2015). The claim seems to be to sell welfare in order to save welfare. However, research shows that financial interest may also involve competing interests between public and private actors when publicly funded research receives fewer funds and innovation in treatment increasingly comes to rely on industry support (Healy 2004; Sismondo 2018). Globally, pharmaceutical companies have taken the front seat to develop new targeted therapies within basic cancer research. Consequently, industrial concerns about, for instance, marketability come to shape how research is conducted and what kinds of questions are explored and which kinds of hypotheses are tested (Fisher 2009; Rajan 2017).

In this chapter, we follow this development on the ground by investigating the daily work of setting up and running so-called early cancer drug trials in collaboration with pharmaceutical companies in a public hospital in Denmark. We draw on fieldwork conducted, from November 2019 through March 2020. During fieldwork, Line followed the oncologists’ daily activities, observing patient consultations, and enrolment meetings in which patient allocation in trials was discussed. She also followed the nurses as they administered the treatment, filled out trial protocols, and reported data to industry partners. In addition, she interviewed clinical staff, research nurses, data consultants, industry partners and participating patients. Based on this ethnographic research, we analyse how practices of competition, investment and exchange shape how welfare resources for personalised medicine are defined, produced and offered. We argue that qualities facilitated by the welfare state – i.e. fast-tracking trial procedures, high-quality data and high compliance of research subjects – become currencies transactable on the global market for drug development.

By exploring the day-to-day collaboration between public institutions and private industry actors invested in developing personalised medicine for treating cancer, the article contributes to the field of political economies of health care markets. Our case from a Nordic welfare state in this regard offers a unique perspective. As cancer research becomes increasingly entangled with big pharma interests, it becomes crucial to understand how welfare state practices and values intersect with commercial interests. We show that this development exposes the inherently contested character of the current welfare state, aiming to secure the health of citizens and the wealth of the state.

**Cancer Currencies and Trial Qualities**

When Tarkalla and colleagues argue that the promise of personalised medicine is determined “more in terms of wealth than health” (Tarkalla et al. 2019: 149), they point to the presence of a discourse of investment and potential economic gain going hand in hand with the promise of new discoveries in cancer treatment. Analysing the Finnish national policies and strategies, they show how justifications...
related to science and health care are being eclipsed by economic and business rationales. Similarly, anthropological work on the global medical industry has unravelled the role of pharmaceutical companies in defining clinical research, determining available treatment, and setting drug prices (Sismondo 2007; Petryna et al. 2006; Dumit 2012). In his work on drug trials in India, Sunder Rajan provides critical analytical attention to the confrontation between global economic structures and local democratic institutions, in particular when he unfolds how national policy changes have been implemented to facilitate corporate interests with major consequences for public health in India (Rajan 2017). In general, research on bioeconomies, including the economy of trialling, has exposed the exploitation of vulnerable populations (Petryna 2009) when tissue and biological samples become commodified in transnational relations of exchange (Cooper 2011; Mitchell and Waldby 2010; Rose and Novas 2005; Rajan 2006).

In contrast to these studies of transnational bio-economies, our case is situated in the Danish health care system, where care and treatment are delivered within the frame of a social contract between state and citizen. In this context, entering a clinical trial and becoming a research subject is inseparable from relationships of state-citizen reciprocity and questions of social belonging. In stepping into a Danish hospital unit, we analyse the practical and collaborative work that goes into running the trials between the clinic and the pharmaceutical company in a welfare state that values egalitarianism and comprehensive universal welfare services.

By analysing how the entanglement and collaboration between the pharmaceutical industry and the clinic shape and stir research and care practices, we draw out specific ‘trial qualities,’ such as a strong bureaucratic infrastructure, well-described and compliant patients, and accessible public biobanks. Notably, we highlight how the ‘gold-standardness’ or procedural excellence of the trial (Timmermans and Berg 2003) is facilitated by these local infrastructures, patients, and biobanks yet becomes recognized as a universal value that can be bought and sold on a global market. With the notion of ‘cancer currencies’, we aim to capture how ‘trial qualities’ get an economic life of their own when transacted beyond the local clinic and enter a global market. We argue that the competencies and resources already made available by a strong welfare state condition what can be ‘made in Denmark’ and sold to other countries to make money on a global market.

Unit One1: A Research Business at the Heart of a Public Hospital

Unit One at the national hospital in Denmark specialises in early phase one drug trials of new personalised or targeted therapy, which targets specific genetic mutations in cancer tumours. The unit offers treatment to patients with advanced cancer

1The names of the hospital unit, staff and patients are all pseudonyms.
disease who have exhausted all standard treatment. The unit receives approximately 500 patients each year, with around 100 being included in trials. Upon entering the unit, all patients will be offered a whole-genome sequencing of cancer tissue to identify whether they have a specific genetic mutation that a trial drug can target. If their cancer tissue expresses the genetic mutation, they are allowed to enter the trial. Only one in five will have mutations leading to enrolment in such a trial. Most other patients will be redirected to trials testing other new drugs though not selected based on genetic targets. All trials at the unit are in the earliest drug development phase (phase 1) testing the dosage’s safety and toxicity level (Smith and O’Donnell 2006). The aim of the early trials is to identify at what dosage the drug is likely to have an effect without causing severe side effects. At this stage, it is not expected that the drug will have an effect on the individual person’s cancer disease.

Unit One has a unique history. From the start, it was designed to be a research business at the forefront of current efforts to develop and deliver personalised cancer medicine to a global market. It was established in 2001, and contrary to other public phase 1 units run as an integrated part of the hospital’s clinical work. Four doctors and ten nurses are responsible for coordinating and running the trials, along with recruiting patients. As the head of the unit recounts in an interview held at his office:

_We said from the start that we want to take on those tasks, but primarily we want to make a professional unit for phase 1 trials, that is similar to what I had seen in Europe. We closed a bed section and said: here we make a phase 1 unit. Here’s how we could attract foreign trials from pharmaceutical companies....to begin with it was quite impossible to get any of the companies to say, well, maybe we should also try trials in Copenhagen. It was hard, so it required a lot of work. Both for me, but also for the Danish subsidiaries for all companies, it became a bit of a success and a prestigious project for the hospital. It was an investment that returned. So, it was not something that cost money; on the contrary, it was a good business, plus it was research merit, and the companies invested a lot, the offices grew, and ... So there was growth in many areas._ (Medical lead of the unit)

Elaborating further, he stressed how the timing was right as the unit was established around the last financial crisis. The large pharmaceutical companies were shutting down their regional offices, and many people were losing their jobs. He saw a strong incentive for everyone, publicly or privately employed, to work hard to attract more trials to keep their local business running. Moreover, there was a strong political agenda pushing Danish initiatives on personalised medicine onto a global market. Together, this momentum secured the unit’s rare popularity among global pharmaceutical companies that saw multiple benefits of setting up trials in Denmark despite the number of patients being lower and cost per patient higher than larger countries.

Today, the unit comprises a small clinical ward with six beds located next to the standard oncology treatment wards. The unit’s business of running experimental drug tests for the pharmaceutical industry is hardly visible to visitors. Only the small whiteboard hanging in the staff office lists all the current company ‘sponsors’ and protocols. In addition, consent forms and information material mention the companies when introducing the potential trial to the patients at their first
consultation. During the day, patients enrolled in trials come in and receive their treatment. Their health status is meticulously followed by the project nurses doing measurements of, e.g. ECG, blood samples or assessing symptoms of their cancer disease or documenting if side effects are experienced from the new drug. Most patients have a personal oncologist whom they will see weekly to get a status on their wellbeing or the results from their latest scan, being performed monthly.

Located near Unit One is the Clinical Research Unit (CRU), taking care of the administrative tasks required to conduct the drug trials. On average, the unit has about 150 open protocols receiving or treating patients with new medicine. CRU has approximately thirty employees (project nurses, research assistants, lab technicians, IT staff, secretaries, service staff and doctors), all working on clinical trials of new and known drugs for adult patients with cancer. Their core expertise is to collect and document data and coordinate the administrative and clinical tasks required in conducting drug trials. In this space, the concurrent aims of securing better treatments for patients, doing good research, and sustaining local budgets by earning money on drug development intersect to produce personalized medicine. In the following section, we unpack the daily trial practices in the clinic in which the doctors have to balance a variety of considerations simultaneously.

Fast-Tracking Trialling at the Unit

You have to be able to act quite quickly to get these phase 1 studies. It’s not like big phase 2 and 3 studies where it is possible to say that you start [recruitment] two months later than those in Poland and those in Germany. Here, time is such a crucial factor … We have no advantages in Denmark other than time. (Head of the oncology unit)

Doctors in Unit One have to balance their concern for the patient, the business, and the studies’ scientific quality. In this context, speed is a key and defining trial quality. Getting patients ready for enrolment to deliver high-quality data fast is central to the daily work in the unit. To this end, many of the unit’s operational procedures have been through a process of optimization. Such forms of fast-tracking are of direct economic value since a delay in the production and marketing of what might turn out to be a blockbuster drug may very well cost a drug company millions of dollars per day (cf. Rajan 2003). However, the ideal of speediness potentially conflicts with other temporalities, such as the time needed for the clinic to sort out new symptoms reported by the patients, which unsolved will not allow patients to stay in the trials, thus confronting the doctors at the unit with the question of how to produce excellent and ethical science fast.
**Competitive Enrolment**

Most discussions in the unit revolved around recruitment. The intense international competition among the trial centres to quickly find the right patients and deliver high-quality data was a constant and daily issue to handle. On the wall in the doctors’ shared office hangs a small notice board with the unit’s recruitment statistics depicted in bar charts. Next to the chart, someone has written: “recruitment is everything!” Every week the unit doctors and a project research nurse responsible for the practical enrolment of patients meet here to do a status on the allocation of patients to the many trials running in the unit. On spreadsheets lying on the table are listed all the trial protocols currently running at the unit, the number of open or upcoming slots to be filled, and the names of patients ready to be screened or enrolled. Some of the protocols recruit only patients with specific genetic mutations, and it can be hard to find patients matching, other protocols include more broad diagnoses of cancers (“all-comers”), and they fill up more easily.

Running the recruitment by keeping up the right flow of patients is crucial to the unit’s work. Indeed, the pharmaceutical company starting up a phase 1 trial would often do so in several countries simultaneously, but only a few patients were included in the first cycles. The competition to get a ‘slot’ (a place in the trial) for a patient means that the unit’s staff will line up patients even before the trial opens, to be able to report immediately that they have a patient ready. This procedure means that the unit doctors screen the list of patients waiting. They look for patients with only little signs of disease, as the ideal research subject is what they term “healthy sick” (cf. Bogicevic and Svendsen 2021). This person is well enough to stay in the trial for at least a month and able to report on side effects. Moreover, the doctors select patients with different diagnoses of cancer to present a broad ‘catalogue of patients waiting’, making them able to respond to new studies opening up.

Even if the doctors optimize their procedures and try to secure a diverse group of patients waiting to be enrolled, the daily work is still unpredictable. Patients and procedures are continually changing, and the doctors need to adjust accordingly to make ends meet. A patient’s condition may suddenly and rapidly deteriorate. Because the unit runs early drug tests, the protocols receive many amendments, which mean more waiting time and postponement of the enrolment. Sometimes, trials are even put to a stoppage. At one status meeting, the unit doctor Sarah mentions that a patient she had hoped to include has developed some strange tics, hypertonia: “He has got an appointment with the neurologist. If it is some strange side effect, he will not be ready to enrol.” Similarly, another study to which they have patients waiting was suddenly closed due to: “acute adrenal insufficiency in the French arm”. The discovery of possible adverse side effects in one arm (site) of the study shuts down all sites across countries at once while amendments to the protocol are written and approved. Esben, another of the unit doctors, compares that situation to Formula One racing. When an engine is down with oil leaking on the track and all cars are pulled in to wait until a new go-ahead is given. The contingencies of open and closed slots are worrying, and at the status meeting, the unit’s lead
physician Doctor Matthew concludes that they need to be ahead of things: “We have to be on the ball ourselves. We cannot wait for them to call us. We also say there is an open slot; we have to register when we have some. And also ask around, at unit A [the regular oncological unit] if there are patients in late line [the last chemotherapy cycles], who are likely to fit.”

Producing Good Care and Good Science Fast

The unit’s chief medical lead had urged the company to get rid of competitive enrolment. It occasionally led to “screen failure” instances where patients were lined up for a trial to secure an open slot but without all the necessary assessments finished. The time allocated to collect all the data needed to enrol a patient was often insufficient. Talking to one of the nurses collecting the data for the “eligibility package” – a standard package containing the selected patient’s data – she told us that many of the blood samples could not be more than 72 h old when the patient entered the trial. Similar measures, i.e. EGC, had to be taken immediately before the enrolment. If the patient experienced new symptoms in the week leading up to the trial, there was simply not enough time to treat and keep them under control while preparing and securing the final regulatory green light.

At the site initiation visit described at the beginning of the chapter, the company representative had mentioned “fairness” as the principle guiding the allocation of slots. She had proposed a waiting list to give the different study sites in Denmark, France and Britain an equal opportunity. In discussing enrolment, the unit’s medical lead, Mathew, underlined how the patients’ needs should be guiding the allocation of slots, rather than the waiting list. This would guarantee a high-quality selection, and enrolment of the right patients, rather than patients who are first on the waiting list.

As Doctor Mathew pointed to, on the one hand, the competition to get the open slots does not always benefit the patient as the time to deliver the correct data might lead to the exclusion of the patient. On the other hand, enrolling patients and providing data fast is valuable to their collaborators and benefits the business. As the trial proceeds, commercial pressures come into play and reveal how the marketing of new drugs and innovative research at public hospitals go hand in hand (cf. Lakoff 2007). Doing things fast remains operative for the commercial life of the product. Many clinical trials are conducted not merely to assess efficacy and safety, but to secure regulatory approval at the least possible risk, and to bolster marketability. We see in the Danish clinic that the pace and temporality of enrolment become a transactable trial quality paving the way for patients into transnational trials while funding drugs and staff locally.
The Genomic Project: An Investment in Potentiality

Initiatives aimed at developing personalised medicine rely on data collection and data pooling (Prainsack 2015). Concurrently, storing valuable patient data in a publicly owned biobank to develop and deliver treatment for future patients (Hoeyer 2019) has been central to the strategies supporting public funding. At the unit, the project, ‘Copenhagen Prospective Personalized Oncology’ – in daily conversation referred to as ‘the genomic project’ – is a particular research protocol collecting tumour biopsies from patients and mapping the cancer genetics of their tumour (see Tuxen et al. 2018). The hospital funds the biopsies, data collection and storage. The unit considers this heavy public investment in biomarker-driven cancer research as crucial to their business. As explained by the head of the oncology unit:

_The genomic project is a critical condition for the growth we have seen. At a very early stage, we could go out and say, well, we know everything about our patients; we can do a full gene sequencing on our patients. We were among the first in Europe to do it on such a large scale. After all, it costs money, it’s expensive, and I was lucky to get some public funding to do it. And the other big sites in Europe, they said ‘how can you do that? How can you afford it?’ Because they did not have the opportunity. Even the places that were much bigger than us couldn’t do the things we could. And that meant that we were often preferred over other sites, too._

(Head of the oncology unit).

At the site initiation visit we described at the beginning of this chapter, Line noticed how discussions centred on the role of mandatory biopsies upon entering a trial at the unit (see also Peppercorn et al. 2010). On discussing the first cycles of the trial and the first patients to be enrolled in the trial, the industry partner voiced the possibility of not taking a research biopsy, to which the medical lead immediately refused by saying: “We follow the protocol”. This tension points to the doctor’s focus on securing the resources for doing research, which will ensure the unit a competitive market position. In contrast, the company does not need the biopsy data at this early stage of drug development. For them, securing data through the fast and successful inclusion of a patient is more important. Getting data as fast as possible is the company’s main objective, allowing them to move on to the subsequent development cycles.

In the weeks following the site initiation visit, Line observed the consultations with the first patient to be enrolled in that particular first-in-human trial as described in the following field note:

Doctor Sarah makes herself ready to meet Bryan for his baseline examination, the final assessment before being enrolled in the trial. She gathers the papers she has just finished looking though, squeezes a booklet under her arm and heads for the patients’ waiting area. On the way, she mentions that Bryan will be the first in the world to receive this treatment. “He is really tough. But I am not sure if he is aware of how sick he is” – she pauses with a sad look, “I just saw his scan, and he has many metastases in his liver”. Bryan greets us smiling, throwing a heavy rucksack on his back. He is in his late 50s and has never been ill before he was diagnosed with cancer, he says. Sitting down in the consultation room, Doctor Sarah and him discuss the recent biopsy procedure last week. He had seven biopsies taken from tumours in his liver, which caused him to throw up and then faint. Doctor Sarah wants to know whether he is still in pain: “do you take Panodil [painkillers]?” “Nah, one
or two”, he answers. “You are allowed to take more, you know”. She asks him if there is anything new since they spoke together last week. Bryan says, no. She gives him a status: “It is mostly your blood count I was worried about. It was a bit low, but it is up again, I can see”. Bryan confirms, “Yes, this is also what I sense when I’m out for a run.” Sarah continues: “Your blood count is related to the number of days since your last Chemo, so that it will come up again. I cannot see anything that would stop you from entering the trial. Then I just need to have a look at you”, she points to the couch in the room, and puts on her stethoscope, saying: “What do the kids say?” Bryan: “they just say go for it!” Doctor Sarah goes through the last test result needed to be included in the ‘eligibility packet’, a data package to be sent off to the company. Looking up at Bryan, she clarifies: “the company needs to look at all these numbers and approve. As soon as we have their approval, we can get started”. Bryan nods, and she rounds off the consultation: I will call you on Friday to see if you are still in pain. Then I will tell you if we can start on Monday.

Shortly after the biopsy procedure and Bryan’s consultation with Doctor Sarah, Bryan developed a fever lasting for more than a week, which was difficult to get under control and ultimately led to Bryan’s exit from the trial. The inclusion of mandatory tumour biopsies as a condition for enrolment in early phase studies of little direct benefit for the patient is critiqued for not letting the choice of biopsy be up to the patients. Despite the low prevalence of complications, most patients would say no to biopsies if they had the choice (El-Osta et al. 2011). More generally, Barbara Prainsack has pointed to how personalised medicine intensifies data collection and pooling to deliver the promise of personalised medicine, a data practice that puts additional responsibility on the patients for contributing personal data to shared resources (Prainsack 2015). In Bryans’s case, the unit doctors would argue that the biopsy was essential to assess whether the patient’s cancer tumour had the genetic mutations matching the experimental drug. To them, careful selection of patients based on genetic profiling showed promise of better clinical results even in early phase trials (Tuxen 2019). Furthermore, the research biopsy was also important in getting more knowledge on tumour specific variation for the biobank targeted future drug testing (Green et al. 2021). In contrast, the company representative suggested the possibility of getting this knowledge at a later stage because the company’s first priority was to get data on safety and toxicity. Had the clinic not taken the biopsies, Bryan might have stayed in the trial – yet he would not have contributed to the unit’s research.

The unit is interested in pursuing research that they hope eventually will lead to better treatment for future patients. This entailed both profiling the patients to match treatments as a way to attract more industry targeted trials and an ambition to build national resources for developing better treatment in the future. Because the unit entered the market early and was able to deliver genomic profiling, it was able to attract many of the new targeted trials. Therefore, by investing in the precise selection of patients based on publicly funded genetic profiling, the unit aimed to deliver yet another valuable trial quality to the industry while ensuring that patients entering trials had a chance of benefiting from trials drugs. In this way, the genomic project underlines the role of public ownership of data in legitimizing investments in biobanking (cf. Salter and Salter 2017) and shaping economic exchange trajectories or specific partnerships to sustain research and development.
Research Bodies: High Patient Compliance

A national selling point in attracting international research investments and research to Denmark is reliable research subjects. The Danish civil registration system allocates a personal identification number to all citizens making potential trial participants easy to track over time and across data sources, as exemplified in the following quote from the branding material sent out from the Ministry of Foreign Affairs and the Regions in Denmark:

*With its unique social security number system, longstanding tradition for patient and population registration and access to comprehensive biobanks, Denmark is an ideal location for medical and clinical research. Furthermore, Denmark has a homogeneous and compliant population, and individual patients are easily traced, which makes for a low lost-to-follow-up rate. In addition, Danes are very open to participating in clinical trials. (Start with Denmark 2016)*

Here the Danish population is promoted as a particularly resourceful population with high compliance and willingness to participate in trials. Furthermore, the welfare state’s lifelong registration and tracking of its citizens has proven an excellent trial quality. In contrast, the companies running trials in other countries experience many “lost-to-follow-up,” i.e. cases where patients are unreachable, and data cannot be obtained due to lack of a central registration (Dettori 2011).

At Unit One, the patients volunteering for trials have been referred by their general practitioner or local oncologist. The patients are invited to an introductory visitation to assess their possibilities of participating in a trial. The ideal patient should have a solid tumour from which a biopsy can be drawn and tested. Moreover, the potential patient needs to be well enough to endure the many weekly trips to the clinic, and has to be able to report back on side effects of the drug and not mixing up side effects with the progressed disease (cf. Tuxen 2019).

Anne, a former schoolteacher and patient we interviewed, had participated in several trials at the unit. She had been ill with bowel cancer for 9 years. She described the importance of being in a trial and the effort she put into reporting back and keeping herself as healthy as possible:

*I was flattered when they told me that I had a good performance status. Because then you might be able to take part in an experiment. Because you cannot do that when you are poorly. They [doctors] can see if you are feeling well or badly. Of course, you can overplay or underplay how much headache you have or how much of the one and the other. But I do not. I am honest about that. But the thought is there. If you get too poorly, you are out. And that’s why I’m exercising all the time, and that’s why I eat healthily and live a sensible life because I know well that if I suddenly lie down and I am not in shape... It’s for my own good. So I am top motivated for it. I have a little notebook where I write what medicine I take. I also write if I get any side effects because I have to answer whether there is a connection [to symptoms] or not. If I say I have had a headache, they will ask what day I had a headache. So I have trained myself to be a professional patient. There was not much choice for me in saying yes to a trial. For me, it was hope. Yes, there are some tough things you read in the papers you need to read and sign. So, I am well aware of the likelihood of side effects and I have tried many side effects. But I must try it. I am not ready to leave. (Anne, 67 years old)*
Like Anne, the patients enrolled at the unit were primarily well-educated and with will and resources put into being a research subject. They were all diagnosed with incurable cancer but in good health, showing no sign of disease. Because they had incurable cancer but were not yet terminal, they did not receive any treatment and had been discharged from their former oncology units. They all had a deep wish to receive treatment, even if it meant treatment with unknown effects. As one patient said: “if you are a part of the unit, then you do not feel you have been abandoned.” Another patient voiced the despair she felt of sitting at home waiting as: “there can’t be nothing,” with which she expressed her need for receiving treatment but also an expectation to be treated, pulled back into to being seen by the health care system, and thereby being asserted as deserving of care and resources (see also Dam et al. 2022). The fact that patients in the unit experience trial participation as a form of care is very clear and has also been shown to be the case for patients elsewhere (cf. Will and Moreira 2016; Keating and Cambrosio 2012; Kaufman 2015).

One of the unit doctors explained the unit as a specific space of care where data collection created more time with the patients than in standard oncology treatment:

> It takes a huge amount of data collection to do these phase 1 studies, so when we see the patients, there is time set aside, both to talk to them of course, where we have to ask a little more about all sorts of things and examine them, more than we might otherwise want, and so also to report all the data through the various systems and such. So more time has been set aside. And the time set aside is, in principle, something that the pharmaceutical companies help pay for. If we did not take a high price from the companies to do these studies, both to start the studies and to include and treat each patient, then it would not be possible at all.

(Unit doctor)

The patients value the attention and being in a trial connects them to the social contract and exchange with the state. The patients are a valuable resource but not in the narrow sense of delivering bio-resources. Rather, their wish to be in an exchange with a health care system and be part of a national collective secures high compliance and thus the qualities of trialling that the unit is capable of providing. The social contract with the welfare state is meaningful to patients, and they are willing to give back by participating in trials and doing so with high compliance and trust but also with the expectation of being seen as deserving of care by the state. This commitment to the collective is also what becomes fragile when the exchange is not reciprocated.

During autumn of 2019, news spread at the Unit One that a drug being trialled to treat ovarian cancer showed very promising results could now be offerd in treatment. Many patients were hoping to start on the new drug.

Due to the rise in drug prices, a national council, the Danish Medicine Council, was founded in 2017 to provide guidance about new medicines for use in the Danish hospital sector. In this case, the medicine council decided that only women with BRCA mutations, representing just 20% of patients with advanced ovarian cancer, were eligible to be treated with the drug, even though patients without the specific mutation had also shown to have some effect.

The Danish Medicines Council’s reason for recommending the new drug only to patients with a BRCA-mutation, associated with hereditary breast and ovarian
cancer, was that “the council found that there is a reasonable relationship between the drug’s clinical added value and the cost of treatment with Zejula [new drug] compared to Lynparza, which is Danish standard treatment. The reason for not recommending Zejula to patients without a BRCA mutation, on the other hand, is that the council considers that there is no reasonable relationship between the clinical added value of the drug and the cost of treatment with Zejula compared to placebo” (Danish Medicines Council 2019, translation by the authors). The argument of not granting all patients access built on a comparison of the price of the placebo pills compared to the price of the new drug, which made the relatively little benefit of the drug look very costly compared to cheap calcium pills. The Zejula case illustrates the economy of prioritisation as a consequence of limited resources in public healthcare. In the end, the collaboration between pharma and public clinics may develop new medicine too expensive for the public health care budgets to pay for. This tension challenges the promise of personalised medicine, which is sought to deliver more precise medicine “to the benefit of patients,” as the first Danish national strategy of precision medicine is named (Ministry of Health 2016). In the case of Zejula, only a very small subpopulation came to benefit from the national precision medicine investment (see also Day et al. 2017; Tannock and Hickman 2016; Marquart et al. 2018). Moreover, considerable doubts have been raised about whether targeted treatments would be affordable in practice, and the fairness of resource allocation compared with other priorities, such as cancer prevention (see Vineis and Wild 2014, a.o.). There is a lot of pressure from patients to get new drugs on the market. If the development of the drugs – conditioned on the collective resources delivered by citizens – does not result in citizens’ access to the new medicine, public trust may be challenged (cf. Petryna 2011).

Discussion

The chapter has aimed to analyse how public-private entanglements shape and stir the research and care practices at a public hospital in Denmark. We have unpacked the concrete ways the exchange and interdependence between the public hospital unit and the pharmaceutical industry shape what personalized medicine becomes in clinical practice. Where social science studies of transnational bio-economies have focused on how clinical trials exploit disadvantaged populations, our study shows how clinical trials operate in wealthy nations already providing comprehensive and equal access to health care. Here, the contract between citizens and the state becomes an important context for understanding how trial qualities gain traction as currencies ready to be transacted on the global market for drug development.

Internationally, concern has been raised about whether medical innovation has become too dependent upon industrial sponsors and whether medical innovation creates sufficient benefit for the patients. Most of the new cancer medicines only promise a small ‘survival increase’, which at best means slowing the growth of cancer for a few months. As these drugs are expensive, the pharmaceutical
industries receive a considerable profit in delivering a small survival increase. At present, the success of personalised medicine is debated, as the endpoint measured in trials is often not ‘overall survival’, but typically ‘progression-free survival’. Furthermore, the current focus on precision responses to cancer has led scientific and policy communities to eschew primary prevention measures that might ultimately prove a more effective and cost-efficient way to fight cancer since a third to a half of all cancers are deemed preventable based on present knowledge (Plutynski 2020). The patients we met represent a highly selected group of citizens who want treatment and will accept a drug that might only give them a few months more to live in. However, letting hugely expensive drugs with only very little promise in terms of overall survival hit the market testifies to the role of the market in defining available care. Patients demand these products, yet what about the tax-financed health care services, which are to pay for them? Paradoxically, maybe, the Danish welfare state comes to both profit from and help produce a demand for drugs, which it is not willing to pay for.

References


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