

## Approaches in Post-Experimental Science. The Case of Precision Medicine\*\*

Robert Meunier\*

**Summary:** In the introduction to his *Spalt und Fuge*, Hans-Jörg Rheinberger points to the possibility that we are currently experiencing a new turning point regarding forms of experimentation, which is characterized by the growing importance of high-throughput methods and big data analytics. This essay will explore the thesis that data-intensive research indeed constitutes a form of post-experimental research by interrogating research practices in precision medicine. Section 1 will introduce this thesis and highlight salient features of precision medicine as an example of post-experimental research. Section 2 suggests *approach* as a category that is broader than *experimental system*, as discussed by Rheinberger, and can serve to analyze and compare diverse forms of research, including experimental and post-experimental practices. The essay concludes with a reflection on how categories developed for the historiography of recent science might require an update when the science or its context changes (section 3).

**Keywords:** approach, research problems, method, experimental systems, historiography, precision medicine, data-intensive science

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R. Meunier

Institute for History of Medicine and Science Studies, University of Lübeck

E-mail: robert.meunier@uni-luebeck.de

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## 1. Precision Medicine as a Case of Post-Experimental Research

Hans-Jörg Rheinberger suggests “a turning point characterized by the acquisition and processing of data in mass format” regarding experimentation.<sup>1</sup> I put forward the thesis that data-intensive research is post-experimental in the precise sense that the experimental production of data is no longer the seat of innovation. Instead, it is in the processing of data where crucial methodological and epistemic novelty arises. Not that data production is not an important part of such research—to the contrary, large investments go into high-throughput technologies. But while these methods are increasingly standardized and automated, the knowledge claims are shaped by ever more intricate ways to analyze the data. Research in the context of precision medicine is an example of post-experimental science.

The term *precision medicine* (PM) was promoted by US health care policy advise committees in the last decade and is often taken to replace *personalized medicine*.<sup>2</sup> In any case, the practices falling under these headings are among the life sciences fields that build on the new cultures of data-intensive research.<sup>3</sup> Here is one often-reproduced definition of PM:

Precision medicine is an approach to disease treatment and prevention that seeks to maximize effectiveness by taking into account individual variability in genes, environment, and lifestyle. Precision medicine endeavors to redefine our understanding of disease onset and progression, treatment response, and health outcomes through the more precise measurement of potential contributors – for example, molecular measurements as captured through DNA sequencing technologies or environmental exposures or other information captured through increasingly ubiquitous mobile devices.<sup>4</sup>

The definition formulates a goal and delineates a set of methods adequate to achieve it. The goal has two aspects, first, to understand disease and treatment effects on the molecular level and, second, to develop interventions adjusted to individual patients, mainly by distinguishing sub-populations according to which patients can be classified (stratification). These goals constitute specific interpretations of the broader problem horizon of medical research and clinical practice, which aim to achieve knowledge about diseases and develop ways to prevent, predict, or treat them. Regarding methods, the definition emphasizes measurements on several levels, molecular and non-molecular, and thus implies the production of vast amounts of data and the development of appropriate tools for the analysis of large and heterogeneous datasets. Such an alignment of goals (as interpreted problems) and methods is what I call an *approach* (section 2), a term that is also used in the definition.

The merging of epistemic and practical goals shows that PM is seen as both, a biomedical research field and a way to practice medicine in the clinic. Here, my focus will be on research. Science studies commentators have often

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<sup>1</sup> Rheinberger 2021, on 9; in English as Rheinberger in press.

<sup>2</sup> Green et al. 2019; König et al. 2017.

<sup>3</sup> There are others, such as microbial ecology, which share some characteristics; see Meunier and Bayır 2021.

<sup>4</sup> PMI Working Group 2015, on 6.

pointed to the promissory character of the rhetoric of proponents of PM.<sup>5</sup> While the cited goals are indeed not yet realized in standard health-care, research is conducted that is perceived as pursuing these goals.<sup>6</sup> My analysis aims to characterize these practices, independently of the extent to which they will deliver what they promise. In the following, I will briefly discuss how PM can be characterized as an example of post-experimental science with respect to four important dimensions of research: materials, experiments, data, and collaboration.

#### Materials: Cohorts and Collections

The term *materials* refers to biological matter used in a study. Many research projects in the life sciences generate the materials in the lab (e. g., experimental organisms) or collect field samples. In PM research, materials are often acquired from patients. This also happened in earlier biomedical research with close links to the clinic. However, today materials acquisition is connected to institutionalized routines and repositories. Samples might come from cohorts enrolled in clinical trials or other types of studies, which are analyzed by various research groups and in various respects simultaneously, or they might come from biobanks in which samples are collected according to specific criteria established independently of the studies that use them.<sup>7</sup> The logic of these cohorts and collections thus shapes the design of individual research projects based on them, for instance, regarding the selection of appropriate cases and controls.

#### Experiments: Standardization, Automation, and Outsourcing

Today, researchers often use standardized kits provided by industrial suppliers (*convenience experimentation*).<sup>8</sup> Additionally, they rely on technological platforms established in their institutions.<sup>9</sup> Most strikingly, much of the experimentation is not performed by researchers engaging in a project, but by technicians in core facilities or by contract technology providers.<sup>10</sup> Standardization and automation of the production of data appear to reduce the possibility for unprecedented events emphasized by Rheinberger.<sup>11</sup> Furthermore, it seems that such research is built on the assumption that there is nothing left to discover with respect to, say, constituents of cells (at least for humans or

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<sup>5</sup> Kenny et al. 2021. For a long-term perspective on the promissory nature of biomedicine, see Löwy, this issue.

<sup>6</sup> There are, however, often-mentioned success stories, such as that of the *HER-2* oncogene, a prognostic breast cancer classifier and therapeutic target; see, e. g., König et al. 2017.

<sup>7</sup> Vegter 2018.

<sup>8</sup> Krohs 2012.

<sup>9</sup> Keating and Cambrosio 2003.

<sup>10</sup> Pichler and Turner 2007; Meder et al. 2016.

<sup>11</sup> Rheinberger 1997. See the discussion of the *Widerstandsavisio* by Borck, this issue.

established model organisms). Hence, it is rational to rely on standardized ways to further assess known entities.

#### **Data: Novelty in Data Processing Techniques and Regarding Relational Properties**

With the sources of materials and the ways to process them being standardized or outsourced, novelty is often generated on the level of data processing. Indeed, not few publications are based entirely or partly on data the production of which was not even commissioned by the authors, but where the data is simply retrieved from databases. If such research is less open to encountering entirely new kinds of material epistemic objects and often even relies on information generated by others, how can it result in new knowledge at all? Data processing procedures typically aim at identifying novel relational properties of known entities, for instance, the statistical correlation of certain genetic variants with a specific pattern of disease progression or treatment response. Also new types of meta-objects might be delineated, which are in a way immaterial or at least composed of elements that are not in permanent temporal and spatial association, such as network modules identified in molecular systems biology, an approach that is also part of PM.<sup>12</sup> The findings are generated by operations in the digital space that can still be compared to material experimentation. Where classical experimentation produced limited data sets in a targeted manner, in post-experimental science there is always an excess of data. The specific query or algorithm then generates differences in this data space similar to the way in which, say, a staining technique creates differences in the material space of a cell.<sup>13</sup> Even if many researchers rely on standardized software packages, here then is another occasion for adding new elements to a research system in a manner that is productive of novelty in a way that was described for data production in experimental systems by Rheinberger.<sup>14</sup> Researchers continuously develop new mathematical and computational techniques for the statistical treatment and integration of data. These practices, accordingly, must be studied in the same detail as the material innovations in research systems analyzed by science studies scholars before.

#### **Collaboration: Consortia, Workflows, and Epistemic Dependence**

Research projects in PM are rarely conducted by a single lab group. Instead, many projects are developed and pursued in research consortia of various sizes. To achieve this, the tasks are often modularized, such that the parties involved can pursue their work without the requirement that all researchers need to

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<sup>12</sup> Darrason 2018.

<sup>13</sup> See Rheinberger 2021, on p. 33. This work involves new roles for and forms of visualization; see Borck, this issue.

<sup>14</sup> Rheinberger 1997.

understand each stage in the workflow. This creates strong epistemic dependencies.<sup>15</sup>

In summary, PM is pursued through highly interdisciplinary and data-intensive research. The shift of emphasis from data production to data processing in such post-experimental science entails a re-evaluation of what constitutes relevant knowledge. Discovery does not aim at new molecular objects. Instead, what is considered valuable outcomes is models of relations and these are often not causal-mechanistic, but rather statistical or topological.<sup>16</sup> They are also often holistic, but in a way that is still reductionistic in the sense that a totality (say, the metagenome of an organism and its microbiome) is represented in terms of a highly restricted set of dimensions (e.g., DNA and transcribed RNA sequences).<sup>17</sup>

## 2. The Analysis of Approaches as a Novel and Versatile Analytic Framework

If the above considerations are adequate, then the category of an experimental system that was so fruitful for the study of twentieth century laboratory research in the life sciences, might not be optimally suited for the analysis of post-experimental science. As long as the focus of innovation was on experimental work and data consisted mainly of traces produced in the experiment or in their numerical representation, data interpretation and the (paper-)tools it required could be seen as part of an experimental system and its use. Data-intensive research is characterized by the fact that data production and processing are quite separate practices, often organized in a distributed manner. For this reason, it is important in these contexts to distinguish the often standardized and automated experimental methods of data production from the often innovative statistical-computational methods of data processing also analytically, while, at the same time, having a framework that allows to show how they are combined in relation to a research problem. This, together with the fact that increased collaboration requires co-ordination under shared goals and in the context of cohort studies and the creation and use of repositories, calls for categories that allow to analyze the process of adjusting problems and methods to each other and with respect to the work of others. For Rheinberger, speaking in terms of “experimental systems” was meant to de-emphasize the role of researchers as the “authors” of experiments and to suggest, instead, that experiments, like texts, have a dynamic that is not determined by the researchers’ intentions.<sup>18</sup> While this insight holds true, important questions on the construction and use of research systems with respect to goals, the interplay of surprises and goal adjustment, the positioning

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<sup>15</sup> Andersen and Wagenknecht 2013.

<sup>16</sup> Russo and Williamson 2011; Darrason 2018.

<sup>17</sup> For microbial ecology, see Meunier and Bayır 2021.

<sup>18</sup> Rheinberger 1997, on 224.

of researchers through the use of research systems, and the resultant dynamics of research fields, require an account that is explicit about researchers' intentions. I suggest that the category of an approach, which is broader than that of an experimental system, in so far as approaches involve experimental or other types of research systems, is suitable for such an analysis.

Approach, like experimental system, is an actors' category.<sup>19</sup> Researchers routinely speak of approaches; they promote their approach and distinguish it from other approaches in their field. The term seems, however, to have various meanings in different contexts. Below, I will explicate one meaning based on the assumption that at least in many cases where the term is used, this meaning is invoked. It is not important whether this is the meaning invoked in most instances (which would be difficult to prove). However, I take this meaning to be most relevant for two reasons: First, it is non-redundant. Often *approach* is used synonymously with *method*. These cases are already covered by philosophical analysis of concepts of method (in itself an ambiguous term). Second, I argue that an analysis along the lines of the suggested explication is epistemologically fruitful.

To explicate an ambiguous term used by scientists (the explicandum) requires giving an explicatum, typically in the form of a definition.<sup>20</sup> I propose the following definition of an approach in science: *A practice constitutes a unique approach if it constitutes a unique alignment of a problem and a method for the purpose of making phenomena accessible.*

Obviously, for further development and use of the definition it will be necessary to define its central terms (problem, method, alignment, access to phenomena). For the given purposes, I characterize problems as broad research topics shared within a community and methods as a combination of an abstract study design and a material research system (experimental or otherwise) that can implement it.<sup>21</sup> Developing an approach consists of two interrelated activities. Based on abstract ideas of what could be possible results, a problem is interpreted by formulating specific goals (answerable questions or desirable and realizable states of affairs) that can be achieved by a method. At the same time, a method is assembled or refined (designs are amended; elements are added to a research system) such that it can be used better to achieve the specified goal. Alignment then is an iterative process involving both activities that might be carried on throughout the research process, such that a workable approach stands as an endpoint rather than the beginning of research. Defining a goal typically involves selecting aspects of the phenomenon to which the overarching problem pertains, and methods are meant to make these

<sup>19</sup> For the rationale in turning actors' categories into analysts' categories, see Meunier 2021.

<sup>20</sup> A full explication involves other steps, such as making explicit the purpose, demonstrating the vagueness, identifying synonyms, and discussing previous accounts; see Cordes and Siegwart n.d. For *approach*, see Meunier 2021.

<sup>21</sup> As mentioned, the term *method* is ambiguous as it can refer to meta-strategies such as induction vs hypothetico-deductivism or to specific techniques. My characterization covers a middle ground.

aspects accessible for material interaction (intervening on it, measuring it), and hence for cognition (reasoning about it), and representation (referring to it).

Literally, to approach something means to move toward it from a given vantage point and in a directed and selective manner. Hence, as a metaphor, unlike perspective, approach emphasizes interaction. A point of contact with a phenomenon is constituted by the way a problem is interpreted, including the selection of aspects of a phenomenon, and by the way a method enables representational, cognitive, and material access to selected aspects.<sup>22</sup> Metagenomic approaches within PM, for instance, highlight the role of microbial symbionts in health and disease, but, as mentioned, tend to make microbes accessible only through their DNA and inferred metabolic functions, thus orienting theoretical models accordingly.<sup>23</sup> Hence an analysis in terms of approaches roots the perspectival character of representations in the level of practice.<sup>24</sup>

An important step in explicating a concept consists in evaluating its adequacy. I will concentrate on the fruitfulness of the suggested definition.<sup>25</sup> In general, the proposed explication is fruitful because it provides a conceptual structure that can serve as a framework to analyze research by identifying shared problems and specified goals as well as research designs and systems, and by tracing the iterative process of alignment and thereby the relevant decision points.<sup>26</sup> I will here only argue for its fruitfulness for historiography and indicate how this could be applied to the recent history of PM.

The concept of an approach is particularly suitable for addressing questions concerning the historical dynamics of research. On the one hand, the analysis of the development of approaches demands to show how methods travel, are transformed, or merge (including the differential reproduction or hybridization of experimental systems<sup>27</sup>). In the case of PM, an interesting example would be the introduction of AI.<sup>28</sup> On the other hand, such an account highlights how the perception of relevant goals changes, possibly under the influence of social currents. For instance, the promise (and its metaphorical framing) of treatments tailored to the individual vs one-size-fits-all solutions positions PM not only in a medical but also in an economic environment. Novel alignments of problems and methods can result in a reframing of phenomena, initiate the formation of fields, or lead to conflicting perspectives.

The main advantage of the framework for such historical analysis is that it is scalable. It facilitates synchronic or diachronic comparisons on various levels from disciplines to individual projects. It can be used to characterize a whole

<sup>22</sup> The vantage point and hence interaction is also shaped by training, institutional affiliation, social position, political interests, etc. and thus implies situatedness; see Haraway 1988.

<sup>23</sup> Again, similar to metagenomic approaches in ecology; see Meunier and Bayır 2021.

<sup>24</sup> For perspectivism, see Giere 2006.

<sup>25</sup> Other criteria of adequacy are similarity, regularity, and simplicity; see Cordes and Siegwart n.d. For *approach*, see Meunier 2021.

<sup>26</sup> On the “decision ladenness” of knowledge production, see Knorr-Cetina 1981.

<sup>27</sup> Rheinberger 1997.

<sup>28</sup> Subramanian et al. 2020.



field such as PM and thus distinguish it from previous or alternative (bio)medical fields by the way it specifies a broader problem (e.g., addressing disease in terms of individual variation) and by its broad methodological choices (e.g., the reliance on cohort studies, high-throughput technologies, and advanced data processing). It can also be used to compare specific research projects within PM that interpret the problem differently by locating individuality in different biological aspects (e.g., genome or metabolome) and hence assemble different methods (e.g., sequencing-based or mass spectrometry-based).

It can thus be argued that an analysis in terms of approaches, rather than experimental systems alone, can be used to track broader shifts in a research landscape and to zoom in on the specific choices taken by research groups. Rheinberger speaks of “experimental cultures” to capture the broader dynamics.<sup>29</sup> The approach framework combines this with an analysis of changing problem agendas.<sup>30</sup> It emphasizes the iterative alignment of experimental designs and systems with problem interpretations and thereby contextualizes the local differential reproduction of experimental systems in a space of multiple interests that shape such interpretations. Scalability then makes the account suitable for integrating macro- and micro-histories through tracing the emergence of approaches broadly construed, as defining fields or even disciplines, through the development of specific approaches on the level of individual research projects.

### 3. How the Categories of Science Studies Age

The categories of science studies might need updates, extensions, or reinterpretations when the way science is done changes. Rheinberger developed his account in the 1990s, looking back on the recent history of molecular biology at a time when data-intensive research was just emerging. As the discussion of PM showed, the focus of experimental systems might be too narrow for an analysis of what I termed *post-experimental research*. I suggested *approach* as a broader category that can accommodate experimental and post-experimental work and hence can also serve to trace the historical shift.

This illustrates that commentators of today’s science will ask different questions than earlier scholars, simply because science is organized differently and exhibits new ways of knowledge production, distribution, and use. Hence science studies will consider different aspects as epistemologically or sociologically important and need to develop new analytic categories that suit their aims.

There is also a second way in which categories of science studies age that is not directly pertinent to the advantages of an analysis in terms of approaches, but is relevant with respect to the assessment of the recent history of PM. For today’s scholars studying science in the 1990s, the focus of interest might have

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<sup>29</sup> Rheinberger 1997, chapter 9.

<sup>30</sup> Love 2014.



changed from that of contemporary scholars. This is of course not different to the situation where today's historians and historians active in the 1990s ask different questions about a more distant past, say, the early twentieth century. In any case, science studies scholars of the past, whether they looked at their contemporaries or at more distant scientists, will later be seen as actors of their time and as part of the cultural history of the science they commented on. A good example for this process is the science studies scholarship produced in the context of the human genome project (HGP).<sup>31</sup> Much of this work had a critical, political agenda and can be read as a response to the deterministic rhetoric of some proponents of the HGP.<sup>32</sup> Also earlier science, say, classical genetics, was represented by these scholars as the past of the gene-centered present of the 1990s and thus criticized for laying the ground for the genetic determinism of the HGP.<sup>33</sup> Before and after the HGP attracted all the attention, however, histories of classical genetics might instead focus on different aspects and emphasize non-deterministic and epigenetic ideas. Likewise, with the wisdom of hindsight, we see the HGP itself as setting the stage for the post-genomic study of cellular (and ecological) complexity.<sup>34</sup> From this perspective we might ask if researchers pushing for the sequencing of human and model organism genomes were not interested in (and hence assuming) this complexity all along, despite the simplistic promises, such as gene-to-drug pipelines, used by some actors to garner political support.

PM is interesting in this respect, because it represents what has become of these visions of genomic medicine in post-genomic times. As mentioned, PM itself has been described as "promissory." And yet, among the various kinds of studies conducted under this heading, even the most gene-centric ones, such as genome-wide association studies (GWAS), have toned down with respect to genetic determinism. Instead, there are many new forms of research, taking into account complexity in studying disease, focusing on more molecular layers (transcriptome, proteome, metabolome), on the genomes and other omics layers of microbial symbionts (microbiome), as well as on environmental factors (exposome).<sup>35</sup> This, of course, draws other types of critical scrutiny by science studies scholars, for instance, regarding the multiple uncertainties of knowledge claims.<sup>36</sup> Nonetheless, sequencing technologies, computational tools (software, algorithms), and crucial infrastructures (dry labs, core facilities, databases) were initially developed in the course of the HGP and in many ways constitute the social and material conditions for today's post-genomic, data-intensive research agendas, and approaches as exemplified in PM. The HGP will thus be evaluated quite differently in science studies today.<sup>37</sup>

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<sup>31</sup> See also Hilgartner, this issue.

<sup>32</sup> E.g., Nelkin and Lindee 1995.

<sup>33</sup> E.g., Keller 2000.

<sup>34</sup> Richardson and Stevens 2015.

<sup>35</sup> König et al. 2017.

<sup>36</sup> Lohse 2022.

<sup>37</sup> Richardson and Stevens 2015.

Robert Meunier

Similarly, younger science studies scholars develop their categories in dialog with those of their predecessors and their work is enabled by the institutions, societies, journals, and other aspects of the profession that earlier scholars created and shaped. The many contributions by Hans-Jörg Rheinberger are in these respects particularly important for my own work.

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