

GOTHAM CITY RESEARCH

Sumitomo Chemical and Sumitomo Pharmaceutical: Part II

CiRA, Dr. Yamanaka, and the undisclosed history of image duplication concerns

CIRA & Dr. Shinya Yamanaka past papers scrutiny						
#	Date of scrutiny	Name of paper	Publication date	Yamanaka author?	Scrutiny	Status
1	Apr-2014	'Essential role of NAT1/p97/DAP5 in embryonic differentiation and the retinoic acid pathway'	Oct-2000	Yes	Image duplication concern.	CIRA investigation disclosed original data to the figures were not preserved.
2	Jun-2016	'Generation of pluripotent stem cells from adult mouse liver and stomach cells'	Aug-2008	Yes	Large correction to study behind paywall.	N/A
3	Jan-2018	'In Vitro Modeling of Blood-Brain Barrier with Human iPSC-Derived Endothelial Cells, Pericytes, Neurons, and Astrocytes via Notch Signaling'	Mar-2017	No	Fraudulent data.	Fraudulent data was found in all six main figures and five of six supplementary figures, invalidating the paper's conclusions. Yamanaka nearly resigned following the incident.
4	Oct-2020	'Function of IRE1 alpha in the placenta is essential for placental development and embryonic viability'	Sep-2009	Yes	Image duplication concern.	No response from authors.
5	Oct-2020	'The effects of cardioactive drugs on cardiomyocytes derived from human induced pluripotent stem cells'	Jul-2009	Yes	Image duplication concern.	No response from authors.
6	Oct-2020	'Aggregation of embryonic stem cells induces Nanog repression and primitive endoderm differentiation'	Nov-2004	Yes	Image duplication concern.	No response from authors.
7	Oct-2020	'The homeoprotein Nanog is required for maintenance of pluripotency in mouse epiblast and ES cells'	May-2003	Yes	Image duplication concern.	No response from authors.
8	Mar-2025	'Generation of Human Melanocytes from Induced Pluripotent Stem Cells'	Jan-2011	Yes	Image duplication concern.	No response from authors.
9	Mar-2025	'Modeling familial Alzheimer's disease with induced pluripotent stem cells'	Dec-2011	Yes	Image duplication concern.	Admission of duplication error and antibody names in Figure 1. Original raw data no long available.
10	Aug-2026	'Zonisamide promotes survival of human-induced pluripotent stem cell-derived dopaminergic neurons in the striatum of female rats'	Jun-2020	No	Image duplication concern.	Jun Takashi is director at CIRA and led the Amchepry study at Kyoto university.

- Sumitomo Pharma targets 350 billion JPY in iPSC revenue, including from Amccheptry
- The Center for iPSC Cell Research & Application (CiRA) is SP's research partner
- CiRA is iPSC cells supplier for the Amccheptry trials, conducts the trials + research
- CiRA is paid by Sumitomo Pharma, with a relationship since 2011.
- Sumitomo Pharma is going all-in on CiRA while Takeda recently terminated its 10 year partnership with CiRA.
- There are two well documented cases of fraud involving CiRa and its founder Shinya Yamanaka, in 2014 and 2018.
- **However, we have discovered 8 additional problematic cases, including 1 research paper where the Amccheptry trial's lead investigator is an author**

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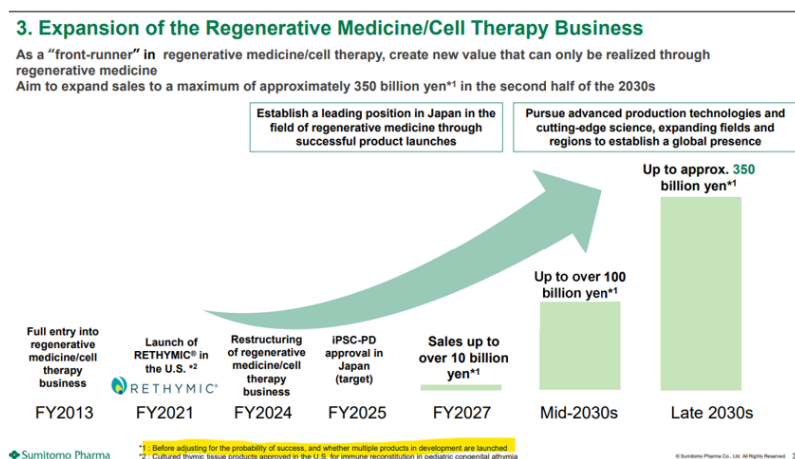
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Introduction

Sumitomo Pharma targets 350 billion JPY in regenerative revenue

Sumitomo Pharma and Chemical project 350 billion in revenue from regenerative drugs:



Source: Sumitomo Pharma May 2025 presentation

The 350 billion revenue target assumes 100% probability of success, even though 92% of clinical trials fail. The revenue forecast also assumes that Amshepri, an experimental treatment for Parkinson's Disease, will success with 100% probability of success.

Here's the problem with that: although Amshepri was granted "a conditional and time limited approval" in Japan as announced on March 6th 2026, 0% of drugs have succeeded under this controversial program (see appendix for more details as to why), since its inception in 2014.

We believe Amshepri is existential for Sumitomo Pharma. The Latuda patent cliff nearly destroyed their business just a few years ago. Pharma's business is in worse position today than it was before the Latuda patent expiration, for all the reasons shown below.

Sumitomo Pharma			
Factors	Pre 2023 patent cliff (Mar-22)	Present (Mar-26)	
Drugs at risk		Latuda	Orgovyx & Gemtesa
Total drug revenue concentration		38%	55%
Newly developed drugs ready to grow revenue		Orgovyx & Gemtesa	None
Number of pipeline assets in phase 2 & 3		*7	**1
R&D spend (JPY mln)		94,903	43,996
Net debt (JPY mln)		66,064	172,876
Group gross margin		71.9%	56.7%

* EPI-589, DSP-788, rodatristat ethyl, URO-902, Ulutaront, Gemtesa, SEP-4199

** Enzomenib

60% of Pharma's revenue (Orgovyx + Gemtesa) are at risk – it's only a matter of when and how exactly, in our opinion – and thus we think Pharma needs to fill that void (350 billion would do).

Sumitomo Pharma		
FY End 31 March (JPY bln)	Mar-26	Mar-27e
Group revenue	453.3	540.0
Orgovyx	155.0	209.9
Gemtesa	96.0	106.3
Orgovyx & Gemtesa total revenue	251.0	316.2
% of revenue	55.4%	58.6%
Regenerative revenue target	350.0	350.0
% of revenue	77.2%	64.8%

Amchepry is dependent on CiRa, its research provider, but CiRa and its founder are suspect

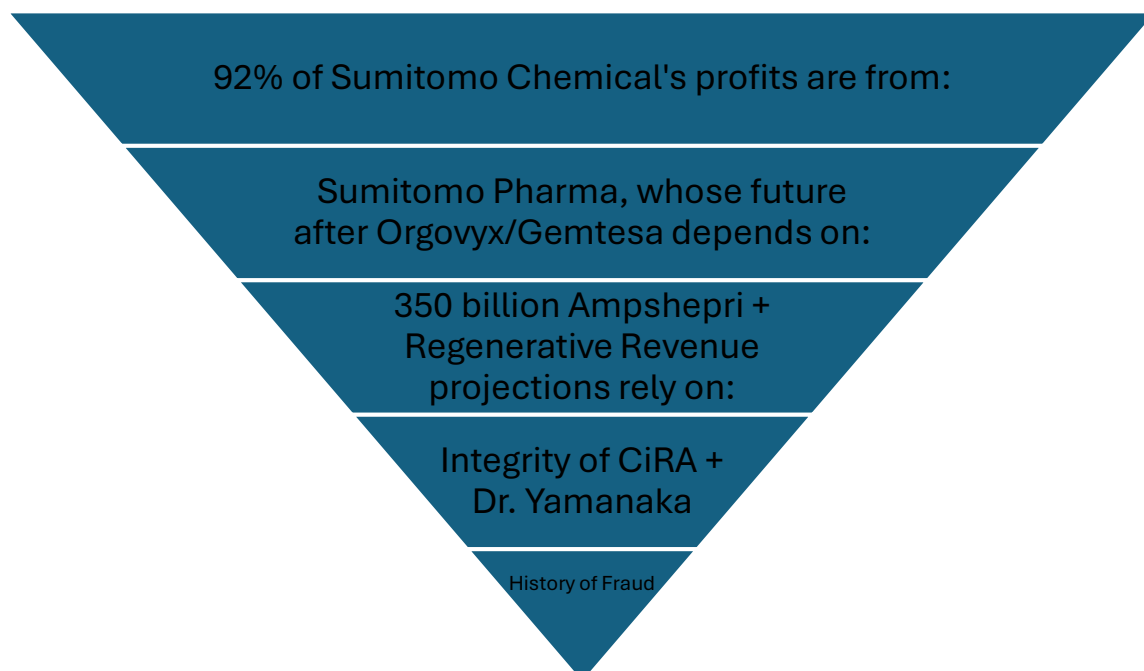
This desperation would explain why both Sumitomo Pharma and Chemical have been aggressively promoting Amshepri in any and all corporate communications: for example, Amchepry has appeared a total of 33 times in the last 6 months across the annual report, presentation and earnings calls by Pharma mgmt. Pharma refers to Amchepry as a “product” and “medicine”, as if they were widely available, and ready-to-go, products, even they are not.

Although we find Amchepry suspect for many reasons, in this report we will focus on Sumitomo Pharma’s research partner – CiRA and its President, Shinya Yamanaka. CiRA plays many important roles in the Amchepry experiments: CiRA provides the cell materials, CiRA scientists conduct and administer the experiment, and CiRA scientists process the data, and public the research. Finally, CiRA and its scientists receive payments from Sumitomo Pharma.

These are conflicts of interest, but they are not problematic by themselves. The issue is that CiRA and its head Dr. Yamanaka have two documented cases of fraud. Worse, we have discovered 8 additional cases where we see fraud, including a paper where the Amchepry trial’s lead investigator is an author. As a result, we believe the Amchepry and regenerative research are compromised.

Gotham City Research’s thesis for Part II summarized with a diagram

We believe the Sumitomo Pharma’s future depends on Regenerative revenue. But we see a clear and troubling pattern of behavior with CiRA and Dr. Yamanaka. Seeing that CiRA oversees Sumitomo Pharma’s regenerative research, we believe Pharma’s future is on incredibly weak and suspect foundation:



Amchepry depends on the integrity of CiRA

CiRA is Sumitomo Pharma's research partner, for the Amchepry program

At Sumitomo Pharma's iPS Cell Approval press conference held in Osaka city on March 6th following the acquisition of the conditional and time-limited approval, Sumitomo Pharma President Toru Kimura, Sumitomo Chemical President Nobuaki Mito, and **Director Jun Takahashi of Kyoto University's Center for iPS Cell Research and Application (CiRA), were all present.**



Sumitomo Pharma President Toru Kimura (second from the right) and others attend a press conference after receiving manufacturing and sales approval for Amchepry on March 6 in Chuo Ward, Osaka City (Photo by Shigetaka Doi).

Source: <https://www.sankei.com/article/20260307-PTZVFR367BIN3GHXHSV67PZHVI/>

Who is Jun Takahashi? What is CiRA? CiRA's scientists conduct the Amchepry experiments, CiRA supplies the key materials for the experiment. Finally, CiRA is paid by Sumitomo Pharma.

CiRA is IPS cells supplier for the Amchepry trials, both past and future

CiRA was responsible for supplying the IPS cells, for the 7-person Kyoto university Amchepry trial that received conditional approval, as shown below:

The technology for manufacturing iPS cell-derived dopaminergic neural progenitor cells:

The Product contains the dopaminergic neural progenitor cells differentiated from iPS cells stock **provided by CiRA Foundation** based on differentiation and manufacturing technology owned by Kyoto University and other parties. In addition, the Product, in one of its production steps for dopaminergic neural progenitor cells, employs a proprietary cell purification technology discovered by KAN Research Institute, Inc. (currently Kobe Research Laboratories, Eisai Co., Ltd.) and owned by Eisai Co., Ltd.

Source: <https://www.sumitomo-pharma.com/news/assets/pdf/ene20260306.pdf>

CiRA will also be supplying the iPS cells for the coming 35-patient, Amchepry trial:

This section introduces **research being conducted by other institutions** using iPS cell stocks **provided by the iPS Foundation**, as well as regenerative medicine products derived from iPS cell stocks with conditional and time-limited approval.

Conditional/Time-Limited Approval: Regenerative medicine products derived from iPS cell stocks

Manufacturing and sales company	Sumitomo Pharma Co., Ltd.
Product name	Amchepry
common name	Ragneprocell
Approving Countries/Regions	Japan
source	Pharmaceuticals and Medical Devices Agency (PMDA) "Amchepry Package Insert"

Source: <https://www.cira-foundation.or.jp/j/achievement/provision-of-ips-cells/>

Sumitomo Pharma and CiRA and CiRA scientists have a financial relationship

We see various conflict of interest between CiRA and its members, and Sumitomo Pharma. CiRA scientists administer and authored the study on which the approval rests while holding a direct financial interest in its success, receiving grants from Sumi Pharma, which itself stands to benefit commercially:

Amchepry nature study conflict of interest		
Name	Affiliation	Conflict of interest
Nobukatsu Sawamoto	Kyoto Universtiy	Grant received from Sumitomo Pharma Led Amchepry nature study
Ryosuke Takahashi	Kyoto Universtiy	Grant received from Sumitomo Pharma
Jun Takahashi	CiRA	Grant received from Sumitomo Pharma. Led Amchepry nature study
Satoe Hiramatsu	CiRA/Sumitomo Pharma	Disclosed as employee of Sumitomo Pharma
Daisuke Doi	CiRA	Employee of CiRA
Tetsuhiro Kikuchi	CiRA	Employee of CiRA
Asuka Morizane	CiRA	Employee of CiRA

We are not saying conflicts of interest are inherently wrong, but rather that the integrity and trustworthiness of CiRA and its members matter that much more because they play so many different roles, that in the wrong hands, can lead to very bad outcomes.

Jun Takahashi is CiRA Principal Investigators

Jun Takahashi, who sat along with the CEOs of both Chemical and Pharma, plays a critical role in at CiRA and in the Amshepri program. As shown below from the CiRA website, the person purported to be Takahashi in the above picture matches Takahashi profile picture taken from the CiRA website below:



Jun Takahashi M.D., Ph.D.

> [Lab Website](#) 

> [Research Progress in FY2024](#) 

> [Contact: takahashi-g@cira.kyoto-u.ac.jp](#) 

Please change * to @

Source: https://www.cira.kyoto-u.ac.jp/e/research/takahashi_summary.html

Jun Takahashi is described by Sumi Pharma in a press dated December 2023 as having led the study "In Japan, Kyoto University Hospital has been conducting an investigator-initiated clinical study since 2018 to confirm the safety and efficacy of the therapy by a research group led by Professor Jun Takahashi of CiRA".

Source: <https://www.sumitomo-pharma.com/news/20231226.html>

The ethics declaration section of the 7-person Kyoto Amchepry study published in Nature which was published on 16/04/2025 which led to its conditional approval, reveals

- J.T. (Jun Takahashi) co-author of the study, lead investigator, is a director at CiRA, having received a research grant from Sumi Pharma
- J.T. additionally runs CiRA, the institution whose sister body (CiRA Foundation, chaired by Yamanaka) supplied the cell stock.

- S.H. (Satoe Hiramatsu) who co-authored the study, co-lead investigator, is declared as an employee of Sumi Pharma
- 2 additional co-authors of the Amchepry nature study, (Nobukatsu Sawamoto & Ryosuke Takahash) received grants from Sumi Pharma as seen in the screenshot below

The Ethics declaration section of the study:

Ethics declarations

Competing interests

N.S., R.T. and J.T. received a **grant** for collaborative research from Sumitomo Pharma. R.T. received a research **grant** from Nihon Medi-Physics. T.O. received a research **grant** from Siemens Healthcare. S.H. is an employee of Sumitomo Pharma. The other authors declare no competing interests.

The Author contributions show CiRA tied to it:

Author contributions

J.T. and R.T. were the lead investigators. N.S., D.D. and Takayuki Kikuchi wrote the first draft of the paper. N.S., E.N., M.S., H.Y., Y.T., A.S., Y.F., T.O., Y.N. and R.T. contributed to the acquisition of clinical data. D.D., Tetsuhiro Kikuchi, A.M. and J.T. contributed to the generation of human iPS cells and DA progenitor cells. **S.H.** contributed to the PD rat experiments. Takayuki Kikuchi, Y.A. and S. Miyamoto contributed to neurosurgery. T.A. and T.S. contributed to immunosuppressive therapy management. K.U. and S. Morita performed statistical analyses. All of the authors contributed to the analysis or interpretation of data and performed critical revisions of the manuscript.

Source: <https://pmc.ncbi.nlm.nih.gov/articles/PMC12095070/>

Sumitomo Pharma and CiRA share ties beyond this Amchepry program/project

Naoko Takasu, who appears to be the second most senior person behind Dr. Yamanaka at the CiRA foundation, being only one to hold the title "Senior executive director". She has a direct connection to Sumi Pharma having worked there up until 2008.



Naoko
Takasu

Executive Director, Kyoto University iPS Cell Research Foundation
 . **Retired from Sumitomo Pharmaceuticals** (Dainippon Sumitomo Pharma) at the end of May 2008. Joined CiRA in June of the same year. After serving as head of intellectual property and then deputy director, assumed current position in 2020.

Source: <https://www.cira.kyoto-u.ac.jp/j/pressrelease/nl/vol48/society.html>

Sumi Pharma and CiRA foundation are joint research partners

CiRA foundation's "partners" page lists Sumitomo Pharma as joint-research partner:



Source: <https://www.cira-foundation.or.jp/e/about/team/>

CiRA and Sumitomo Pharma: joined at the hip for over 15 years

We have observed that CiRA and/or Yamanaka are often mentioned by Pharma within its financial presentations. Within these, CiRA and Yamanaka are mentioned in the context of clinical trials and potential clinical trial timelines. Given how many times, as well as how long (since 2011) CiRA and/or Yamanaka have been mentioned within Pharma's public releases, it would suffice to say that Pharma's ties with CiRA and Yamanaka appear to extend above and beyond just Amchepry:

1. Pharma filings mention CiRA and Yamanaka over 115 times
2. Pharma filings mention them over 15 years: from 2011 until just last month
3. Even Chemical's filings mention CiRA and Yamanaka over 16 times

Please see the Appendix for the specific documents and dates that Yamanaka and CiRA mentioned.

Pharma's going all-in on CiRA while Takeda recently terminated its partnership with CiRA

While Pharma has continued its bet on iPS cells, even providing 350 billion revenue targets, Takeda recently abandoned its partnership with CiRA, implying Takeda does not see a viable commercialization path to iPS cell technology within regenerative medicine:

- Takeda and CiRA announced on February 2026 that their joint research program "T-CiRA" would end.
Takeda invested JPY 20bn over the partnership period. The level of spending resembles the size of a small exploratory pilot program rather than a large scale one.
- Its original goal, according to Takeda's April 17th 2025 press release was to develop clinical applications of iPS in areas such as: heart failure, diabetes mellitus, **neurological disorders** and cancer immunotherapy.
- An article from Nikkei Asia published February 4th 2026 commenting on the end of the partnership that no new drugs reached practical use.
- Takeda CEO Christophe Weber stated the cell therapy program was discontinued because it "is not sufficiently competitive in the current market environment"
 - Source: <https://www.alphabiz.co.kr/news/articleView.html?idxno=143347>
 - Link: <https://asia.nikkei.com/business/pharmaceuticals/takeda-kyoto-university-end-10-year-stem-cell-tie-up-with-no-new-drugs>
- Takeda, at face value is far more successful at internal drug development, than SP. For example, Takeda has 18 drugs in FDA phase 3:
 - Source: <https://assets-dam.takeda.com/image/upload/v1785376660/Global/Investor/Financial-Results/FY2026/Q1/q1 Pipeline table en.pdf>

CiRA, Yamanaka, and 2 documented cases of fraud

CiRA, and its head, Dr Yamanaka, have a documented history

The [CiRA Foundation](#) (established in 2020) is a spin-off organization from [CiRA](#) (the Center for iPS Cell Research and Application at Kyoto University). While CiRA focuses primarily on academic and basic medical research, the CiRA Foundation acts as an industrial bridge to accelerate the practical and clinical application of regenerative medicine. Dr. Yamanaka founded CiRA in 2010 and is the President of CiRA Foundation.

CiRA & Sumitomo Pharma have a long-standing partnership dating back since at least 2018 for the joint research of iPS (induced pluripotent stem cell) technology for the treatment of Parkinson's as per Sumitomo Pharma website:

The Center for iPS Cell Research and Application (CiRA)	① This joint research collaboration between industry and academia, focusing on a rare intractable disease caused by genetic mutation, aims to use induced pluripotent stem cells (iPS cells) to identify the pathognomonic mechanism of the disease, identify the most disease-specific target molecule from various pathological changes of signal transduction, and screen specific inhibitors against the signal pathway. As a result, the aim is to create an epoch-making treatment to suppress detrimental conditions in patients. ② CiRA and Sumitomo Pharma are conducting joint research and development to establish the world's first Parkinson's disease treatment using allogeneic iPS cell-derived dopaminergic neural progenitor cells.
The Center for iPS Cell Research and Application (CiRA) and Hitachi Ltd.	CiRA, Hitachi Ltd., and Sumitomo Pharma are jointly developing the base technology and evaluation methods to establish a production process for dopaminergic neural progenitor cells. This will be used to develop the world's first Parkinson's disease treatment using allogeneic iPS cell-derived dopaminergic neural progenitor cells. These endeavors are part of the "Project Focused on Developing Key Evaluation Technology: Evaluation for Industrialization in the Field of Regenerative Medicine" commissioned by The Japan Agency for Medical Research and Development (AMED).

Source: <https://www.sumitomo-pharma.com/rd/research-alliances/>

The CiRA Foundation, and Dr Yamanaka have a troubling history tied to documented fraud in the following two cases:

Publication date	Name of study	Allegation date	Years to discovery
Mar-2017	In Vitro Modeling of Blood-Brain Barrier with Human iPSC-Derived Endothelial Cells, Pericytes, Neurons, and Astrocytes via Notch Signaling	Jan-2018	0.8
Oct-2000	Essential role of NAT1/p97/DAP5 in embryonic differentiation and the retinoic acid pathway	Apr-2014	13.5

Given how important CiRA is to the Amcchepri program – they provide the cell materials, they conduct the research, and also have a financial relationship with Sumitomo Pharma (SP stands to financially benefit from the outcome of the program), We believe it is important to assess CiRA's integrity. In our view they are unreliable and we explain why in this and in the next section. Note that the time between when alleged fraud occurred, and its discovery, are fast shrinking.

Dr. Yamanaka 2014 fraud investigation – first public case tied to Yamanaka

Dr. Yamanaka was the lead author of a paper in 2000 concerning "Essential Role of NAT1/p97/DAP5 in Embryonic Differentiation and the Retinoic Acid Pathway". Yamanaka's paper turned out to be problematic – we think fraudulent – but it was not discovered until 2014.

In 2014, Japan was involved in a major stem-cell related scandal: Haruko Obokata, a young researcher at RIKEN, published two papers in Nature in January 2014. Turned out to be fraud. Amidst heightened scrutiny due to this scandal, online bloggers found that Yamanaka's paper published in 2000, contained 2 suspect images, leading to a Kyoto university investigation, from second-hand reporting:

- Sources concerning online bloggers pointing to mistakes:

“fault with one of his older publications.”

“At a press conference today, he said that a paper published in 2000 contains an image that may be incorrect.”

Source: <https://www.science.org/content/article/japans-latest-stem-cell-apology>

“According to the institute's website and other sources, there were suspicions that **images in Yamanaka's paper had been "cut and pasted," and it was pointed out that the standard deviation values, which indicate the variability of experimental results, were similar across all samples with different results, which was considered unnatural.**”

Source: <https://the-liberty.com/article/7773/>

The original data for the figure could not be found in Dr Yamanaka's notes or materials:

Regarding the PCR in Figure 3A of the scientific paper, the bands were similar but not identical. Even after the contrast was altered, no trace of cutting and pasting was observed. Professor Yamanaka's notes and documentation were confirmed to contain experimental data (Appendix 1 and Appendix 2) from a PCR assay carried out using the same primer as in the figure which confirmed the presence of NAT1^{-/-}ES cells. However, the original data for the figure were not found in Professor Yamanaka's notes and documentation.

Regarding Figure 7B of the scientific paper, experimental data from Northern blot analysis of Oct3/4 gene expression were found present in Professor Yamanaka's documentation. When these data were plotted as a figure, they indicated, as in Figure 7B of the scientific paper, that the decrease in the amount of Oct3/4 expression in NAT1^{-/-}ES cells was suppressed under conditions stimulating differentiation (Appendix 3). However, since the mean values and the standard deviation value differed from those in Figure 7B of the paper, these did not appear to be the original data.

Source: <https://www.cira.kyoto-u.ac.jp/e/pressrelease/other/140430-192946.html>

CiRA investigates itself – er, Yamanaka – amidst the fraud

Additionally, within the same press release mentioned just above, “In response to a request from Professor Yamanaka, CiRA has carried out an investigation to establish the facts.”,

1. Background

Professor Shinya Yamanaka of Kyoto University's Center for iPS Cell Research and Application (CiRA) has found a website on which questions are raised over graphic figures that appeared in a scientific paper published in 2000 by a research group to which the professor belonged.

In response to a request from Professor Yamanaka, CiRA has carried out an investigation to establish the facts.

Source: <https://www.cira.kyoto-u.ac.jp/e/pressrelease/other/140430-192946.html>

Yamanaka was director (highest position) of CiRA since 2010, consequently, at the time of the investigation in 2014 concerning the Yamanaka 2000 paper. CiRA, an organization highly dependent on donations as their funding source, was tasked with investigating the person likely responsible for most funding driven by his reputation as a Nobel Laureate. If the leader of CiRA were to have committed research misconduct, there would be significant funding consequences, if not major reputational damage, at the minimum. Thus CiRa's “investigation” into Yamanaka was inherently a highly conflicted one. We doubt it was a sincere investigation.

A CiRA study involving iPS cells was found to be fraudulent in 2018

4 years later, a CiRA study involving iPS (induced pluripotent stem cells) cells was found to be fraudulent on January 22, 2018, 10 months after the original study publication (March 17, 2017).

The study name *"In Vitro Modeling of Blood-Brain Barrier with Human iPSC-Derived Endothelial Cells, Pericytes, Neurons, and Astrocytes via Notch Signaling"* released on 17 March 2017 purported to show CiRA successfully recreating the blood brain barrier using iPS cells. **However, it later turned out, according to official explanation provided by the university that a "single" researcher at CiRA falsified all main figures presented in the study (example below). In addition, 5/6 supplementary figures were falsified completely invalidating the study.**

Dr. Yamanaka in his public apology noted "I want to stress that the research fraud has no direct influence on any ongoing or planned clinical research involving iPS cells". A press release states Yamanaka was penalized by university for "poor supervision of research integrity" concerning the incident. How he was punished not disclosed, to our knowledge.

Sources: <https://www.cira.kyoto-u.ac.jp/e/pressrelease/other/180122-181000.html>
<https://www.cira.kyoto-u.ac.jp/e/pressrelease/other/180328-180000.html>

Yamanaka suggested he might resign as a result of the 2018 fraud

"Shinya Yamanaka, who won a share of the 2012 Nobel Prize in Physiology or Medicine for the discovery of induced pluripotent stem (iPS) cells, has suggested he could resign as director of Kyoto University's Center for iPS Cell Research and Application (CiRA) in Japan over a fraudulent paper published by center researchers"

Source: <https://www.science.org/content/article/nobel-laureate-suggests-he-could-resign-leadership-post-over-colleague-s-bogus-paper>

All of the research fraud was blamed on Kohei Yamamizu: we find this suspect

All of the research fraud was blamed on 1 person "Kohei Yamamizu", however, there were 10 other researchers involved in this fraudulent CiRa paper:

Kohei Yamamizu¹, Mio Iwasaki², Hitomi Takakubo³, Takumi Sakamoto⁴, Takeshi Ikuno³, Mami Miyoshi³, Takayuki Kondo⁵, Yoichi Nakao⁴, Masato Nakagawa², Haruhisa Inoue⁵, Jun K Yamashita³

Source: <https://pubmed.ncbi.nlm.nih.gov/28238797/>

The study's disclosures indicates:

- Koyei Yamamizu "conceived the project, performed all experiments, and wrote the manuscript"
- However, within the following sentence, the paper contradicts itself stating the other researchers performed experiments also "M.I. and M.N. performed nanoLC-MS/MS for drug kinetics; H.T., T.I., and M.M. helped with the iPSC maintenance and EC and pericyte differentiation; T.S. and Y.N. Performed nanoLC/MS/MS for DHA; T.K. and H.I. helped with the neuron and astrocyte differentiation"
- Furthermore, Jun K Yamashita "supervised the experiments"

AUTHOR CONTRIBUTIONS

K.Y. conceived the project, performed all experiments, and wrote the manuscript; M.I. and M.N. performed nanoLC-MS/MS for drug kinetics; H.T., T.I., and M.M. helped with the iPSC maintenance and EC and pericyte differentiation; T.S. and Y.N. performed nanoLC/MS/MS for DHA; T.K. and H.I. helped with the neuron and astrocyte differentiation; J.K.Y. supervised the experiments.

Source: [https://www.cell.com/stem-cell-reports/pdf/S2213-6711\(17\)30039-5.pdf?returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS2213671117300395%3Fshowall%3Dtrue](https://www.cell.com/stem-cell-reports/pdf/S2213-6711(17)30039-5.pdf?returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS2213671117300395%3Fshowall%3Dtrue)

We find the officially provided explanation suspect: that this research fraud was conducted by 1 person given that there were multiple other co-authors who ran experiments alongside Kohei.

Several people would have handled and seen the underlying data firsthand from running the experiments. The research was also supervised by Jun Yamashita. For the official explanation to make sense, one would have to accept (i) multiple people ran experiments (ii) they all saw the raw data directly (iii) likely shared the same laboratory yet, (iv) not one of them noticed the data discrepancies, and that (v) none of them flagged the errors upon reading the final paper, where the presented results contradicted their own results they had observed first-hand when they conducted the experiments themselves.

Yamanaka was supposedly penalized by Kyoto University

A CIRA press release includes a quote from Yamanaka claiming he “received a penalty”:

Director Shinya Yamanaka’s message

I feel a strong responsibility for not having prevented research misconduct at our institute. As CIRA Director, I have received a penalty from the university for my poor supervision of research integrity. To express my remorse, I have decided to donate to the iPS Cell Research Fund voluntarily. I will do my best to regain the public trust to our institute by conducting preventive measures against research misconduct.

Source: <https://www.cira.kyoto-u.ac.jp/e/pressrelease/other/180122-181000.html>

News reporting on the incident states the nature of his punishment was not made public:

- Nikkei: “Director Shinya Yamanaka issued a statement saying that he “received disciplinary action as a supervisor,” but Kyoto University has not disclosed the details of the disciplinary action, stating that reprimands, severe warnings, and warnings do not meet the criteria for public disclosure.”
 - Source: <https://www.nikkei.com/article/DGXMZO28689760Y8A320C1CR8000/>
- Shikoku: “Director Shinya Yamanaka issued a statement saying he “received disciplinary action as a supervisor,” but Kyoto University has not disclosed the details of the disciplinary action, stating that reprimands, severe warnings, and warnings do not meet the criteria for public disclosure”
 - Source: <https://www.nikkei.com/article/DGXMZO28689760Y8A320C1CR8000/>

It is theoretically possible that Yamanaka had no role in the 2018 CIRA fraud. It is also, theoretically possible that one single scientist committed all the fraud in 2018. However, we dug deeper into Yamanaka and have found more problematic academic papers. This raises the question: does lightning strike twice? Eight times in a row? Our new findings lead us to believe that Yamanaka is either an unrepentant fraudster, or a recklessly sloppy researcher who attracts fraudsters, and that he uses his Nobel Prize credentials to evade scrutiny.

Dr Yamanaka and 8 additional suspect research papers

Gotham City Research believes Amchepry depends on the integrity of CiRA and Yamanaka

Amchepry approval lies on a very thin base of evidence. And Amchepry relies on the integrity of CiRA. Yet Yamanaka and his CiRA foundation have been associated with two documented cases of fraud as discussed in the prior section:

- The 2014 paper scandal involving Yamanaka's 2000 paper was attributed to poor record keeping. Yamanaka was unable to disprove allegations that 2 images in the paper were manipulated/fabricated.
- The 2018 CiRA fraud was conveniently attributed to 1 researcher.

Gotham City Research investigated Yamanaka and found way too many examples where there is suspicious similarity between images in research papers where Yamanaka is an author. Pubpeer forums suggest a **persistent pattern of behavior concerning image duplication within his papers. Recall, this was exactly the same problem during the 2014 research paper scandal!**

Here is a list of problematic papers where the scientific community question the accuracy and integrity of paper images where Yamanaka or CiRA scientist is listed as an author:

CiRA & Dr. Shinya Yamanaka past papers scrutiny						
#	Date of scrutiny	Name of paper	Publication date	Yamanaka author?	Scrutiny	Status
1	Apr-2014	'Essential role of NAT1/p97/DAP5 in embryonic differentiation and the retinoic acid pathway'	Oct-2000	Yes	Image duplication concern.	CiRA investigation disclosed original data to the figures were not preserved.
2	Jun-2016	'Generation of pluripotent stem cells from adult mouse liver and stomach cells'	Aug-2008	Yes	Large correction to study behind paywall.	N/A
3	Jan-2018	'In Vitro Modeling of Blood-Brain Barrier with Human iPSC-Derived Endothelial Cells, Pericytes, Neurons, and Astrocytes via Notch Signaling'	Mar-2017	No	Fraudulent data.	Fraudulent data was found in all six main figures and five of six supplementary figures, invalidating the paper's conclusions. Yamanaka nearly resigned following the incident.
4	Oct-2020	'Function of IRE1 alpha in the placenta is essential for placental development and embryonic viability'	Sep-2009	Yes	Image duplication concern.	No response from authors.
5	Oct-2020	'The effects of cardioactive drugs on cardiomyocytes derived from human induced pluripotent stem cells'	Jul-2009	Yes	Image duplication concern.	No response from authors.
6	Oct-2020	'Aggregation of embryonic stem cells induces Nanog repression and primitive endoderm differentiation'	Nov-2004	Yes	Image duplication concern.	No response from authors.
7	Oct-2020	'The homeoprotein Nanog is required for maintenance of pluripotency in mouse epiblast and ES cells'	May-2003	Yes	Image duplication concern.	No response from authors.
8	Mar-2025	'Generation of Human Melanocytes from Induced Pluripotent Stem Cells'	Jan-2011	Yes	Image duplication concern.	No response from authors.
9	Mar-2025	'Modeling familial Alzheimer's disease with induced pluripotent stem cells'	Dec-2011	Yes	Image duplication concern.	Admission of duplication error and antibody names in Figure 1. Original raw data no long available.
10	Aug-2026	'Zonisamide promotes survival of human-induced pluripotent stem cell-derived dopaminergic neurons in the striatum of female rats'	Jun-2020	No	Image duplication concern.	Jun Takashi is director at CiRA and led the Amchepry study at Kyoto university.

Sources: GCR analysis of PubPeer article and CiRA press releases

As they say: "Fool me once, shame on you; fool me twice, shame on me." The evidence we have reviewed lead us to believe there's intentional misconduct – otherwise known as fraud – as there are too many research papers authored by Yamanaka with image duplication concerns. Therefore, we believe this makes Amchepry suspect.

Dr Yamanaka papers appear to have fabricated data according to Pubpeer comments

Pubpeer: "PubPeer is a website dedicated to post-publication peer review and scholarly scrutiny. It allows researchers, authors, and readers to comment on scientific papers after they have been published, offering a platform for discussing potential issues such as errors, retracted articles, or image manipulation." "While peer review typically happens before publication, PubPeer serves as a way for the scientific community to continue checking and questioning the validity of research long after a paper is published. It's an essential tool for maintaining the integrity of the scientific record."

Source: <https://guides.library.upenn.edu/check-it-before-you-wreck-it/pubpeer-explained>

As shown below, Pubpeer is frequented by scientists/researchers, with noted responses observed from paper authors lending credibility to the comments we highlight below. Why it matters: This lends weight to the allegations/criticisms presented below, given the accreditation and knowledge of the commenters in reading and understanding studies, compared to investors who are not scientists by trade.

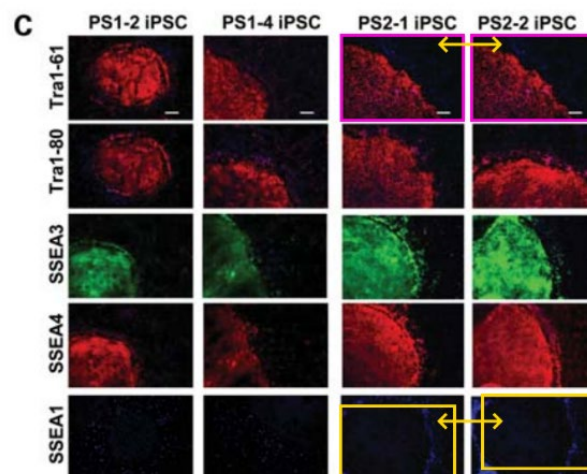
2011: Modeling familial Alzheimer's disease with induced pluripotent stem cells

Similarly to the 2000 Yamanaka paper scandal, a user by the name of David Sholto noted similarity within 2 images of the paper of which Yamanaka is listed as an author.

#1 Sholto David comment accepted March 2025

Figure 1C: Unexpected similarity between images that should show different cell lines. I've added the coloured shapes to show where I mean.

Would the authors please double check?



Source: <https://pubpeer.com/publications/0B7127F4ED2D7D5CA83B160390E36E>

David Sholto is famous scientist known for correctly identifying flaws in scientific papers.

One of the authors of the paper responded:

"Dear Dr. Sholto David

After received the comment, we were notified of a duplication error and antibody names in Figure 1 . Specifically, the Tra1-61 and SSEA1 staining images for the PS2-1 and PS2-2 induced pluripotent stem cell (iPSC) clones were inadvertently duplicated in the two right-

hand columns of panel C. Additionally, the antibody names were incorrectly listed as TRA-1-61 and TRA-1-80; the correct names are TRA-1-60 and TRA-1-81, respectively.

These experiments were conducted approximately 15 years ago, and unfortunately, the original raw data are no longer fully available. We have re-performed the immunostaining of both clones using the same antibodies to confirm their findings. We have contacted the journal editor and the corrected panel is provided on <https://doi.org/10.1093/hmg/ddaf134>.

We believe this duplication resulted from an unintentional error during the figure assembly. These errors do not affect the results or conclusions of the article. The authors apologize to the readers for any inconvenience caused. We sincerely appreciate your attention to detail and your constructive comment.

Sincerely, Daisuke Ito

Source: <https://pubpeer.com/publications/0B7127F4ED2D7D5CA83B160390E36E#>

2011: Generation of Human Melanocytes from Induced Pluripotent Stem Cells

The same user as above (Sholto David) who astutely pointed out inconsistencies in a Yamanaka paper above, **highlighted with no response from authors additional similarities in the picture of another paper of which Yamanaka is an author**

#1 Sholto David comment accepted March 2025

Figure 4C and D: 3F and 4F are supposed to be different cell lines, but the images in this figure overlap each other, there is a difference in the intensity of the colours.

Identified and annotated with coloured rectangles with the help of [ImageTwin.ai](#).

Would the authors please check and comment?

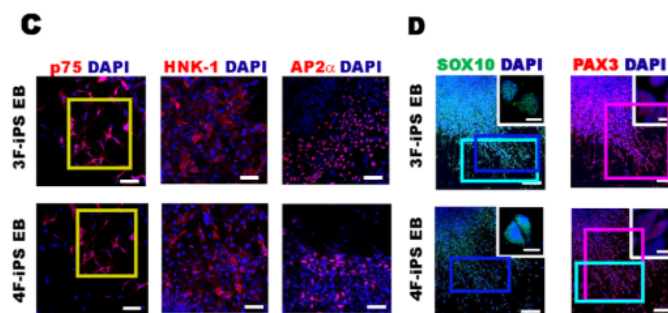


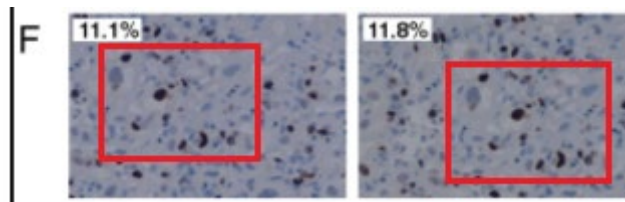
Figure 4. 3F- and 4F-iPS cells can be differentiated into NCSC and MELSCs. (A) Gene expression analysis of a neural crest stem cell marker (Sox10), a melanocyte stem cell marker (PAX3), a melanocytic marker (MITF), pluripotency marker (NANOG) in 3F-iPS cells, differentiated cells derived from EBs on fibronectin-coated plates in melanocyte differentiation medium at 7 days after differentiation (EB-DIFF), and 3F-iPS derived melanocytes (3F-iPS MEL). Transcript levels were normalized to GAPDH. The graphs show the average of two independent experiments. Error bar indicates mean $\pm$ S.E.M. (B) Representative flow cytometry results for HNK-1 and p75 staining in 3F-iPS EB derived cells cultured in melanocyte differentiation medium for one week. Dead cells were excluded using PI staining. (C) Immunocytochemistry revealing cells positive for NCSC markers (p75, HNK-1, and AP2α) in both 3F- and 4F-iPS cells derived EB-differentiated cells 7 days after differentiation. Scale bar, 50 μ m. (D) Images show cells positive for neural crest cell marker SOX10, as well as possible melanocyte stem cell marker, PAX3 in both 3F- and 4F-iPS cell-derived EB-differentiated cells 7 days after differentiation. Scale bar, 50 μ m and 10 μ m (insert images). doi:10.1371/journal.pone.0016182.g004

Source: <https://pubpeer.com/publications/DF180A378AFDAEA6F3B20049DDFBDC#>

2009: Function of IRE1 alpha in the placenta is essential for placental development and embryonic viability (cropped to show only relevant picture to take up less space)

Additional paper of which Yamanaka is listed as an author, **with questions surrounding similarity of paper images with no response from authors.**

More similar than expected, could authors check please?

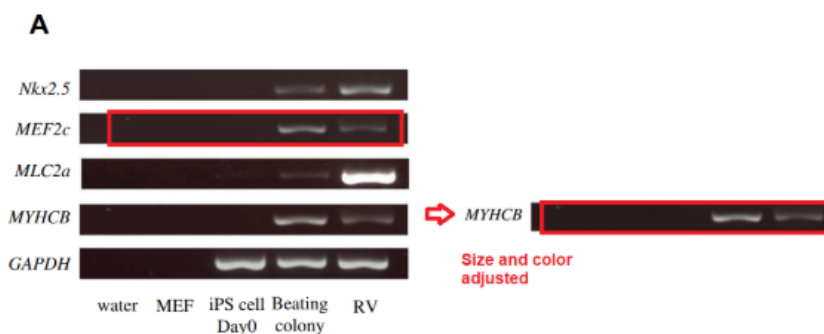


Source: <https://pubpeer.com/publications/2CA5D05183C1676688E24AED9B97C2>

2009: The effects of cardioactive drugs on cardiomyocytes derived from human induced pluripotent stem cells

Additional paper of which Yamanaka is listed as an author, **with questions surrounding similarity of paper images with no response from authors.**

Fig. 2A: More similar than expected. Could authors check please?

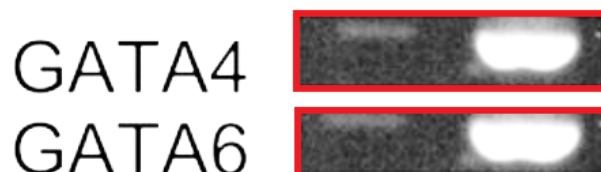


Source: <https://pubpeer.com/publications/60A5BCBF69A2E2FA8B473D4351988B#>

2004: Aggregation of embryonic stem cells induces Nanog repression and primitive endoderm differentiation (cropped to show only relevant picture to take up less space)

Additional paper of which Yamanaka is listed as an author, **with questions surrounding similarity of paper images with no response from authors.**

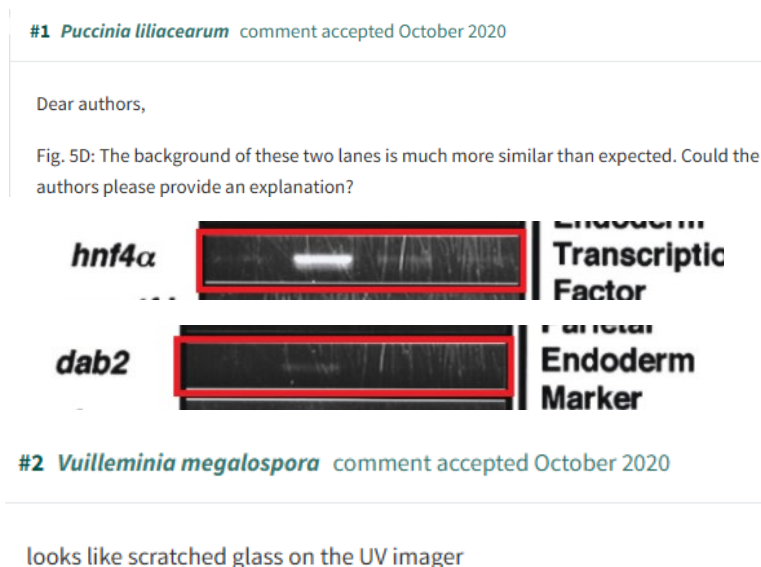
Fig. 2: More similar than expected. Could authors check please?



Source: <https://pubpeer.com/publications/A5FA660EFA9D36B244898B2538B7DF#>

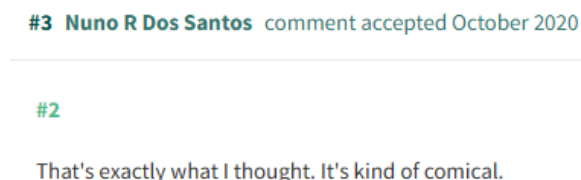
2003: The homeoprotein Nanog is required for maintenance of pluripotency in mouse epiblast and ES cells (cropped to show only relevant picture to take up less space)

Additional user commenting on similarity of 2 pictures in a paper of which Yamanaka is listed as an author with no response from authors. Additionally, a separate user comments “its kind of comical”. **No response from authors.**



Sources: <https://pubpeer.com/publications/AA7FD962946504169CEA9EBE38CA43>

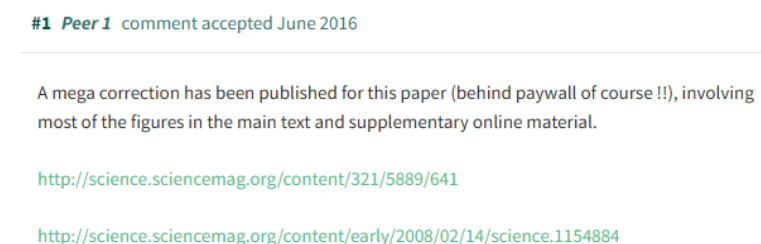
On the scratched glass comment: we think she is providing an explanation as to why the background of the image appears similar (e.g. lines appearing like scratches, which is what the original comment is pointing to when it says background of lanes is much more similar than expected. Vuilleminia is saying, due to scratches on the camera, the same background is getting carried over in different shots, which is why the background appears similar in different photos)



Source: <https://pubpeer.com/publications/AA7FD962946504169CEA9EBE38CA43>

2004: Generation of pluripotent stem cells from adult mouse liver and stomach cells

In a paper where Yamanaka is listed as an author, a User notes that the paper had to issue significant corrections behind a paywall, further implying a lack of transparency.



Source: <https://pubpeer.com/publications/D9E999F68E4F8CCC3242B6DCA09547>

2020: Zonisamide promotes survival of human-induced pluripotent stem cell-derived dopaminergic neurons in the striatum of female rats

User notes paper Jun Takahashi is listed as an author, director of CiRA and person who led Amcchepny nature study which led to its conditional approval, has suspected duplicate images.

#1 *Peoria approximella* comment accepted August 2026

In Fig. 4a, the immunofluorescence images labeled ZNS 10 μ M and ZNS 100 μ M appear to contain the same image.

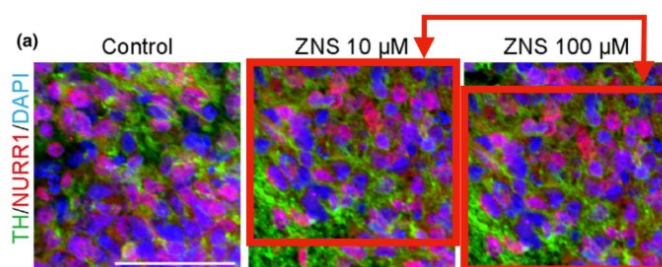


FIGURE 4 A Zonisamide (ZNS) direct effect was not observed by maturation or oxidative stress test. (a) Immunofluorescence images of sections of neurospheres at Day 42 (after 14 days exposure to ZNS). TH (green), FOXA2 (red), and DAPI (blue). Scale bar = 50 μ m.

Specifically, the regions highlighted in red in the attached figure show an apparently identical pattern of cells and fluorescence signal. The correspondence extends to multiple cellular features, making it difficult to explain as an independent acquisition.

Could the authors clarify whether the same image was inadvertently used for both conditions? If so, could they provide the correct immunofluorescence image for each treatment condition?

Source: <https://pubmed.ncbi.nlm.nih.gov/32506530/>

Yamanaka: a Nobel Prize Winning Scientist, or a Serial Fraudster? Why not both

The Korean stem cell fraudster/scientist Hwang Woo-suk who was awarded many recognitions turned out to be a fraudster: *“The case of Hwang Woo-suk, a prominent South Korean scientist, centers around his groundbreaking yet ultimately fraudulent research on creating human embryonic stem cells through somatic cell nuclear transfer (SCNT). In 2004 and 2005, Hwang and his team claimed to have successfully cloned human embryos and derived patient-specific stem cell lines, which garnered immense attention and praise from the scientific community. However, serious ethical concerns emerged regarding the procurement of eggs for this research, as it was revealed that some donations came from junior members of Hwang’s own team, raising allegations of coercion. Subsequent investigations uncovered that Hwang had fabricated data and misrepresented his findings, leading to the retraction of his published papers in 2006. Hwang faced significant legal consequences, including indictment for fraud and violations of bioethics laws. The fallout from this scandal not only halted progress in embryonic stem cell research but also prompted a reevaluation of ethical standards in the field, particularly regarding egg donation practices. The incident served as a cautionary tale about the importance of integrity in scientific research and the potential repercussions of misconduct on public trust and investment in biotechnological advancements.”*

Source: <https://www.ebsco.com/research-starters/law/scientist-indicted-faking-his-research-creating-stem-cells>

If you do a google search for Yamanaka, seems to only show him as Nobel prize winner. For example, top google search results, news results show no sign of fraud or research misconduct:

Google front page

Shinya Yamanaka
Japanese Researcher



Age: 63 years
1957-09-01
Kyoto, Japan

Awards: Nobel Prize in Physiology or Medicine 2012

Research: Shinya Yamanaka is a Japanese stem cell researcher and a Nobel Prize laureate. He is a professor and the director emeritus of Center for IPS Cell Research and Application, Kyoto University, as well as... [Read more](#)

People also ask

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What is Shinya Yamanaka doing now?

Did Shinya Yamanaka win a Nobel Prize?

What are the four Yamanaka factors?

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Shinya Yamanaka was born in Akishima, Japan. He studied for his medical degree at Kobe University and then moved to PhD from Osaka City University in... [Read more](#)

Shinya Yamanaka, MD, PhD

Shinya Yamanaka discovered that adult somatic cells can be reprogrammed into an embryonic-like pluripotent state by introducing transcription factors.

Shinya Yamanaka's 2012 Nobel Prize and the radical change ...

by M. Oda (2012) Cited by 15 — Professor Shinya Yamanaka of Kyoto University won the 2012 Nobel Prize in Physiology or Medicine. He discovered that mature cells can be reprogrammed to...

Videos

Lecture video - Shinya Yamanaka

Nobel Prize - NobelPrize.org

1 Nov 2012

The Big Question | Shinya Yamanaka

Nov 1, 2012

Can Stem Cells Extend Life? Nobel Laureate Shinya ...

YouTube: Museum of Science

14 Jun 2019

About

Shinya Yamanaka is a Japanese stem cell researcher and a Nobel Prize laureate. He is a professor and the director emeritus of Center for IPS Cell Research and Application, Kyoto University, as well as... [Read more](#)

Born: 4 September 1957 (age 67 years), Akishima, Osaka, Japan

Awards: Nobel Prize in Physiology or Medicine, 2012

Parents: Shizuko Yamanaka, Shiroko Yamanaka

Spouse: Chika Yamanaka

Education: Osaka City University (1980-1983), Kobe University (1983-1985), Graduate School of Science (University)

Profiles

Google Scholar

People also search for

John Gurdon, Rudolf Jaenisch, Haruko Obokata, Masahito Saito

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https://www.cira.kyoto-u.ac.jp/~yamanaka_summary

Research Overview | Shinya Yamanaka (Director Emeritus ...

Shinya Yamanaka (Director Emeritus & Professor) M.D., Ph.D. embryonic stem (ES) cells, in regenerative medicine and drug discovery.

ScienceDirect.com
<https://www.sciencedirect.com/science/article/pii/S0092867412000000>

Shinya Yamanaka

by S Yamanaka 2020 — Dr. Shinya Yamanaka is recognized for the generation of induced pluripotent stem cells (iPSCs) from fibroblasts by a combination of multiple... [Read more](#)

Encyclopedia Britannica
<https://www.britannica.com/topic/cells/Organs-&Tissues>

Shinya Yamanaka | Japanese Stem Cell Scientist

Shinya Yamanaka is known for his work in stem cell research, specifically for developing a method to generate stem cells from existing adult cells.

Books

Nuclear Reprogramming and Stem... 2011

The Winding Road to Discovering... 2011

The Gairdner Foundation
<https://www.gairdner.org/en/people/shinya-yamanaka>

Shinya Yamanaka - Gairdner Foundation Award Winner

Shinya Yamanaka received his MD from Kobe University in 1987 and his PhD from Osaka City University in 1993. From 1987 to 1989 he was a resident at the... [Read more](#)

UCSF Profiles
<https://profiles.ucsf.edu/shinya-yamanaka>

Shinya Yamanaka, MD, PhD

Dr. Shinya Yamanaka is a Senior Investigator and the L.K. Whittier Foundation Investigator in Stem Cell Biology at the Gladstone Institute for Cardiovascular... [Read more](#)

Short videos

Nobel Prize winning scientist Shinya Yama... [Instagram](#) [Globe](#)

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End of Aging... [Instagram](#) [On G...](#)

Shinya Yamanaka on becoming a scientist... [YouTube](#) [Aval](#)

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Source:

https://www.google.com/search?q=Shinya+Yamanak&rlz=1C1GCEA_enGB1215GB1215&oq=Shinya+Yamanak&gs_lcrp=EgZjaHJvbWUyBggAEEUYOTIJCAEQLhgNGIAEMgkIAhAAGA0YgAQyCQgDEAAAYDRiABDIJCAQQABgNGIAEMgkIBRAAGA0YgAQyCQgGEAAAYDRiABDIJCAcQABgNGIAEMgkICBAAGA0YgATSAQgyMTAxajBqNkGcALACAA&sourceid=chrome&source=chrome.ob&ie=UTF-8

Google news section

 NobelPrize.org Lecture video – Shinya Yamanaka Shinya Yamanaka · Nobel Prize in Physiology or Medicine 2012 for the discovery that mature cells can be reprogrammed to become pluripotent. Recommended Clips... 6 May 2026	
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 The Scientist The Rise of Induced Pluripotent Stem Cells Explore the major milestones of induced pluripotent stem cell (iPSC) research, from Shinya Yamanaka's discovery to current clinical trials... 7 May 2026	
 Medical Xpress A gene that keeps intestinal stem cells stable offers insight into how tissues repair themselves Years before he conducted the research that would earn him a Nobel Prize in Physiology and Medicine, Shinya Yamanaka, MD, Ph.D.,... 30 Apr 2026	
 Lifespan Research Institute Cellular Reprogramming: The Expert Roundup Cellular reprogramming is one of the technologies most associated with longevity. The field was created in 2006, when Shinya Yamanaka showed... 27 Feb 2026	
 The Economic Times Shinya Yamanaka Was Ranked Last in School—Then Won a Nobel Prize Shinya Yamanaka, a Nobel laureate, did not follow a typical path to success. His curiosity and persistence led to a groundbreaking discovery in... 15 Feb 2026	
 The Times The secret of living forever? Science's best answers so far As Putin and Xi discuss living until 150, the Nobel prize-winning scientist Shinya Yamanaka's work suggests that humans could possibly turn... 3 Sept 2025	
 South China Morning Post Japan approves world's first regenerative medicines using iPS cells Drugs made with iPS, or induced pluripotent stem cells, will be used to treat patients with severe heart failure and Parkinson's disease. 19 Feb 2026	
 The Japan News Warning Issued After Fake Social Media Account Impersonating Nobel Laureate Shinya Yamanaka Discovered Since December, numerous photos have been posted on the Facebook account, including one that appears to be of Yamanaka finishing a marathon. The... 15 Feb 2026	
 finance.biggo.com Kyoto University to Seek 5-Year Extension on Fundamental iPS Cell Patent Before December Expiration, Aiming for Stable Research Funding Kyoto University has confirmed plans to file an application with the Japan Patent Office by June to extend the fundamental patent for... 6 May 2026 <i>Some results may have been removed under data protection law in Europe. Learn more</i>	

Source:

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Appendix

Criticism related to Japanese conditional approval program (even outside of Amchepry, the international scientific community has been highly critical)

- *Stem cell-based therapies for spinal cord injury (SCI) have generated substantial global interest; however, no regenerative treatment has yet demonstrated sufficient efficacy to achieve full regulatory approval in major jurisdictions. In Japan, an expedited regulatory framework enabled the conditional approval of Stemirac, an autologous mesenchymal stem cell therapy for SCI, based on limited and uncontrolled clinical evidence. This Perspective examines the scientific, methodological, and ethical implications of that decision. Focusing on trial design, outcome assessment, extensive public and media attention during the confirmatory trial period, and downstream societal consequences, we explore how premature commercialization under public reimbursement may compromise scientific rigor and erode public trust. "*
 - Link: <https://www.sciencedirect.com/science/article/abs/pii/S1529943026000100>
- "Stemirac's conditional approval has drawn international criticism [7,8], as it was granted on the basis of a small, uncontrolled case series of only 13 patients relying on historical comparisons [9]. This level of evidence falls far short of international regulatory standards, which typically require large, randomized, double-blinded trials to confirm efficacy before marketing authorization. In contrast, no comparable stem-cell therapy for traumatic SCI has been approved in the United States"
 - Link: <https://www.sciencedirect.com/science/article/abs/pii/S1529943026000100>
- "In 2013, Japan undertook a bold, two-pronged policy experiment with a new act, the Act on the Safety of Regenerative Medicine (ASRM), and revisions to its Act on Pharmaceutical and Medical Devices (Revised PMD Act). The ASRM, which established standards for cell-processing facilities and gave private clinics broad leeway to introduce certain cellular therapeutics, has been criticized for subjecting patients to treatments of dubious clinical value"
 - Link: <https://www.sciencedirect.com/science/article/pii/S1934590923002163>
- To begin with, Professor Yamanaka's Nobel Prize in Physiology or Medicine was awarded for "reprogramming," demonstrating that differentiated and mature cells can be reverted to the fertilized egg level. While this is undoubtedly a groundbreaking discovery that overturns conventional wisdom in developmental biology, it is an achievement in a fundamental field of medicine and biology. The hurdles that must be overcome to clinically apply iPS cells as transplant therapy, such as standardizing the creation method and preventing tumor formation, are extremely high. Moreover, directly linking this to regenerative medicine for organs at the clinical level and providing concentrated support as a cornerstone of the national growth strategy is short-sighted and a huge leap in logic. In fact, in the UK, the home country of Professor John Gurdon, a co-recipient of the Nobel Prize for the same theme, while some related ventures have been established, I have not heard of regenerative medicine becoming a national policy.
 - Link: <https://medical-tribune.co.jp/rensai/articles/?blogid=11&entryid=524259>
- "Under the guise of a "national project," Japan's regenerative medicine program has been running amok for over a decade, involving patients and the public, but now dark clouds are beginning to gather over it. Or rather, its true nature is starting to crumble."

- Link: <https://medical-tribune.co.jp/rensai/articles/?blogid=11&entryid=564216>

Had to readjust pricing for drugs in conditional approval program down due to failure

- *"Under this new model, the profit margin coefficient used for cost-based pricing of conditionally approved products will be set at 50% of the average profit margin of fully approved products. This is because the efficacy of drugs at this conditional stage is only "presumed." Premiums related to usefulness and innovativeness will not be assessed at the initial listing. However, adjustment premiums (for example, the foreign average price and other special adjustments) will continue to be taken into account after launch."*
Link: <https://www.pacificbridgemedical.com/news-brief/japan-issues-new-pricing-rules-for-conditionally-approved-regenerative-medicines/>
- 2 products in 2024 (HeartSheet & Collategene) withdrew from the program which started the scrutiny due to disappointing results/data during the conditional approval phase
"The decisions largely align with policy directions outlined by the Ministry of Health, Labor and Welfare (MHLW) at Chuikyo last November and follow renewed scrutiny of the conditional approval scheme after two such products were delisted from the NHI price list in 2024."
Link: <https://pj.jiho.jp/article/254570>

All instances we found CiRa and Yamanaka mentioned: 2011-Present

Date (YR/MM/DD)	Source document	Company	Mention: CiRa or Prof Yamanaka?
20110331	Annual Report 2011	Sumitomo Pharma	CiRa
20110425	News Release	Sumitomo Pharma	CiRa
20110425	News Release	Sumitomo Pharma	Prof Yamanaka
20110512	Company presentation	Sumitomo Pharma	CiRa
20121101	Company presentation	Sumitomo Pharma	CiRa
20121126	Company presentation	Sumitomo Chemical	CiRa
20130510	Transcript	Sumitomo Pharma	CiRa
20140305	Company presentation	Sumitomo Pharma	Prof Yamanaka
20140305	Company presentation	Sumitomo Pharma	CiRa
20140331	Annual Report 2014	Sumitomo Pharma	CiRa
20140331	Annual Report 2014	Sumitomo Pharma	Prof Yamanaka
20141030	Transcript	Sumitomo Pharma	CiRa
20141031	Company presentation	Sumitomo Pharma	CiRa
20150512	Company presentation	Sumitomo Pharma	CiRa
20150724	News Release	Sumitomo Pharma	Prof Yamanaka
20150724	News Release	Sumitomo Pharma	CiRa
20150729	Company presentation	Sumitomo Pharma	CiRa
20151029	Transcript	Sumitomo Pharma	CiRa
20151029	Company presentation	Sumitomo Pharma	CiRa
20151209	Company presentation	Sumitomo Pharma	CiRa
20160127	Company presentation	Sumitomo Pharma	CiRa
20160308	Company presentation	Sumitomo Chemical	Prof Yamanaka
20160331	Annual Report 2016	Sumitomo Pharma	CiRa
20160511	Summary of Consolidated Financial Results	Sumitomo Pharma	CiRa
20160512	Company presentation	Sumitomo Pharma	CiRa
20160601	AGM document	Sumitomo Pharma	CiRa
20160727	Company presentation	Sumitomo Pharma	CiRa
20161028	Company presentation	Sumitomo Pharma	CiRa
20170127	Company presentation	Sumitomo Pharma	CiRa
20170228	Company presentation	Sumitomo Pharma	CiRa
20170331	Annual Report 2017	Sumitomo Pharma	CiRa
20170511	Summary of Consolidated Financial Results	Sumitomo Pharma	CiRa
20170512	Company presentation	Sumitomo Pharma	CiRa
20170512	Transcript	Sumitomo Pharma	CiRa
20170531	Annual Shareholder Meeting	Sumitomo Pharma	CiRa
20170602	Company presentation	Sumitomo Chemical	CiRa
20170728	Company presentation	Sumitomo Pharma	CiRa
20171031	Company presentation	Sumitomo Pharma	CiRa
20171031	Transcript	Sumitomo Pharma	Prof Yamanaka
20171127	Company presentation	Sumitomo Chemical	CiRa
20171219	Company presentation	Sumitomo Chemical	CiRa
20180331	Integrated Report 2018	Sumitomo Pharma	Prof Yamanaka
20180331	Integrated Report 2018	Sumitomo Pharma	CiRa
20180511	Company presentation	Sumitomo Pharma	CiRa

Date (YR/MM/DD)	Source document	Company	Mention: CiRA or Prof Yamanaka?
20180511	Supplementary Financial Data	Sumitomo Pharma	CiRA
20180514	Company presentation	Sumitomo Pharma	CiRA
20180601	Company presentation	Sumitomo Chemical	CiRA
20180727	Company presentation	Sumitomo Pharma	CiRA
20180730	News Release	Sumitomo Pharma	CiRA
20181031	Company presentation	Sumitomo Pharma	CiRA
20181120	Company presentation	Sumitomo Pharma	CiRA
20181127	Company presentation	Sumitomo Chemical	CiRA
20181211	Company presentation	Sumitomo Chemical	CiRA
20181221	News Release	Sumitomo Chemical	Prof Yamanaka
20181221	News Release	Sumitomo Chemical	CiRA
20181221	News Release	Sumitomo Pharma	Prof Yamanaka
20181221	News Release	Sumitomo Pharma	CiRA
20190131	Company presentation	Sumitomo Pharma	CiRA
20190312	Company presentation	Sumitomo Chemical	CiRA
20190331	Annual Report 2019	Sumitomo Chemical	CiRA
20190510	Company presentation	Sumitomo Pharma	CiRA
20190510	Summary of Consolidated Financial Results	Sumitomo Pharma	CiRA
20190513	Transcript	Sumitomo Pharma	CiRA
20190515	Company presentation	Sumitomo Chemical	CiRA
20190515	Company presentation	Sumitomo Chemical	CiRA
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20200130	Company presentation	Sumitomo Pharma	CiRA
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20200514	Company presentation	Sumitomo Pharma	CiRA
20200730	Company presentation	Sumitomo Pharma	CiRA
20201029	Company presentation	Sumitomo Pharma	CiRA
20201130	Company presentation	Sumitomo Chemical	CiRA
20201231	Supplementary Financial Data	Sumitomo Pharma	CiRA
20210128	Company presentation	Sumitomo Pharma	CiRA
20210128	Company presentation	Sumitomo Pharma	CiRA
20210323	Company presentation	Sumitomo Pharma	CiRA
20210331	Integrated Report 2021	Sumitomo Pharma	CiRA
20210512	Supplementary Financial Data	Sumitomo Pharma	CiRA
20210513	Company presentation	Sumitomo Pharma	CiRA
20210729	Company presentation	Sumitomo Pharma	CiRA
20210729	Supplementary Financial Data	Sumitomo Pharma	CiRA
20211028	Company presentation	Sumitomo Pharma	CiRA
20211028	Supplementary Financial Data	Sumitomo Pharma	CiRA

Date (YR/MM/DD)	Source document	Company	Mention: CiRA or Prof Yamanaka?
20220131	Supplementary Financial Data	Sumitomo Pharma	CiRA
20220131	Company presentation	Sumitomo Pharma	CiRA
20220331	Integrated Report 2022	Sumitomo Pharma	CiRA
20220513	Supplementary Financial Data	Sumitomo Pharma	CiRA
20220516	Company presentation	Sumitomo Pharma	CiRA
20220729	Supplementary Financial Data	Sumitomo Pharma	CiRA
20220729	Company presentation	Sumitomo Pharma	CiRA
20221030	Supplementary Financial Data	Sumitomo Pharma	CiRA
20221101	Company presentation	Sumitomo Pharma	CiRA
20230131	Supplementary Financial Data	Sumitomo Pharma	CiRA
20230131	Company presentation	Sumitomo Pharma	CiRA
20230331	Investor Handbook 2023	Sumitomo Chemical	CiRA
20230515	Fact Book	Sumitomo Pharma	CiRA
20230515	Supplementary Financial Data	Sumitomo Pharma	CiRA
20230515	Company presentation	Sumitomo Pharma	CiRA
20230623	News Release	Sumitomo Pharma	CiRA
20230731	Supplementary Financial Data	Sumitomo Pharma	CiRA
20230731	Company presentation	Sumitomo Pharma	CiRA
20231031	Supplementary Financial Data	Sumitomo Pharma	CiRA
20231130	Fact Book	Sumitomo Pharma	CiRA
20231226	News Release	Sumitomo Pharma	CiRA
20231226	News Release	Sumitomo Pharma	Prof Yamanaka
20240131	Company presentation	Sumitomo Pharma	CiRA
20240131	Supplementary Financial Data	Sumitomo Pharma	CiRA
20240131	Transcript	Sumitomo Pharma	CiRA
20240514	Supplementary Financial Data	Sumitomo Pharma	CiRA
20240731	Supplementary Financial Data	Sumitomo Pharma	CiRA
20240805	News Release	Sumitomo Pharma	CiRA
20241030	Supplementary Financial Data	Sumitomo Pharma	CiRA
20241129	News Release	Sumitomo Pharma	Prof Yamanaka
20250131	Supplementary Financial Data	Sumitomo Pharma	CiRA
20250513	Supplementary Financial Data	Sumitomo Pharma	CiRA
20250731	Supplementary Financial Data	Sumitomo Pharma	CiRA
20250805	News Release	Sumitomo Pharma	CiRA
20251031	Supplementary Financial Data	Sumitomo Pharma	CiRA
20260130	Supplementary Financial Data	Sumitomo Pharma	CiRA
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20260306	News Release	Sumitomo Pharma	CiRA
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20260513	Transcript	Sumitomo Pharma	Prof Yamanaka
20260513	Webpage: Profile of Major Products under Dev.	Sumitomo Pharma	CiRA
20260715	News Release	Sumitomo Pharma	CiRA
20260727	Webpage: Research Alliances	Sumitomo Pharma	CiRA